



**Volume 1**

**Development and Feasibility Testing of a  
Supervised Pharmacy Student-Led  
Medication Review of Patients with  
Diabetes in Primary Care**

Richard Paul Adams

PhD

School of Pharmacy

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## Abstract

**Introduction:** The expected outcomes from medicines are, frequently not realised due to adverse reactions, inappropriate prescribing and patient failure to take their therapy as intended. Whilst medication review provided by pharmacists is designed to address these issues evidence for the effectiveness is weak, and sometimes counterintuitive. Reasons postulated are poor study design, inappropriate intervention location and limited consultations skills demonstrated by pharmacists. This thesis is designed to develop, feasibility test and pilot a supervised medication review service for patients with type 2 diabetes (T2DM) in primary care provided by undergraduate pharmacy students as part of their undergraduate education.

**Method:** Literature review and focus groups were undertaken to refine the intervention. Ethical approval was obtained. Medication reviews were undertaken within the medical practices and supervised by a primary care based pharmacist. Students reviewed patient's medicines and then one-to-one medication reviews with two patients. A range of outcome measures were utilised and tested. Recruitment and attrition rates were recorded. Patient and practitioner acceptability of the intervention and education experience was obtained.

**Results:** 5 medical practices were recruited, from which 133 patients with T2DM consented to participate with 67 randomised to the intervention group. Thirty-two students undertook 58 medication reviews with patients. Patients reported satisfaction with student-led medication reviews and information received about medicines. No improvement in patient reported medication adherence or clinical outcomes were identified. The mean change in quality of life and patients' satisfaction with information about medicines was significantly greater in the intervention group. Pharmacy students reported increased confidence and improved communication skills.

**Discussion and conclusions:** The feasibility and pilot study provided data which would enable delivery of a future definitive trial. The intervention was deemed acceptable by patients and demonstrated improved quality of life and satisfaction with information about medicines. Educational benefits of this study were also observed

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## **Glossary of Abbreviations**

ADE	Adverse Drug Events
ADR	Adverse Drug Reaction
BMQ	Beliefs about medicines questionnaire
BP	Blood Pressure
CCG	Clinical Commissioning Group
CNS	Central Nervous System
CPD	Continuous Professional Development
CTU	Clinical Trials Unit
DMR	Domiciliary Medication Review
DUSOI-A)	Duke Severity of Illness Checklist
DTSQ	Diabetes Treatment Satisfaction Questionnaire
EBM	Evidence Based Medicine
HSCIC	Health and Social Care Information Centre
HES	Hospital Episode Statistics
GMC	General Medical Council
GP	General Practitioner
GPhC	General Pharmaceutical Council
HEDIS	Effectiveness Data and Information Set
IRAS	Integrated Research Application System
LREC	Local Research Ethics Committee

LTC	Long term conditions
MARS	Medication Adherence Report Scale
MCA	Medicine Compliance Aid
MCQ	Multi-choice questions
MMAS 4	Morisky Medication Adherence Scale (4 item)
MMSE	Mini Mental State Examination
MR	Medicines Review (or Medication Review)
MRC	Medicines Related Consultation
MRCF	Medication Related Consultation Framework
MRP	Medication Related Problems
MTM	Medication Therapy Management
MUR	Medicines Use Review
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICE CG	National Institute for Health and Care Excellence Clinical Guideline
NPC	National Prescribing Centre
NSF	National Service Framework
OBE	Output based education
OBRA	Ombudsman Reconciliation Act
ONS	Office for National Statistics
OSCE	Objective Structured Clinical Evaluation

PCP	Patient Care Plan
PCT	Primary Care Trust
PDRA	Preventable Drug Related Admission
QALY	Quality adjusted life year
QOF	Quality Outcomes Framework
QOL	Quality of life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RCGP	Royal College of General Practitioners
RPSGB	Royal Pharmaceutical Society of Great Britain
RR	Relative Risk
SAE	Stamped addressed envelope
SD	Standard Deviation
SF-36	Short Form Health Survey (36 Questions)
SIMS	Satisfaction with Medicines Information Scale
SOP	Standard Operating Procedure
T2DM	Type 2 Diabetes Mellitus
UEA	University of East Anglia
UK	United Kingdom
UK-MAI	UK Medication Appropriateness Index
USA	United States of America

## **Appendices**

List of Appendices. These are bound in two separate volumes.

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Appendix B Development of the project

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At the start of my PhD, one of the first references I came across, when searching for information about experiential teaching, was this:

*"Tell me, and I will forget. Show me, and I may remember. Involve me, and I will understand."*

Confucius around 450 BC.

I think that the study proved him right.

Now, at the end of the study, I would like to take up a quote attributed to be the last words of the first British professional cyclist to wear the yellow jersey in the Tour de France. However, I would like to make use of it for many years to come.

*"Put me back on the bike."*

Tom Simpson, Mt. Ventoux 1967.

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# **CHAPTER 1**

## **INTRODUCTION: INCORPORATING A LITERATURE REVIEW.**

## Chapter 1 Introduction

### 1.0 Medication use, misuse and iatrogenic disease.

Medicines are central to the delivery of western health care, being widely used to cure, relieve and prevent ill health. With an ageing population[1] and an expansion in the number of medicines available to manage chronic illness, the cost of providing medicines continues to increase. Between 2000 and 2010 the number of prescription items dispensed in primary care in the UK increased by 67.9%, with the total bill to the national health service increasing by 58% to £8.8billion in 2011[2], or just over 7% of the total health bill of £121billion in 2010/11[3]. Safe, efficient and cost effective use of medicines is essential within a resource-limited health care system and the current scenario of expanding demand makes this more difficult to ensure. There is significant evidence to demonstrate that when medicines are not managed appropriately they can increase resource utilisation through iatrogenic disease and also waste resources when sub-optimally used by patients.

A systematic review by Garfield *et al.*[4] (2009) estimated that between 4% and 21% of patients in primary care in the UK achieved the optimum benefit from their medication. In addition, they reported that errors occurred at all stages of the process of the medicines management system within primary care, with particular areas of concern including repeat prescribing review and patients not adhering to their prescribed medication. In 2002 in 'room for review', a guide to medication review, it was estimated that within an average primary care population of 100,000 patients, non-steroidal medicines caused 18 hospital admissions for gastrointestinal bleeds and 22 admissions with congestive heart failure each year[5]. Whilst the decision to prescribe a medicine is based, in part, on the knowledge of the potential risk of adverse drug reaction (ADR), the risk can be reduced or prevented by ensuring appropriate prescribing and monitoring to prevent prescribing errors and to ensure that patients are not suffering ADRs[6].

A recent 2012 review of 6048 prescription items for 1777 patients by the General Medical Council (GMC)[7] found prescribing or monitoring errors within one in eight patients, involving one in twenty prescribed items. A further in-depth analysis of prescribing errors with 177 patients reported that the odds ratio of a prescribing or monitoring error was related to both patient age and the number of medicines prescribed, with increasing age and number of medicines displaying higher risk. Children below 15 years and people over 75 years were at higher risk, with odds ratios of an error of 1.87 and 1.95 respectively, whilst patients between 65 and 74 years displayed a lower odds ratio of 1.68. The error

rates recorded in patients receiving one medicine was 17.8%, increased to 30.1% in those receiving 5 or more medicines and 47% in patients receiving 10 or more medicines. As older patients, including those with long-term conditions, are prescribed more medicines it is evident that their risk of problems will increase to unacceptable levels.

A review of UK hospital episode data between 1999 and 2009[8] found that 557,978 admissions were recorded as primarily due to ADRs, which represented a 0.9% incidence. This is, however, likely to be an underestimate as many ADRs are not identified until later on within the hospital stay. In line with the increase in use of medicines and ageing population the incidence of hospitalisations due to ADRs was found to increase by 78% over the 10 years.

The issue of recording of ADRs on admission was recognised and resolved by the implementation in 2001 of a prospective analysis by Pirmohamed of 18,820 patients admitted to two large general hospitals[9] in the UK. The study which was undertaken over six months reported that 6.5% of people admitted to hospital had experienced an ADR and that in 80% of those the ADR was the direct cause of admission resulting in an annual cost to the NHS of £455million. The incidence of ADRs reported as causing hospital admissions is believed to have increased by 45% from 1998 to 2005 when it had reached 6.5%[10].

The UK picture of adverse drug reactions resulting in additional resource use is mirrored within other western healthcare systems. A meta-analysis[11] published in 1998 of 39 studies reporting ADRs judged as meeting criteria in US hospitals between 1966 and 1996 found that 6.7% of patients had suffered a serious ADR, with 4.7% resulting in a hospital admission, whilst 0.32% resulted in a fatality. Analysis of 1994 data produced an estimate of 106,000 (95% CI 76,000 to 137,000) patient deaths in USA hospitals making it the fourth to sixth (taking the highest and lowest confidence interval) cause of death in the USA. Studies in the USA estimate the consequences of prescription related illness to be 100,000 deaths or in financial terms \$1billion per annum[12], whilst the costs of unresolved medication related problems exceeds \$177.4 billion with over 200,000 deaths per year[13]. Medication related problems are common, with evidence of 61% out of 2,985 patients in the USA experiencing one or more[14]. A systematic review[15] of publications between 1966 and 1999 reported the prevalence of preventable drug related admissions to hospital as 4.3% (interquartile range 3.1-9.5%). Studies were excluded if cases were identified by screening instrument, computer alert or spontaneous reports. It is important to note that the 4.3% of admissions noted in the last study were judged to be preventable, thus indicating that healthcare intervention may be effective in preventing

some or all of them. Whilst many of the above studies included within the systematic review are based on international data, it is now accepted that these findings can be transferred to the UK NHS setting[16 17].

Preventable drug related admissions are reported to reflect inappropriate management of medication therapy in the community[15], with more than 50% judged to be preventable. In a review of hospital admissions resulting from preventable ADRs in a US hospital in 2002[18] the authors concluded that most resulted from inadequate monitoring of a patient's medication or from inappropriate dosing for that patient. They also reported that a failure by patients to take medication as prescribed for them was a common cause of ADRs. There is, therefore, a large body of evidence confirming that ADRs represent a large and increasing problem, with resultant health problems for patients and increased costs for healthcare providers. However, it is also reported that many ADRs are preventable, if prescribing and subsequent monitoring of medication therapy is adequate.

Having established that medication related problems and subsequent hospital admissions occur because of inappropriate prescribing or monitoring, failure by patients to take their medication as intended by the prescriber further compounds the problem. It has been estimated that patients only take 50% of medicines as prescribed for them[19]. Medicines adherence is the term used to describe patient adherence to what was agreed with the prescriber[20] when the medicine was prescribed, whilst persistence describes the patient's decision to continue with therapy[21]. A retrospective cohort study of 34,501 primarily female patients aged over 65 years commencing statin treatment in New Jersey between 1990 and 1998, reported that adherence to prescribed medication regimes reduced over time with the proportion of patients who were adherent with statin therapy demonstrated as 60%, 43%, 26% and 32% after 3, 6, 60 and 120 months, respectively [22]. The authors conclude that, improving patients' understanding of their health, their medication regimen, and the potential benefits of persistence with the medication regimen enhance actual persistence and that these and other interventions deserve further study.

Cramer *et al.*[23] reviewed 139 papers (published between 2000 and 2005) relating to cardiovascular patients and showed that only 63% of patients continued with their medication after one year. Levels of continuation demonstrated for each therapeutic area of diabetes, hypertension and dyslipidaemia did not significantly differ. Whilst persistence with therapy declined with time, as reported in other studies, the large variability in persistence rates could not be explained. The authors state that encouraging patients to adhere to their medication regimen could improve the clinical management of cardiovascular disease. Patients were only found to take their medication for 72% of the



time, however, good adherence was shown to be important as it displayed a positive effect on health outcomes in 73% of the studies which examined its clinical effectiveness. Evidence has been provided that poor adherence to medication regimes results in a reduction in the desired positive outcomes for patients from medication.

In addition to lost opportunities for health gain by patients, non-adherence which is generally manifested as less medication taken than prescribed, represents probable medicine wastage. In 2008 in the UK it was estimated that the cost of medicines returned by patients to GP surgeries or pharmacies exceeded £100million and the cost of unused medicines was approximately £800million[24].

With an increasing recognition of the need to reduce prescribing errors, improve monitoring of medicines and encourage patients to use medicines more appropriately, the process of reviewing prescribing at regular intervals has become increasingly important. The identification that significant numbers of patients do not take their medication as prescribed indicates that the involvement of patients may be beneficial and that processes need to be developed to enable this.

### **1.1 Medication review**

The process of medication review can include all or some of the following:

- review of prescribing decision in light of current evidence base,
- identification of any potential problems such as:
  - side effects,
  - not achieving therapeutic goals,
  - interactions with both co-prescribed and purchased medicines.
- discussion with patients of their experience of their medicines and their information needs to address any identified non-adherent behaviours.

The current UK definition of medication review is:

*A structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste.[5]*

The importance of including the patient within the medication review process was highlighted by the Department of Health stating in 2004 a desire for fully concordant face-

to-face medication reviews to be available to all patients who would benefit from them and demonstrate a desire to undertake them [25].

National guidance produced by a group of experts in 2001[26] recommended an annual review of medicine for people over 75 years of age and a six monthly review if they are prescribed four or more medicines. The current GP contract requires a medication review to be recorded in the preceding 15 months for all patients prescribed four or more repeat medicines as this represents four out of five people over the age of 75 [27]. In addition to recommending the frequency at which reviews should take place, the content of the review is required to be at 'level 2'. The UK definition of medication review with respect to level or content (2002) is provided below[5]:

Level 3 Medication Review	a complete review with access to medical records, laboratory data and all relevant data, e.g. over the counter medicines. The patient should be present and able to participate fully.
Level 2 Treatment Review	a review with access to the full records but without the patient and may focus on just one therapeutic area.
Level 1 Prescription Review	a review of a patient's medicine(s) without access to records or the patient. It might not cover all medicines.
Level 0 Ad hoc	an opportunistic review with or without the patient.

In 2008 the Medicines Partnership (a collaboration of the National Prescribing Centre and Keele University) published a guide to Medication Review[28]. This was due to inconsistency in application and levels of implementation of medication review between sectors and individuals as well as the desire to incorporate new models of working. Examples of changes included community pharmacists providing reviews to improve adherence and pharmacists and pharmacy technicians working in primary care with a focus on cost-minimisation. This alternative definition of level and content of medication reviews provided by Keele University is focussed on the purpose of the review rather than content. This enables the individual delivering the service to determine how the review should be undertaken.

Type 1	Prescription review to address technical issues of the prescription and does not require the patient or their notes present. Notes can be used if wanted.
Type 2	Concordance and compliance review to address medicines taking issues by the patient and requires the patient to be present but notes are optional.
Type 3	Clinical medication review to address issues relating to medicines taking and requires the patient and their notes.

The medicines partnership additionally recommends that type 3 reviews should be aimed at the following groups or situations:

1. Patient related, e.g. older people >75yrs which once again mirrors the NSF for the Elderly.
2. Condition related, e.g. long-term conditions (LTC) such as diabetes or complex conditions.
3. Medication related, e.g. medication regimes, specialist medications or a medication related event.
4. Environmental triggers, e.g. change in care provider or living in a care home.

The National Prescribing Centre (NPC) published a “five minute practical guide” to medication review[29] based on the Medicines Partnership document[28] stating that the components of a level 3 medication review should include:

- pre planning and advance warning for the patient,
- determination of the patient’s understanding of treatment,
- review of physiological test and measurements,
- review of efficacy,
- identification of side effects and interactions,
- review of practicalities of medicine use,
- agreement of future treatment plans,
- opportunities for questions and concerns.

Whilst the evidence for the need to reduce adverse events from medicines and improve the use of medicines by patients is convincing and provides an excellent premise for

medication review, the evidence for the medicines review process itself being an effective means of achieving this is not convincing.

### **1.1.1 Evidence of benefit of medication review**

As the process of medication review became incorporated within the UK healthcare system, the responsibility for delivering this was increasingly handed over to pharmacists, as they were recognised as having appropriate pharmaceutical knowledge and costing less to employ than medical practitioners. As this role was transferred to pharmacists in both the UK and internationally, evidence for the value of this now frequently pharmacist-based intervention has emerged.

### **1.1.2 Medication review by pharmacists in the UK**

A prospective study[30], claimed by the authors to be the first controlled trial of the effects of medication review by a pharmacist was undertaken over eight months in South Manchester by one pharmacist in 2000 with the support of the twenty four GPs serving the 330 consented patients in nursing homes. Fourteen nursing homes were randomised to paired control (standard care) or intervention which comprised standard care during an observational four month period and then medication review during the following four months. The review was undertaken with access to the Medication Administration Record, brief medical history and information provided by the care home staff relating to identified problems. Three weeks later the homes were revisited to identify any problems with medication changes, or if the changes had been implemented. Fifty four percent of intervention patients were identified as receiving neuroleptic medication which did not comply with US OBRA (Ombudsman Reconciliation Act) guidelines whilst the pharmacist made 261 recommendations for medication changes of which 91.6% (239) were accepted by the patient's GP. Patient evaluation was demonstrated to be reliable as it was undertaken initially by the pharmacist and a psychiatrist. Nurses trained in mental health care then also evaluated patients during follow-up to ensure consistency and reliability. Additionally, standard measures of mental capacity were used such a Mini Mental State Examination (MMSE). The study reported minimal impact on mortality of 26 intervention versus 28 control patient deaths over the full study period, however, during the four month intervention period they reported eighteen deaths of which only four were in the intervention arm. No significant differences in falls or accidents between groups were identified. Costs of medicines of £131.54 per patient were lower in the intervention group compared to £141.24 for control group patients. When healthcare appointments were also factored in, the cost was £314.89 per intervention group patient versus £492.98 for control group patients. This study provides support for the implementation of medication review by pharmacists but the generalisability is weakened by using only one pharmacist

in a limited setting of care homes in one area with an emphasis on psychiatric outcomes. It is interesting to note that the pharmacist utilised existing skills with no additional training, however, we are not informed about the level of experience of the practitioner. In addition there was integrated working between the pharmacists and GPs. The authors claimed that this intervention can reduce the number of medicines prescribed to older people, may save costs and can be implemented without detrimental effects on the mental or physical health of patient participants. Without a full economic analysis including all associated costs and with limited generalisability this study, however, provides some evidence for the routine introduction of pharmacist provided medication reviews.

The Randomised Controlled Trial (RCT) undertaken by Zermansky *et al.*[31] in 2002 has been widely used as evidence of the effectiveness of medication review to support government recommendations. Patients were aged over 65 years and not in nursing or residential homes. One expert pharmacist delivered the service over twelve months, which resulted in 97% of the intervention group receiving medication review compared to 40% who would routinely receive a medication review as part of their usual care. The introduction of the pharmacist into the process increased the number of reviews in the intervention group. Pharmacist advice was acted on in 68% of cases, with the mean number of medication changes (primary outcome) found to be significantly higher in the intervention group, 2.2 versus 1.9 (95% CI 0.06 to 0.57). Medication costs rose less for the intervention group (£1.80 versus £6.53) with a saving claimed of £4.75 (95% CI, -7.94 -2.41) per 28 day period equating to an annual saving of £61.75 per patient. As with the Manchester study there was a non-significant lower rate of deaths in the intervention group (15 versus 25). The authors conclude that this provides evidence for suitably trained pharmacists to undertake medication review due to reduced numbers of prescription medicines used, with consequent savings and no evidence of an adverse effect on subsequent use of health services. No effect was reported by the authors on outpatient consultations, GP practice consultations or hospital admissions for the intervention group patients. Whilst this study provides good evidence for the benefit of medication review by a pharmacist its generalisability is reduced again by the delivery by one very experienced pharmacist working in a medical practice with excellent inter-professional relationships.

Another RCT[32] by the same author in 2006 set in care homes and based on 315 intervention patients, identified a significant reduction in falls (0.8 falls per intervention patient versus 1.3 in the control group) as a result of the pharmacist provided medication review service. Falls constituted a secondary outcome measure, which was one of a

number of measures included to address the issue of effects on health outcomes. A non-significant lower incidence of hospital admissions was seen in the intervention group, whilst mortality rates and GP consultation rates showed no significant difference. GPs accepted 75.6% (565/747) of recommendations resulting in a significantly greater number of medication changes (primary outcome) for intervention versus control patients (3.1 versus 2.4). However, this did not result in lower medication costs, as the pharmacist frequently recommended the initiation of new medication, in addition to stopping others. The greatest number of medications stopped, almost one third, was central nervous system medications and this may partially explain the significant reduction in falls with 160 potential falls saved in 331 patients. This RCT, therefore, shows that a pharmacist can complete medication reviews for patients in care homes without a significant impact on hospital or GP practice use, whilst showing significant reductions in an outcome measure of falls experienced by patients. The service resulted in no real change with respect to medication costs but the effect on other costs were not described or determined. Additionally the training of the pharmacist was not described which would have provided useful information for the conduct of future studies or implementation of a service.

These studies provide evidence that a pharmacist can provide medication review effectively both in care homes and with patients living in the community, whilst potentially providing patient benefit. However, the use of only one pharmacist in each case, allied to the lack of knowledge of training reduces both their generalisability and reproducibility. The numbers of patients were, however, sufficient to establish an effect, but larger studies in other areas need to be undertaken with more pharmacists.

The RESPECT trial[33 34] undertaken in 2002 addressed the criticisms of not using substantial numbers of pharmacists to deliver an intervention, introduced a novel model of care which built on the current skills of community pharmacists and encouraged shared working with GP Practices. The trial, a multiple interrupted time series design, was undertaken in 2004 in Yorkshire with sixty two pharmacists working with twenty four GP Practices within five Primary Care Trusts (PCTs). Study design enabled the five PCTs to be randomised to pharmaceutical care in order to act as controls for each other, with pharmacists and GPs being 'blind' until three months before intervention to enable training, whilst acting as controls for each other thus reducing bias. Medication reviews were received by 563 patients on at least one occasion and 551 patients completed the study. Shared sessions aimed at engendering joint working between pharmacists and GPs were included in the intervention development. Patient inclusion mirrored the National Service Framework for Older People[26] recommendations which were for patients of over 75

years of age with five or more medicines prescribed. Novel departures from previous studies included the medication review location, which could be either a private room in a community pharmacy or the patient's home and the provision of repeat medication reviews over twelve months. This is in line with recommendations regarding the delivery of care by pharmacists where emphasis is placed on continuing care rather than one event[35], but is found to be the scenario in many studies. The primary outcome measure was UK-Medicines Appropriateness Index (UK-MAI), an 'anglicised version' of a USA tool providing a score dependent on the number and appropriateness of each patient's medication. Analysis of this was changed from that stated in the protocol due to previous underestimates of medications and time; however, no significant change was seen in UK-MAI. In addition, no statistical effect was seen on quality of life, adverse drug events, hospitalisation or secondary care use. These show that implementation of pharmaceutical care in this model provided no benefit or reduction in care and taking into account the resources involved, the case for pharmacist medication review in this way was not proven. One reason provided was that despite shared training sessions, communication between GPs and pharmacists was not optimal and may have impacted negatively on the outcomes. Pharmacists experienced difficulties in both access to clinical data and arranging meetings with GPs to discuss care plans. Poor communication resulted in reduced implementation of desired actions, and GPs reported frustration when their prescribing was questioned, on occasion, by a pharmacist unknown to them.

Following on from the Respect trial, researchers in Norfolk undertook the HOMER study[36] which attempted to demonstrate via an RCT that medication review provided by a wide variety of pharmacists, with different levels of experience and training to patients over the age of 80 years, immediately after hospital discharge, would result in reduced readmissions. The study recruited 829 patients from four general or community hospitals and randomised them to control or intervention. All pharmacists held a post graduate qualification or had undertaken recent continuous professional development (CPD) in therapeutics, whilst all received a two day training course which included communication skills. Emergency readmission to hospital was 30% greater in the intervention group (234 versus 179 ), whilst the secondary outcome of mortality showed a non-significant lower rate for the intervention group (49 versus 63 with a hazard ratio of 0.75 ) and a non-significant lower rate of intervention group admissions to nursing homes. Quality of Life (QOL) was measured for approximately 80% of patient participants with changes in utility scores showing a non-significant difference between groups. The visual analogue health scale score fell more for intervention versus control (difference of 4.1 units), possibly due to increased anxiety, confusion or dependence on healthcare services resulting from the



extended home visit. Potentially positive outcomes were the recommendation or comments to GPs recorded by pharmacists (933) with 120 of these referring to possible ADRs or interactions between medicines in 81 patients. The results are counterintuitive, with greater emergency admissions and reduced QOL in the intervention group. The paper provides three possible explanations for results, with the first being that pharmacists helped patients to understand their condition better, thus promoting help-seeking behaviour which may have resulted in the admissions. Weak evidence for this is the favourable death ratio which may show a competing outcome where more hospital admissions resulted in fewer deaths. The second explanation proposed is increased adherence to medication regimes following the pharmacists' intervention resulting in increased adverse effects due to medicines. Lastly, the long duration home visit may have increased anxiety and confusion or dependence on health services amongst intervention patients with a greater focus by patients on their health thus resulting in deterioration.

Two papers[37 38] by Zermansky and Silcock & Zermansky and Freemantle discuss study design and specifically that of the HOMER RCT[36], and propose a different interpretation. They state that HOMER was "ill-conceived and almost set itself up to fail" due to factors including the fact that the pharmacists were ill-equipped, which could indicate that they recommend additional training in medication review for pharmacists. Criticism is also made of the timing, as patients were approached shortly after discharge from hospital when medication should have already been optimised and patients educated about their medicines. This also makes them non-generalisable to most medication review situations. Significantly, doubt is cast upon the likelihood of the possibility of the intervention being able to show an effect on the outcome measures and the cost effectiveness interpretations as medication costs before and after were not measured, with the two domiciliary visits deemed to be expensive. It may however be that the post-discharge visit by a pharmacist resulted in an urgent request for a visit by the patient's GP and, therefore, earlier identification of patients who had been discharged too early thus resulting in their subsequent readmission. This scenario would explain the improvement in mortality in the intervention arm and is supported by the large number of interventions made by the pharmacist to request a GP visit. If this explanation was correct then it would demonstrate that the pharmacists themselves had no impact on patient health and the outcomes seen were due to earlier access to primary care services post-discharge.

Holland *et al.* published the HeartMed study, another RCT in 2007[39], which investigated the medication reviews by 17 community pharmacists who provided the intervention to

149 patients diagnosed with heart failure, whilst 144 patients were randomised as control. Pharmacists were provided with a copy of the discharge letter and arranged a home visit within two weeks of discharge, with a follow up at six to eight weeks. The visit comprised a medication review, education about heart failure where appropriate, encouraging completion of a signs and symptoms card and removal of discontinued medications with the patients' consent. The pharmacists then fed back recommendations to GPs and the need for adherence aids to community pharmacists. Pharmacists, as in the previous RCT by Holland *et al.*[36], held post graduate qualifications or had undertaken recent CPD in therapeutics, whilst all received a training day on heart failure issues. The primary outcome measure of emergency hospital readmission showed a non-significantly higher incidence of 134 for intervention patients versus 112 for control, whilst secondary measures showed a non-significant increase in mortality in intervention patients: 30 intervention patients died versus 24 control patients with  $p=0.54$ . QOL was unchanged for intervention but was reduced by 10% for control, whilst health scale did not differ significantly between groups. Pharmacists rated their visit as definitely useful for 50% of patients and probably useful for 38%. Similarly, they reported second visits as definitely useful (31%) and probably useful (49%). The researchers concluded that the intervention showed no benefit, with patients' satisfaction scores not translating into significant improvements in heart failure self-care scores. One explanation proposed for the lack of a positive effect was that the intervention may have been too late in the disease course to evoke behaviour changes, as patients may have already made any possible changes

In parallel to the burgeoning UK evidence base for medication review the international literature has also developed.

### **1.1.3 Medication review by pharmacists outside the UK**

An RCT in Australia[40] published in 2004 was conducted in three states with 177 intervention patients versus 223 control patients in which 53 pharmacists undertook medication review in the patient's home. The pharmacists were trained and accredited by the Australian Association of Clinical Pharmacists; however, in a minority of cases the local pharmacist undertook the visit, with the medication review being completed by an accredited pharmacist. All GPs and pharmacists involved received training via satellite. Data for the medication reviews which included patient diagnoses and medication use was provided by the GP to the pharmacist, with the home based medication review identifying medication-related and other risk factors for discussion at a multidisciplinary meeting. The GP produced an action plan based on this and met the patient for a

medication review to agree implementation. At six weeks, patients were followed-up to monitor outcomes of the plan. The study identified no significant difference in clinical outcomes or health-related QOL although they claim other small improvements for intervention versus control. Intervention patients were less likely to report adverse drug events (ADEs); however, this displayed non-significance. Savings were demonstrated in health-related costs at eight month follow-up for the intervention group which outweighed the slight increase in medication costs and intervention costs which included pharmacist and GP time, resulting in a net saving of AUS\$54 per patient relative to control. Ninety two percent of intervention GPs and 94% of intervention pharmacists stated that the intervention had improved the care of participating patients with 54.4% of recommendations acted upon. Of the recommendations which were acted upon 70.9% demonstrated a positive outcome, 15.7% no effect and 3.7% a negative effect. Twenty one of the pharmacists recruited were unable to actively participate because no intervention GP could be 'linked' to them. This shows the importance of collaboration between pharmacists undertaking medication review and the patient's GP. The authors comment that "a range of health workers could conduct this intervention with minimal input from the research team in a timely and effective manner". The home-based medication review showed that pharmacists can provide such a service whilst identifying important medication related issues with no additional cost, or even a slight saving. A service similar to this intervention was subsequently implemented nationally by the Australian government, with participating GPs and pharmacists receiving reimbursement[41].

Studies performed to date provide tentative evidence for pharmacist-led medication review improving patient behaviours and for reducing potential medication related problems. They also demonstrate that the training of pharmacists to deliver medication review requires careful consideration, as does the location of the pharmacist when undertaking medication reviews. It is essential that inter-professional barriers are overcome, firstly to ensure that the new role for pharmacists is accepted and secondly to integrate them into the patient's immediate care team. This will provide better communication, opportunities for joint decision making and improved access to patient records. In addition, it may enable the implementation of a greater number of recommendations.

Whilst the primary driver for medication review is the improvement of patient outcomes, it was the provision of incentives for GPs in the UK to save money on their prescribing budgets which was the catalyst for medication review by pharmacists in primary care[42]. Initially pharmacists were largely employed to substitute medications of similar efficacy but

less cost for those currently prescribed and their employment was justified by the cost savings realised. Pharmacists have since developed their role in primary care to encompass all elements of medication review where the time spent delivering the service may be offset by discontinuing therapy and prescribing cheaper medicines. Therefore, evidence for the cost-effectiveness of such services has been sought.

#### **1.1.4 Cost of pharmacist-led medication review**

When providing and evaluating interventions such as medication reviews in the UK it is necessary to determine both the costs and effects. Ideally effects will be measured using a quality of life score to enable purchasers of services to compare the value of different types of service. Within the UK, the government adopts healthcare interventions which demonstrate a cost per additional gain of a year of perfect quality of life (QALY) of less than £30,000[43].

An economic evaluation in 2007[44] from an NHS perspective based on the HOMER RCT[36] evaluated costs involved in the provision of medication review by twenty two pharmacists, with EQ-5D as the primary outcome measure. The intervention cost per intervention group patient was £124. However, accounting for the increase in hospital admission rates, the cost rose to £271. QOL and mortality showed a non-significant decrease in the intervention group. Calculation of a QALY resulted in a cost of £54,454 which provides evidence for such services to not be adopted in the UK.

Zermansky undertook a narrative literature review focussing on costs and effects in 2009[38] and highlighted that apart from two studies[36 40], there is a lack of quality data relating to costs and effects of medication review by pharmacists. He states that there is a need for a large RCT, with long-term follow-up, of periodic clinical medication review by pharmacists and significantly calls for documented and appropriate training for participating pharmacists.

A 'quasi-experimental' before and after study[45] was published in 2012 on 117 participants (age >65yrs) who had all been referred to Norfolk Medicines Support Service, which provides medicines management support to people living at home. Patients received a domiciliary visit, including medication review by a pharmacist trained in medication review, with appropriate recommendations made to the patient's GP. At four weeks, a follow-up contact was made by the pharmacist to check implementation of recommendations and to identify problems. Costs, which included staff time, consumables such as medication compliance aids and overall health costs to the NHS

such as medication and emergency admissions were evaluated. Questionnaires were posted to participants for self-reported QOL and adherence at baseline, six weeks and six months. Service costs were £201 per patient which translated to a saving of £307 per patient after inclusion of reductions in medication and hospital costs. The study states a number of limitations, which include a lack of a separate control group which resulted in the introduction of a before and after study design. In addition, the population was referred by healthcare workers involved with this patient group and the care provided by them may have impacted on overall benefit to patients. The patients referred to the service also exhibited problems likely to benefit from this type of intervention and may, therefore, have presented a non-generalisable group. Because the service was deemed to save more money than it cost it was not necessary to calculate a cost per QALY.

RESPECT was the first study to evaluate the cost-effectiveness of community-based pharmaceutical care for older patients[33 46] (2010) over twelve months. With a reported cost of £10,000 per QALY it provides strong evidence for such as service to be cost-effective with a probability of between 78% and 81%. Data presented, however, shows a marked gradation of costs and QALYs with respect to age of patient and number of medications used. Those patients 75 years old with five repeat medications produced an incremental cost-effectiveness ratio (ICER) or £/QALY of £4,661, with results ranging up to patients of 90 years old with fifteen repeat medications displaying an ICER or £/QALY of £35,185. These issues provide guidance for the implementation of future studies and demonstrate that the evaluation of cost-effectiveness of interventions for different patient groups is important when defining the service specification.

A prospective RCT based at two residential continuing-care hospitals in Ireland in 2005[47] with 225 patients (110 intervention) investigated the value of medication review. Randomisation was of all patients on wards allocated by random number to each group with controls receiving no change in usual care ie standard care. Intervention patients received a review of their medication by a team comprising three consultant geriatricians, six specialist registrars in geriatric medicine, two hospital pharmacists and three senior nurse practitioners. Access was available to complete medication lists and comprehensive medical assessments and using standard tools (e.g. Beer's criteria). Patient functionality was assessed blind using standard tools such as Barthel Index. It is of interest, that despite the strength of the intervention team only 80.1% of interventions were acted upon by the medical team responsible for daily care and this supports recommendations made elsewhere, that medication review must be part of the standard care package rather than separate from it. No changes in functional outcomes were

identified, whilst mortality was non-significantly higher in the intervention group. Average total length of stay was 101 days for intervention patients versus 63 days for control patients. Medication costs fell by £19,753 for the combined groups due to reductions in the intervention group but surprisingly separate costs were not shown. Cost of the intervention was £56,113 after deduction of medication savings and inclusion of staff costs etc and demonstrated that the intervention was not cost-effective.

In the USA and UK there is evidence that the time spent by pharmacists undertaking medication review may be justified by savings in medication costs, assuming that there are no additional healthcare costs resulting from the intervention. This assumption may, however, not be appropriate as healthcare resource utilisation costs such as medicines usage, visits to the GP and hospital should be expected to change as a result of improving prescribing quality and patient adherence. RESPECT[33] provides some evidence of cost effectiveness in the UK[46], but currently the evidence base for pharmacist based medication review in primary care is limited. Further research is required to establish costs and effects in terms of QALYs which is the NHS preferred method of evaluating if a service is suitably cost-effective to implement[43].

Various factors have prevented research studies from definitively demonstrating the expected effectiveness and benefit of pharmacist-led medication review. These include poor trial design, particularly with respect to study outcomes, and limited identification of costs. Consistently, studies have failed to provide suitably in-depth training to participant pharmacists before they undertake medication review, and two days is often seen as sufficient.

Pharmacy undergraduates do not routinely receive significant amounts of consultation training or mentored patient experience during their undergraduate course. Furthermore graduates frequently receive post-graduate training and mentoring, from pharmacists who themselves have received no formal training in consultation skills or the provision of medication reviews. Consequently, this impacts on the outcomes of studies considering the potential value of pharmacist delivered services to improve prescribing and patient medicines related behaviours.

Lastly, evidence supports integrated working whereby pharmacists undertaking medication review are part of the primary care team. However, many trials, such as Homer[36], have used the model of a pharmacist unknown to the team undertaking medication review and communicating recommendations in written form. Evidence shows this method to be less likely to achieve positive results.

Research suggests that studies surrounding pharmacist delivered medication review services must be more rigorously planned and implemented.

## **1.2 Complex interventions**

The provision of medication review by pharmacists is defined as a complex intervention when measured against recent UK based guidance by the Medical Research Council (MRC)[48] as it consists of several interacting components and there are a range of possible outcomes. The MRC also strongly recommends that the evaluation of such interventions requires a much more structured approach prior to their implementation. Randomised controlled trials (RCTs), which are the preferred method of testing complex interventions, should be based upon evidence from a systematic review of the literature, stakeholder involvement, feasibility testing, piloting and introducing elements to ensure intervention fidelity. None of the large UK based[36 45 49] studies include all or many of these elements and issues such as training needs, communication barriers and identifying the most appropriate primary outcome measures may have been resolved more effectively if such guidance had been in place prior to their implementation.

Whilst RCTs are the recognised method for testing complex interventions, MRC[48] guidance also suggests that mixed methods are suitable for development and evaluation of complex interventions. Kitzinger[50] and Jones[51] support mixed method research with quantitative methods providing information and an explanation and qualitative data enabling us to understand perspectives, identify problems and solutions in addition to explaining processes and outcomes. Kitzinger[50] states that focus groups are better for exploring how opinions are constructed. Silverman[52] talks of the quantitative/qualitative dichotomy being open to question, with polarities between the methods being dangerous. Researchers are frequently pigeon holed into quantitative or qualitative and traditionally the two have been mutually exclusive. MRC guidance identifies the need for both approaches in the development of complex interventions as it is necessary to understand the system within which the intervention is to operate. Barbour[53] writes from a primary care background, and whilst she supports the case for the role of studies employing either qualitative or quantitative methods, he also asserts that the judicious combination of the two research methods at various stages in a study are supported. In addition to providing triangulation, mixed methods provide insights into processes of data construction, enable identification of relevant variables to be studied, and explain unexpected findings.

The approach recommended by the MRC which supports a mixed methods approach to test complex interventions is not reported within many of the pharmacist-led medication review studies [30-32 36 47 54 55]. The lack of intervention testing and development may provide some explanation for the lack of compelling evidence being identified for this intervention. Zermansky[37], when discussing the effectiveness of studies which sought to evaluate pharmacist-led medication review, criticises the design and set-up of studies. Specifically this includes, detailing the content or 'nature' of the medication review, population characteristics, outcome measures and whether cost-effectiveness is evaluated. There is no mention, however, by the author of the need for literature review and piloting or feasibility testing. An exception is the Respect study[34] which undertook both significant literature review and feasibility testing.

### **1.2.1 Systematic review**

A systematic review by Holland *et al.*[56] in 2008 may provide some insight into the provision of medication services and their evaluations and consequently, in line with MRC guidance, can be used to underpin future studies of the same nature. Including all RCTs in any setting for older people (mean age >60yrs) aimed at improving medication regimens and improving patient outcomes, the primary outcome of concern was emergency hospital admission. The review yielded seventeen studies with 9,900 patients providing significant strength for interpretations. Despite different findings in some, there was moderate heterogeneity showing an overall lack of effect by pharmacist-led medication review: Relative Risk (RR) 0.99. The review also yielded twenty two trials reporting mortality and meta-analysis of these, representing a total of 11,700 patients, suggested no effect on mortality from pharmacist-led medication review, RR 0.96. Marked heterogeneity was observed within the fifteen trials identified as reporting prescribing. With five positive and one negative study, it could be suggested that pharmacist-led medication review reduced the number of medicines prescribed. Interestingly, intermediate outcomes such as effects on medication-related problems, knowledge, adherence, improving storage, reducing unnecessary medicines, all showed a positive effect. In spite of these positive outcomes, QOL showed positive benefit in only one third of relevant trials.

The study summary informs us that there is a rapidly growing body of high quality evidence, but that no trial has yet been of a sufficient size to identify a small but important gain in quality of life and that the inability to demonstrate patient benefit may result from variations in delivery of care and patient selection. This leads to the conclusion that, in



spite of positive outcomes such as adherence and medicines knowledge, these have not translated into an increase in QOL. The authors, therefore, state that there is not yet sufficient evidence to recommend the introduction of pharmacist-led medication review.

Further research is, therefore, required and must be of high quality, whilst following MRC guidance. In order to enable such a study and to follow MRC guidance, key stakeholders' views must be sought.

### **1.2.2 Acceptability of pharmacist-led medication review**

The stakeholders within medication review services are traditionally medical practitioners and patients. Consequently a review of literature to identify their perspectives may provide further insight into how such interventions can be enhanced.

### **1.2.3 Medical practitioner acceptance of pharmacist led medication review**

A postal questionnaire surveying the views of 258 GPs in 2003 in Glasgow[57], regarding pharmacists-led medication reviews received a response rate of 84%. The questionnaire was developed from semi-structured interviews with six GPs and used a five point Likert scale, open questions and free text. Five themes, or messages, emerged with a wide variation in responses observed, with no overall consensus being demonstrated on any theme. The first was a positive impact on prescribing by the pharmacist but with a small sub-set stating that the pharmacist only demonstrated minimal clinical benefit, which demonstrates that it is important to demonstrate clinical benefit to convince prescribers of value. Patient impact also displayed differences in GPs opinions, with large support demonstrated that there had been patient benefit, whilst others quoted problems for patients; mainly patients feeling "unsettled". This informs us that pharmacists must provide a service which feels part of the patient's usual care. Impact on GPs varied, with some stating an increase in workload and a smaller proportion a reduction. This demonstrates that pharmacists must ensure integration of working with the healthcare team. Some GPs reported feeling reassured whilst only two GPs reported feeling "unsettled", although it is reported that both were older. Process issues reported to create barriers included lack of space. Divergence was displayed on the topic of pharmacists' role development, with suggestions of new roles such as prescribing changes, monitoring with blood test and blood pressure measurement: however, some stated that monitoring requests were outside of a pharmacist's remit. Recommendations were made to further improve communication between pharmacists and GPs. Overall, 95% of GP respondents agreed that the service was useful to their medical practice and that benefits outweighed

problems, which provides support for the provision of medication review by pharmacists in the community. An important consideration was that this service, was funded, which eliminated the barrier of GPs providing this funding. In addition, the service was situated in GP practices which reduced barriers to implementation through further facilitating the recommended communication with GPs. This evidence, in spite of some negative responses, provides support for pharmacists undertaking medication reviews in GP practices.

An editorial in 2009[58] reviewed current evidence and, in common with others, decided that the problem is that pharmacists are distant from the healthcare team, and that interventions come too late in the process. Significantly, there is a call to abandon the shop and to learn new ways of interacting with patients and medical colleagues. There was support for adopting the model existing in UK hospitals, where pharmacists work more closely with other members of the healthcare team.

A non-empirical article by an Australian GP[59] aimed at informing other GPs about medication review by pharmacists recommended a home medication review service which is delivered through co-operation between a GP, a community pharmacist and an accredited pharmacist. The author stated that the benefit of the service is improved patient outcomes through teamwork and improved communication, whereas these elements are not always evident in studies involving pharmacist medication review, when recommendations may often be provided in writing. The Australian service, however, required a written report, followed by a GP: Pharmacist discussion which demonstrates good communication opportunities. However, the uptake of the service by 2003 involved only 6.13% of GPs. Reasons identified in focus groups with GPs were lack of knowledge of the scheme, fear of change partly due to feeling that the present service was adequate, and a fear of pharmacists taking over. These views demonstrate that pharmacists may need to communicate the benefits of the scheme to those GPs not currently participating in pharmacist-led medication review schemes in order to overcome existing barriers to implementation.

Face-to-face semi-structured interviews were undertaken in 2010 with thirty eight GPs who had experienced the pharmacist-led medication review service in New Zealand in 2010[60]. The key theme identified was that GPs evaluated the benefits of services in terms of patient outcome against resource utilisation (both pharmacist and GP time) in order to arrive at a concept of value. This approach supports evidence presented earlier that cost-effectiveness of services must be proven. Some participants called for funding

to pay GPs for the time taken to meet pharmacists, whilst importantly this face-to-face feedback mechanism was the preferred method of communication of medication review. Some negative views were displayed when territoriality emerged, with GPs stating that it may be an issue for other GPs, but not themselves, whilst many emphasised the role of GPs controlling the clinical decision-making with this not being the pharmacists' territory. A dichotomy emerged, with ambivalence for the future for community pharmacist-led medication review. Whilst over half of the GPs supported the service, there were caveats that "reviews had to be done well if they were going to work and the pharmacists had to have credibility". Those who had experience of hospital services were impressed by pharmacists' skills ("fantastically useful") whilst emphasising the close working relationship there as a key issue. This study provides useful views on barriers to the introduction of medication review, such as territoriality demonstrated by GPs and that pharmacists must be seen to be part of the team, however, support did exist for pharmacists undertaking medication review.

#### **1.2.4 Patient acceptance of Medication Review**

Whilst there is research exploring GPs and pharmacists opinions regarding medication review, patient opinions have not been extensively explored. Room for Review[5] in 2002 reports opinions from forty patient interviewees aged 50 years to 'nearly' 100yrs, most of whom had never heard of medication review. Of those who had previously received a medication review from specialist consultants, or for older patients from a GP, all but one found it helpful. Some patients who had not experienced medication review had reservations due to the possibility of medicines being stopped, or concerns that healthcare professionals would not have time, which shows us that information must be provided to patients in advance of a review. However, the majority of interviewees stated that they would welcome medication review. Many patients had implemented their own compensatory mechanisms in the absence of medication review, such as reading leaflets, stopping medicines without advice or taking a list of medicines to their doctor or pharmacist. One patient is quoted as saying "I review it. I drive the pharmacist mad". The people involved stated that they "simply wished to tell their health professional how they felt and to see if they were taking the best medicines for their problems".

To achieve a useful medication review the interviewees stated that they would require:

- specific time set aside for medication review,
- someone to listen carefully to questions,
- clear explanations in simple language,

- an open interaction where they could be honest about what they were actually taking, and the health professional would be honest about the consequences of taking (or not taking) the medicines.

These last issues indicate that patients have requirements of consultation styles, and a literature search to establish the ideal style is appropriate.

#### **1.2.4.1 Patients' preferences for consultation style**

Where a medication review involves a consultation the healthcare professional undertaking it must take account of the patient's needs and or preferences in order to ensure patient benefit via agreed outcomes. It is important to identify patients' preferences in order to improve patient acceptability and enhance the effectiveness of medication reviews.

A study undertaken in USA in 2011 which evaluated 207 patient consultations with twenty nine doctors, showed that full involvement of patients in the consultation is important in order to gain better understanding of the patients' health beliefs[61]. However, they found that doctors showed poor understanding of patients' health beliefs and, therefore, expected that the patients' own health beliefs were not dissimilar to their own. Also, it was established that a closer match existed between the patient's self-reported beliefs and the physician's understanding of them, when patients proactively sought and gave information within a consultation. It is, however, unreasonable to expect patients to provide the drive for good communication resulting in effective information transfer and the person conducting the consultation must be aware of these issues and manage the consultation accordingly.

Support for this view is provided by Kaae[62] in 2011 in an evaluation of pharmacy students, based in Danish pharmacies, who undertook medication review with patients with diabetes. Eighteen pairs of letters sent by the students to GPs and patients after the medication review were analysed. Inter-student variation was displayed in communication, with a marked difference in feedback to GPs as well as patients who were found to be given too little information or options about their own condition. The paper concludes that students did not automatically think "in terms of equal partnerships with patients" with this resulting in an asymmetric and potentially paternalistic behaviour. Patients were not encouraged to become involved in their disease management process, providing further evidence of the requirement for the provision of effective communication skills training to students prior to undertaking experiential training.

Little[63] *et al.* in 2001 reported a study undertaken in three Hampshire GP practices utilising pre and post-consultation questionnaires. These were developed locally from data of patients' requirements in consultations and utilised five point Likert scales: there were 865 participants with 824 (95%) returning pre and 661 (76%) returning post consultation questionnaires. Patients reported a preference for a patient centred approach with good communication, partnership and health promotion. Little also reported that patients described as more unwell had a greater desire for good communication, whilst a reported positive approach by the doctor resulted in a reduced symptom burden[64].

A study in 2009 at one GP practice in Norfolk[65] undertook pre and post consultation semi-structured interviews with twenty patients to establish expectations and the degree to which these were met. Doctors were expected to be professional, authoritative, competent, confident, helpful, and courteous whilst showing empathy or sympathy. Interestingly, listening by doctors was not always expected. Doctors were also expected to be interested, demonstrate understanding, provide information and give sufficient time. Negative doctor attributes were associated with the patient feeling uneasy, defensive and inhibited about talking about their condition, which could seriously affect the outcome of the consultation. This is a small study with limited generalisability, however, it identified interesting issues which can be applied to other consultations.

Nair *et al.*[66] in Canada in 2002 undertook focus groups with 88 patients, 27 doctors and 35 pharmacists and established an apparent conflict between the information that patients want and the information that doctors or pharmacists think the patient wants or needs. Patients want specific information about side effects, duration of treatment and, interestingly, the treatment options available. Doctors or pharmacists conversely think that too much information about side effects may deter patients from taking their medicines.

There appears to be agreement that a patient centred approach using good communication, and ensuring that the patient is encouraged to provide information is more effective, whilst the information given to patients must be sufficient to enable full appreciation of the facts. However, evidence suggests that pharmacists providing medication review services in the UK may not demonstrate the required consultation skills and that, therefore, communication skills training focussing on these aspects is required.

### **1.3 Improvement in consultation skills training is required for UK pharmacists**

Salter[67] undertook a qualitative study with participants (twenty nine patients and eleven pharmacists) of the previous HOMER[36] RCT when medication review consultations were undertaken one to one. These were observed, taped and transcribed for future analysis, whilst observations were made directly of the body language of participants by the researcher. Patients were interviewed up to one month post-medication review to collect data on their perceptions of the encounter and in-depth interviews were carried out with pharmacists both pre and post-medication review. Finally the pharmacists received formal feedback and attended a focus group. Discourse analysis revealed a lack of skills by the pharmacists, as they continued to provide advice to patients both in the absence of identified problems and after demonstration of competence by the patients. This was interpreted as potentially undermining and “threatening the patient’s assumed competence, integrity and self-governance”, with ultimately a loss of confidence by the patient in their healthcare regimen. The researcher clearly states that we should question the advice-giving role of the pharmacist and demonstrates “the pharmacy professions’ need for further training in communication skills”. Further, it is stated that pharmacists are not traditionally trained in communication skills to the same extent as other healthcare professionals. It is possible in interpreting these results to conclude that the pharmacists may have been overenthusiastically attempting to record the maximum level of input, as they were being observed. This paper provides support for a review of the consultation skills training provided to pharmacists and recommends identification of novel approaches for delivery.

Further analysis of the Homer study[36] reported in 2009[68] yielded similar conclusions, although greater detail is given of discourse, with comment that the pharmacists’ employed an interrogative style on occasions with a target of medical compliance. The lack of current communication training for pharmacists is once again highlighted. “This study reinforces the importance of the pharmacy profession addressing the communicative competencies required in practice that can take into account the unique interactional dynamics of intimate consultations”. Further comment is made of the complex nature of communication within the counselling context. The author recommends that pharmacists receive effective communication training, specifically in the area of consultation. The comment that effective communication is included in pre and post-registration syllabi possibly supports further training for qualified pharmacists as they are tasked with evaluating competencies of pre-registration pharmacists. It could be

argued that without effective skills themselves, academics and pre-registration tutors cannot evaluate others. Salter refers to technical-rational pharmacy discourse and it is interesting to note that Schon[69] forecasted the need to re-evaluate the use of technical-rational approaches which were defined as 'problem solving with the application of science'. He goes on to point out that agreement in deciding 'ends' should be undertaken and that this is a non-technical process, whilst encouraging the use of learning in practice. Both of these approaches are not yet approaches undertaken in teaching UK pharmacists.

It is essential that healthcare professionals, including pharmacists recognise that effective communication is essential when they interact with patients. Cipolle Strand and Morley[35] in 'Pharmaceutical Care Practice' state that "the ability to communicate with each other and with patients will be the best predictors of whether a practice will succeed. Quality care means quality communication". Silverman, Kurtz and Draper[70] in *Skills for Communicating with Patients*, state that communication is a core clinical skill, an essential component of clinical competence. They also state that communication skills within consultations (which include medication reviews) are not an optional extra and that without these skills, knowledge and intellectual efforts are wasted. These statements from respected practitioners provide strong evidence that communication skills within consultations are a basic requirement of modern healthcare practitioners. This teaching must prove to be effective for pharmacy undergraduate students to ensure that they become effective practitioners. Silverman *et al.*[70] state that these skills need to be taught and learned, as it is not simply a personality trait. However, they state that a variety of methods are required to teach these skills and that "experience alone can be a poor teacher".

Evidence, therefore, exists for the need to train pharmacists in communication skills, particularly within consultations and that this should not be confined to the pre-registration setting. The provision of medication review services in the USA and Australia as an education tool to develop clinical decision making and consultation skills of pharmacy undergraduates has been reported.

#### **1.4.1 Involvement of pharmacy students in medication review**

Whilst consultation skills can be improved whilst working, it has been recognised by other healthcare professions that such training needs to start within the undergraduate degree[71-73]. In addition, the modernising pharmacy careers programme[74] recognises the need to teach these skills within the undergraduate education programme. Outside of

the UK, Schools of Pharmacy have reported utilising the provision of medication review services to patients as one approach to improving consultation skills.

A non-controlled study by Boyatzis and Batty[75] in 2004 in Western Australia was undertaken on thirty six fourth year pharmacy students participating in a programme of domiciliary medication reviews. The study demonstrates positive results and, therefore, increases the sustainability of such training. This form of medication review is an Australian government recognised, and funded method of patient care[41]. Students were recruited during a community pharmacy placement during which they undertook continuous training with university support and a one week series of lectures and workshops prior to intervention. In liaison with a preceptor pharmacist and the patient's GP each student generated a list of patients over 60 years of age with greater than three prescribed medications. The students then used this list to enable recruitment of 189 patients by telephone. During the telephone call students asked questions to estimate patients' recall of medication names and indications. They then undertook a domiciliary medication review (DMR) of approximately one hour duration using a data collection form to guide and standardise the process. Evaluation of the medication review was sought from students and patients by postal questionnaire utilising five point Likert scales. This was undertaken after the medication review, with recommendations forwarded to the patients' GP after moderation by the supervising pharmacist. Incorrect or unknown indications for medicines were provided by 39% of patients, but no data is given for knowledge post DMR. Students identified 2.1 (1.7) problems per patient for 80% of patients with the GPs endorsing 1.1 per patient for 49% of patients, whilst the GP and pharmacist only identified a further 0.4 and 0.2 respectively. Mean scores for patient feedback on the medication review ranged from 4.1 to 4.7 out of 5, with student feedback on themselves showing lower scores of 3.4 to 4.8 out of 5. Qualitative comments from patients showed that patient knowledge regarding their medicines improved, they found the review interesting, important and they would recommend it to other people. No clinical benefit can be claimed following the DMRs by the student pharmacists as no clinical data was collected. The process was found to be acceptable to students, GPs, preceptor pharmacists and patients and provided a method of teaching communication skills to pharmacy students through experiential learning in a DMR.

A novel 'Wellness Center' set up in the USA to provide training to pharmacy students in 2007[76] included risk factor identification, patient counselling and clinical decision making. Over five weeks students undertook activities primarily focussed on health promotion but also including 'disease management' which took the form of a medication review. 83-93%



of participating students agreed via a questionnaire that the experience had helped them to understand their role in 'wellness'. Analysis of student 'before and after self-rated' scores demonstrated significant improvement in students' confidence and effectiveness at communication and problem solving.

In a study in a large USA city[77] in 2007, pharmacy students participated in a six week 'hands-on' programme where they provided medication evaluation, counselling, screening services and immunisation to elderly patients. Again, working with patients prompted students to report "confidence building, strengthened communication skills" and being more aware of patients' needs. Students consistently scored the programme very positively, with free text comments demonstrating that they enjoyed the learning experience whilst learning. Importantly for continuation of such schemes, patients expressed satisfaction with all aspects of the medication review including students' skills and consultation content.

In 2007 a USA based prospective observational study[78] with fourth year pharmacy students participating on internal medicines rotations at a 616 bed community teaching hospital found that ten students made 625 recommendations (42.5% oral) over the five month period. Over 90% of recommendations were medication-related with examples including indication, dose, route, inappropriate medication, allergy, duplication of therapy, with 68% accepted showing that the students are capable of a wide range of patient care activities related to medicines. Of recommendations made, 227 (36.3%) were formulated from evidence based medicine guidelines, with 123 of these provided to the doctor in written form. Oral recommendations were made to resident physicians, in a learning environment, with whom a relationship had been established, whilst written recommendations were made to community physicians. This study provides evidence that communication about medication review is more effective when face to face. It also demonstrates that pharmacy students are capable of identifying recommendations for improving care in real life situations and, as the authors state, undergraduate pharmacists may have the ability to positively impact on patient care.

The University of Illinois developed a programme[79] for pharmacy students to undertake medication review plus falls risk assessment and blood pressure (BP) measurement in patients' homes. Preparation included lectures on undertaking medication review, identifying falls risk, undertaking BP measurement, and practical sessions undertaking medication review with 'mock' patients. Then groups of three students, with a "medically trained chaperone", completed medication review with volunteer patients, and forwarded

interventions to the patient's physician for action. The primary outcome was to establish whether trained undergraduate students could undertake a home medication review and demonstrate patient benefit. 57 (48%) of the 118 patients visited by one of three students had prescription changes made, after student recommendation to their primary care physician. These included nine drug interactions judged to be potentially major by a hospital pharmacist. Many changes were housekeeping issues such as removal of antibiotics or use of over the counter medicines. The authors state that they "expect that this program can be successfully duplicated in other locations", and state anecdotally that patients were appreciative of time and effort, implying that they would participate in a similar programme.

#### **1.4.2 Students working with patients with diabetes**

Studies presented previously demonstrate that undergraduate pharmacy students can undertake work with patients whilst providing benefit for both students and patients. It is of note that a number of these studies are based around providing services to patients with diabetes.

A USA conducted study undertaken in 2009 by one school of pharmacy[80] investigated fourth year pharmacy medication reviews with patients with diabetes in a "diabetes care and education centre" situated within a community pharmacy. Patients were referred by their primary care provider or by pharmacy staff for the service which was provided for free in a system where all services are usually charged for. Then students met individual patients face-to-face for a medication review supervised by a trained pharmacist. In addition to medication review and providing health advice, students undertook HbA1c, total cholesterol, low density lipoprotein (LDL), high density lipoprotein (HDL) and blood pressure measurements. Students were present for six week periods, with access to electronic medical records, and patients returned for up to six visits, therefore, patients met multiple students. Students made 533 recommendations which were faxed to the GP; acceptance varying from zero (four doctors) to over 50% (three doctors). Overall acceptance was 35% for dose changes and 28% to start or stop of medication. However, 214 recommendations were duplicates, demonstrating a possible lack of records or effective communication between participating students. The study fails to state if the acceptance rate quoted is of all 533 recommendations or the 319 non duplicates as they represent only approximately 60%. In spite of this, significant improvements were observed in patients' HbA1c, cholesterol, LDL, HDL, BP and body weight, with the control of all of these parameters important for controlling the health of patients with diabetes.

Experiential inter-professional learning was developed in San Francisco[81] with trainee doctors ('medicine residents'), nursing students and fourth year pharmacy students providing care in teams to patients with type 2 diabetes (T2DM). All students participated in a training course for half a day each week during their rotation comprising a lecture on aspects of diabetes care, a clinical discussion session and clinical visits with patients. An on-line course focusing on practical aspects of diabetes care was also made available. Whilst collectively responsible for quality of care, the student team divided the work, with pharmacy students primarily responsible for medication therapy management, insulin initiation, smoking cessation and patient education. Patients were randomised to intervention or usual care and those in the intervention arm attended repeat appointments with the member of the team appropriate for any needs identified. Team rotation resulted in patients seeing more than one person of each discipline as medicine residents participated for two months, nursing students for ten to twelve weeks and pharmacy students for twelve weeks. Intervention group patients received more tests and examinations than control (not significant other than foot care with  $p < 0.001$ ) and, unsurprisingly, statistically more planned general medicine visits ( $p < 0.006$ ). An important finding was that there was a non-significant reduction in 'emergency room visits' for intervention patients. The authors conclude from this that overall there was an increase in healthcare visits, but a reduction in cost and improved care through utilisation of the appropriate care setting. Both patient groups improved in clinical status, although it is stated that both groups improved possibly due to a confounding factor, the introduction of new treatment guidelines for diabetes, released during the study period. Data for intervention students compared to non-participant students showed significant improvement in ability to provide diabetes care. Problems with team working are mentioned, mainly around communication, as the team was frequently changing. The study is interesting in demonstrating that students of different disciplines can work together, provide benefit to patients with type 2 diabetes and develop clinical competence.

Whilst the results from student led medication reviews have been published outside of the UK there is currently no evidence of a similar nature from within the UK. Additionally, no single model of teaching consultation skills within a medication review has been agreed, either within or outside the UK.

It was established earlier in this chapter that evidence exists demonstrating that pharmacists lack consultation skills, however, these skills have also been demonstrated to be important for effective patient care. Evidence has also been presented that the teaching of these skills to undergraduate pharmacists, within the context of medication

review, has been demonstrated to be effective outside the UK. It is important to identify if providing training in consultation skills within the context of medication reviews to undergraduate pharmacy students in the UK can be demonstrated to be effective.

## **1.5 Summary**

Medicines are central to the provision of western healthcare and as such need to be utilised appropriately. Whilst medication review is identified as the process to promote this there is no compelling evidence of effectiveness and cost-effectiveness for pharmacist-led medication review with patients in the community. Whilst aspects of research design have potentially contributed to the failure to prove this, a lack of effective communication skills by pharmacists has also been identified and reported as an additional factor.

Most research which seeks to evaluate pharmacist-led medication review provides brief training, including consultation skills, prior to implementation. However, this has failed to produce positive results, thus indicating that more intensive training is required. Consultation skills can potentially be developed within the undergraduate taught curriculum through the provision of patient services by students, as demonstrated by research published outside the UK. Such teaching is, however, complex and expensive to deliver. Consequently evidence to demonstrate its potential benefit for patients and students is required to support its implementation. Following MRC guidance for complex interventions, this thesis will, therefore, involve stakeholders in the introduction of such a service, feasibility test and pilot it and then obtain stakeholder views post implementation. The education intervention will also be evaluated to enable enhancement and future repetition in a definitive trial. Mixed methods will be utilised to triangulate and enable a fuller understanding of the results obtained and the acceptability of them to stakeholders.

For services to be adopted within the UK it is necessary for the cost-effectiveness to be demonstrated. This is generally achieved through randomised controlled trials (RCT), with MRC guidance recommending that these should be preceded by a pilot study. This thesis seeks to develop a pilot study with the aim of providing sufficient data to enable the design of a definitive study.

## **1.6 Aims and Objectives**

In preparation for a future definitive study the aim of this thesis was to develop a supervised student led medication review service for patients with T2DM and to feasibility test and pilot it as a complex intervention in primary care.

The rationale for choosing patients with Diabetes Type 2 (T2DM) as the patient group for inclusion in this study is that they are representative of patients with a Long Term Condition (LTC). They are potentially able to benefit from medication review input to improve the use of medications, adherence to prescribed medication regimens, information about medication and lifestyle advice. T2DM is a disease with a high and growing prevalence, both in the UK and other countries. This results in a rising demand for healthcare resources and, therefore, increased pressure in terms of cost to the NHS. NICE CG66[82] stated that only 11% of people with T2DM have received structured education, yet it is a LTC managed predominantly by the patient or their carer. It also highlighted the need to ensure lifestyle advice whilst reminding us of the need for patients to take medicines correctly; a theme also identified in other publications[23]. Government advice, therefore, recommends that healthcare professionals should interact with patients with T2DM in order to promote improvements in health. Teaching pharmacy students through the provision of medication review for patients with T2DM potentially presents benefit by both parties.

### **Objectives**

- to develop the medication review service and research design through stakeholder engagement
- to develop and assess a training course designed to prepare pharmacy students to undertake medication reviews.
- to describe the educational effect of utilising medication review with real patients,
- to test the feasibility of pharmacy student-led medication review for patients with T2DM in primary care,
- to describe recruitment and retention rates and provide reasons for non-retention and to test the randomisation process,
- to determine the acceptability of the medication review service to patients and students i.e. describe the contribution made to patient care by students during the medication review process,
- explore the potential effect of student medication review on a range of outcome measures and identify those which are most suitable as primary outcome measures.

# **Chapter 2**

## **Methods**

## **Chapter 2 – Methods**

### **2.1. Design**

This was a randomised controlled feasibility and pilot trial involving patients recruited from general practices in Norfolk. The intervention was provided by final year pharmacy students recruited from the School of Pharmacy at the University of East Anglia.

### **2.2 Ethical approval**

An application was made for ethical approval via the Integrated Research Application System (IRAS) under the title “Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care”, with full approval being granted by Cambridgeshire 3 Research Ethics Committee (REC) on 18<sup>th</sup> January 2011 Reference: 10/H0306/77 (Appendix D1).

### **2.3 Participants**

Recruitment and sample size were determined pragmatically based on numbers of final year pharmacy students likely to volunteer to join this study which involved input outside their usual curriculum. Assuming that 40 students would volunteer to participate and that each student could review two patients, then 80 patients would be required for the intervention arm and 80 for the control.

As a feasibility study no formal power calculation was required. However, a calculation to provide an estimate of the accuracy of the outcome data was undertaken and is included in the protocol (Appendix B).

#### **2.3.1 Medical Practices**

Medical practices were required as part of this study to facilitate recruitment of patients, enable integrated working of the students and medical practice and provide access to patient medical records once consent had been obtained. The GPs in the medical practices were also funded to meet students post review to discuss recommendations.

##### **2.3.1.1 Medical practice recruitment**

Assuming that each general practice could recruit 30 to 40 patients with T2DM, four or five medical practices were, therefore, required.

A representative of the Primary Care Research network (PCRN) based in the research and development department at NHS Norfolk, the local primary care trust (PCT), was used for recruitment purposes and deemed that the study should be performed in 'research active' medical practices. Only practices utilising Systmone® as their medical record access software were included as this is the most common system in Norfolk and it was more practical to train students in only one system.

A medical practice information sheet (Appendix B) was circulated to all research active medical practices deemed suitable for the study by the PCT and included the following:

- trial design including student activities,
- recruitment and patient numbers,
- activity requirements for the Practice,
- costs and methods of reimbursement.

### **2.3.2 Patient**

#### **2.3.2.1 Inclusion and Exclusion criteria**

Patients within recruited medical practices were deemed eligible for inclusion if they met the following criteria:

Inclusion criteria:

- registered with one of the four participating medical practices,
- prescribed non-insulin medication for T2DM for at least two years,
- over the age of 16 years.

Exclusion criteria:

- deemed unsuitable for inclusion in the trial for any reason by their GP,
- enrolled into other clinical trials,
- terminal illness.

The timescale of prescribed non-insulin medication for T2DM for at least two years was chosen as it was believed that students would not have the skills to influence patients or their clinicians when the disease was not stabilised. Additionally it was considered that an intervention at that stage may affect patient/physician relations.



### **2.3.2.2 Patient recruitment**

To estimate the potential response rate, eligible patients from one medical practice were initially identified by medical practice staff and randomly selected from the practice records. A letter inviting participation, a patient information leaflet, a consent form and a stamped addressed envelope were all posted out (Appendix D2). The response rate was 20%. This suggested that approximately 160 patients should be mailed in each practice so as to ensure recruitment of 32 patients. The number of patients required in each practice was reduced from 40 to 32 because an additional fifth practice expressed interest and ethical approval was provided to make this change. Consent forms (including permission to access medical records) were returned to the researcher at the UEA. Consent was provided for:

- joining the study,
- access to the patients' medical records,
- filming of the student-led consultation.

Full details of required involvement was provided in the patient information leaflet. (Appendix D2)

### **2.3.2.3 Randomisation**

Randomisation was conducted using a web-based system provided by Norwich Clinical Trials Unit (CTU). This process used a pre-prepared list of codes in random order to allocate study participants to either the control or intervention group. Participants were stratified according to their GP surgery. Within each stratum, codes were grouped into blocks of four to ensure an approximately equal number of control and intervention patients in this study.

The CTU database manager provided details of the randomisation process as follows: "The randomisation database was built using MS SQL Server and the access pages built using MS Visual Studio, ASP.NET and VB.NET. The web-site and database both resided on the Norwich CTU secure server at UEA. Access to the randomisation web-site was protected by username and password and web-traffic was encrypted using SSL technology."

Access to the database itself was restricted to the Norwich CTU database manager.

Randomisation was performed by the researcher utilising the database created and managed by the Norwich CTU database manager who had no knowledge of, or contact with, the patients recruited. Patients were randomised at the point of recruitment. Results were maintained on the database (the researcher had read-only access to this data) and on a spreadsheet held in the School of Pharmacy. at the UEA. This web-based randomisation process ensured concealed allocation.

### **2.3.3 Students**

#### **2.3.3.1 Recruitment**

It was estimated that within the time available each student could undertake a medication review for two patients. With a target number of 80 intervention patients, 40 final year pharmacy students were recruited. A simple email survey of all final year pharmacy students (n=83) the previous year established that a 50% recruitment rate was probable which would result in approximately 40 students potentially able to be recruited for this study.

All final year pharmacy students in 2011 (n=84) were eligible for inclusion in the study and were, therefore, sent an email at the end of their third year providing information about the study, including the information leaflet (Appendix D3), and inviting expressions of interest. All students who replied were sent an invitation letter, information leaflet and consent form (Appendix D3) with all replies to be sent by internal UEA post to the researcher. Any student who was unsure whether to join the study was offered the chance to discuss this with the researcher. It was agreed that if more than 40 students volunteered to join the study that they would be accepted in order of recruitment, with those in excess of 40 held on a reserve list. For practical reasons, students on the reserve list were offered the training package to enable them to join the study later if any student withdrew.

#### **2.3.4 Primary care trust (PCT) pharmacists**

The rationale for recruiting PCT pharmacists was that students undertaking activities within medical practices, and with patients, required supervision to ensure patient safety and to enhance the learning experience. PCT pharmacists were chosen as they work regularly with practices, including undertaking medication reviews. They, therefore, should have developed relationships and skills which would effectively facilitate the student-patient medication review.

No recruitment target was set, as the decision to include the pharmacists was pragmatic and based upon their availability, experience with a medical practice and the pharmacists' skills. Logistics were an additional factor, as pharmacists with suitable knowledge and relationships would enable working within a medical practice, as they knew the staff and systems. The final decision of which pharmacists to enrol in the study was, therefore, based on the above, as three of the six pharmacists expressing interest in the study already worked with medical practices recruited to the study. The researcher also had experience of working with medical practices and was currently working with one of those recruited to the study.

## **2.4 Development Phase – Confirmation of study design**

### **2.4.1 Focus groups**

Focus groups were arranged comprising six to eight participants from each of the representative stakeholder groups of general practitioners (GPs); specialist nurses; patients with T2DM; final year pharmacy students at the School of Pharmacy, UEA; and PCT pharmacists. Each focus group consisted of representatives from only one stakeholder group in order to maintain group homogeneity and encourage discussion. It has been stated that qualitative research methods, such as focus groups, enable the establishment of improved protocols[51]. The rationale in this case was to explore the current protocol and method to establish if planned interventions were acceptable to potential participants as well as identifying any changes required in order to obtain maximal recruitment and an improved intervention.

### **2.4.2. Recruitment for focus groups**

Participants for the focus groups stakeholders were recruited as detailed below. Up to two weeks was provided for all potential participants to decide if they would agree to provide consent, by signing the forms sent to them.

#### **2.4.2.1 Medical Practice Staff**

A letter of invitation, information leaflet, consent form and stamped addressed envelope were sent to all GPs from the recruited medical practices (Appendix D2) with replies sent to the researcher at the UEA. It became apparent that recruitment of GPs to the focus groups was problematic, and that recruitment would not achieve its target, as medical practices stated that the GPs were too busy. An application was made to the Local

Research Ethics Committee (LREC) for an amendment to ethical approval (Appendix D1) to allow the inclusion of practice nurses, in addition to GPs, and to allow individual interviews with staff at the medical practices instead of centrally arranged focus groups. Nurses were then provided with the same recruitment documentation as GPs. The aim of this change was to improve recruitment and ensure that all key opinions were captured. This was agreed and approval was granted (Appendix D1 - approval letter).

#### **2.4.2.2 Primary care based pharmacists**

A letter of invitation for a focus group, information leaflet, consent form (Appendix D2) and stamped addressed envelope was sent to all Norfolk Primary Care Trust pharmacists from the Medicines Management Team office at NHS Norfolk, with replies returned to the researcher at the UEA.

#### **2.4.2.3 Patients**

A letter of invitation, information leaflet, consent form (Appendix D2) and stamped addressed envelope was sent to people recruited as representative of participants in the intervention. They were patients recruited via the local diabetes patients' advice group and by advert for people with T2DM in the staff newsletter at the UEA. Replies were sent to the researcher at the UEA.

#### **2.4.2.4 Students**

All current final year students (who had just completed their course) were invited by email to express interest in focus group participation, after their final examinations. A letter of invitation, information leaflet, consent form (Appendix D2) and SAE were sent to all interested students. These students were recruited as representative of the student participants in the intervention.

### **2.4.3 Focus group and semi structured interview design and delivery**

#### **2.4.3.1 Logistics**

Locations and times of focus groups and semi structured interviews were chosen as being acceptable to potential participants.

Because the focus group for the medical practice staff proved to be impossible to arrange, discussions were undertaken as a series of semi structured interviews. This was a purely

pragmatic decision, as the alternative was that the views of these stakeholders would be lost. The interviews were undertaken in meeting rooms at the GP practices at lunchtime, with a buffet lunch provided.

The focus group for the PCT pharmacists was undertaken in a meeting room at a local hotel chosen as accessible for all participants. A buffet was provided prior to the meeting.

Focus groups for students and patients were undertaken (separately) in committee rooms at lunchtime at the UEA, which appeared an acceptable location for all participants. A buffet lunch was provided prior to each meeting.

#### **2.4.3.2 Delivery**

All meetings were run by the researcher with supervision by a senior member of the academic staff at the first meeting.

The researcher and one other person, not trained in qualitative research techniques, were present at each focus group, but only the researcher at semi structured interviews. It is recommended[83] that two team members are present to overcome problems with recording and logistics, including meeting participants, dealing with problems with the location etc. This left the facilitator free to concentrate and focus on the meeting, however, this was not deemed necessary for interviews due to the simpler logistics.

A suitably trained person was not available to take notes and assist with transcribing by noting the identity of speakers as recommended[84]. This would have enabled more effective analysis by providing the identity of the participant of individual quotes and thus revealing if those relating to one, or related themes, were all from one person.

Participants received a five to ten minute presentation of the proposed study from the researcher at the start of the session, following which the meeting lasted for approximately one hour. The following themes were considered:

- perceived benefits,
- identified concerns,
- barriers to recruitment and participation,
- methods for optimising recruitment and participation,
- opinions on the patient questionnaire and covering letter (patients only),
- logistical issues.

See Appendix C for introduction and questions used during each meeting.

Open questions (see Appendix C) were asked, with subsequent questions asked as appropriate to probe and establish the meaning of replies when judged by the researcher, as moderator, that this was required. Consensus was sought in the first (student) focus group, but when the error was realised this did not reoccur. The researcher sought to obtain the views of all participants through direct questioning of individuals who had not commented on a particular issue.

All focus groups and semi structured interviews were later transcribed by an administrator. Analysis was then undertaken by the researcher to identify common themes and issues as well as solutions which could be used to modify the final intervention.

The main findings from the four focus groups and interviews were presented to the management and steering committees, together with the data from the literature review, to enable the study design to be optimised. Following this, ethical approval was sought for amendments to study documents and methods. (Appendix D)

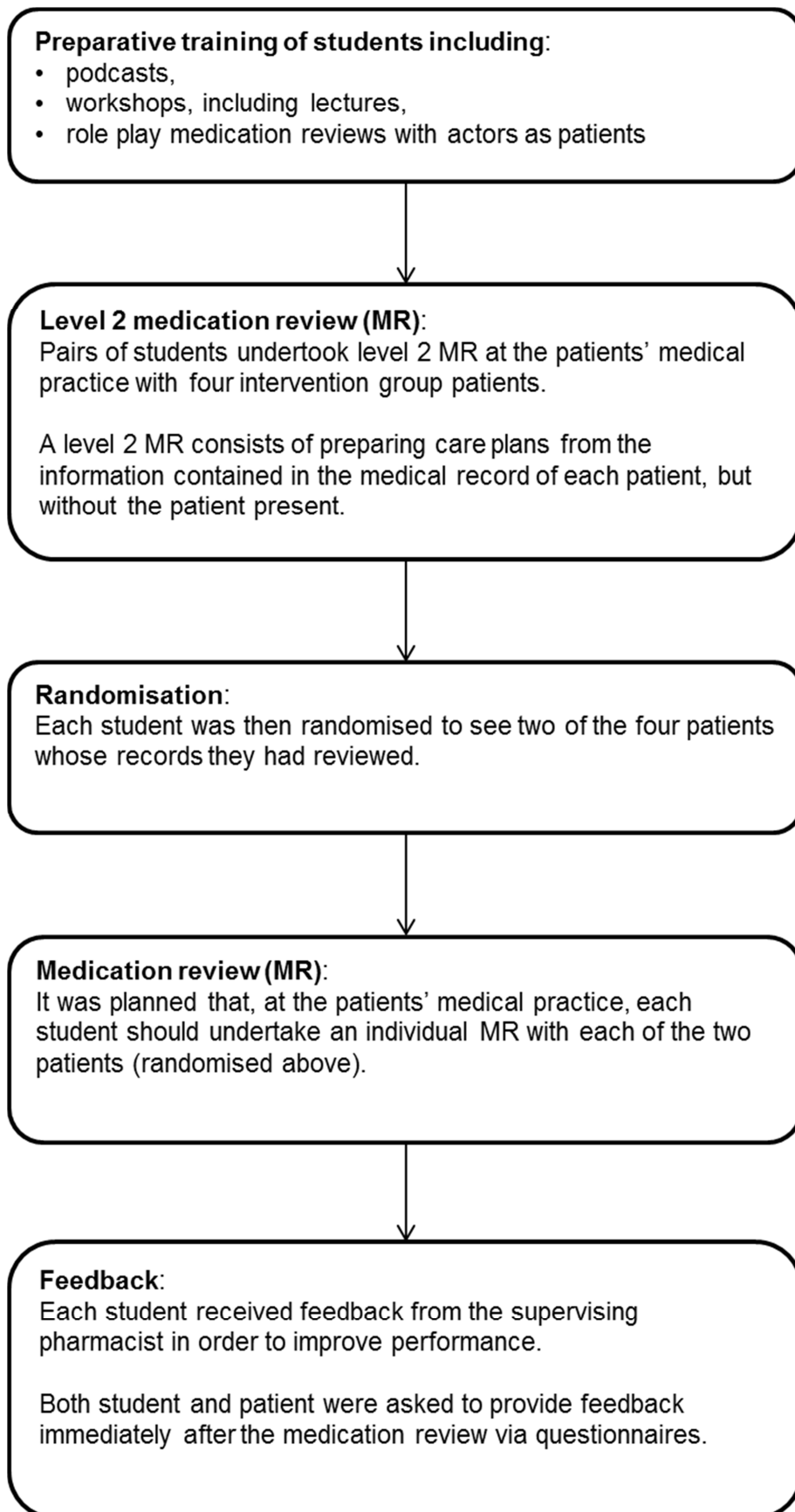
The main changes requested and approved include:

- location of the medication reviews moved from the university to the patients' medical practice,
- students were provided with transport to medical practices,

## **2.5 Intervention**

### **2.5.1 Medication review process**

Figure 2.1 displays the process of medication review commencing with preparatory training of students and subsequent level 2 and level 3 medication reviews. It demonstrates that each part of the process was undertaken in sequential order to provide preparation and experience from each activity to inform and prepare for the next process.



**Figure 2.1** Medication review process

## 2.5.2 Preparative training and development of participating students

All final year pharmacy students had already received the following training as part of their usual undergraduate experience:

- basic lectures and practicals on communication skills,
- lectures and workshops on data protection and confidentiality,
- attendance at a GP Practice to observe GP/patient consultations for at least two hours,
- diabetes aetiology, pathophysiology and therapeutics.

The preparative training for study student participants was designed to include the following knowledge and skills:

- ability to access the IT system at medical practices:
  - identify information required,
  - identify relevant information,
  - understand the relevance of information and where to find related data.
- process of care planning for people with diabetes,
- ability to communicate effectively ,
  - in a medication review.
  - when feeding back issues to medical practice staff,
- knowledge of lifestyle issues (diet, smoking, alcohol) and guidance of how to apply them in a medication review,
- motivational interviewing (via a lecture, and workshop practice session) to facilitate healthy lifestyle promotion,
- knowledge of diabetes pathophysiology, pharmacotherapy, management and evidence based guidelines.

Students obtained research passports and smartcards to enable secure access to electronic patient records via the Primary Care Trust.

Recognition that there was limited time available for teaching participant students, as they were all volunteers undertaking this in their own time, resulted in the following training structure:

- podcasts over the summer vacation,
- three half day teaching sessions,



- an interactive role-play session with actors to practice skills learned.

Time required to be provided by each participating student to undertake the preparative training.

- each podcast would require one hour of private study,
- each teaching session would require three hours attendance. Due to unavailability of training rooms at the PCT, travel of thirty minutes each way was required to an alternative training venue,
- each student was allocated a two hour session within the role-play.

No additional private study was requested of students.

### **2.5.2.1 Podcasts**

Two podcasts consisting of voiced-over lectures were provided over the summer. These included updates on National Institute for Health and Care Excellence (NICE) guidance, discussion of recent evidence, treatment options, case studies, prioritisation of treatment and treatment targets. In addition, information was provided on therapies relating to diabetes plus cardiovascular disease management with respect to people with diabetes.

The podcasts were made available to both study participants and non-participants on the UEA teaching intranet site. The system provides notification to students of new content, such as these podcasts, in order to facilitate access.

### **2.5.2.2 Use of electronic medical records**

A three hour training session to provide the skills required to access participating patients' medical records was provided by the IT training department at NHS Norfolk. During this session, a dummy patient record created by the researcher and entered into the IT system by the IT training department, was used by students to practice data capture and use of the system (Appendix E). To structure care planning by students and to enable data capture of individual patient care plans, an electronic care planning document was produced by the researcher (Appendix G). During level 2 and level 3 medication reviews the protocol plan was to utilise and record the care plan on the laptops used in the study. Within this training session, students utilised this care plan on computers in order to practice retrieval and recording of relevant information in the manner planned within the study.

### **2.5.2.3 Pharmaceutical care planning**

Session content included care-planning and lifestyle issues relating to diabetes. Students were provided with a copy of the dummy patient profile used in the previous session. This included patient details to enable practising the creation of care plans using the electronic form. Students were required to identify factors within the dummy patient's medical record which required changes to ensure optimal health gain(s). Additionally, they were required to identify gaps in information in the record which required questioning of the patient to establish if a problem existed. These constituted care issues. Examples of lifestyle issues, with targets and methods of resolution of problems were provided to students as a short discussion.

### **2.5.2.4 Consultation skills**

A podcast providing guidance on consultation skills and motivational interviewing was made available on the UEA intranet one week before the workshop.

A workshop of three hours duration comprised:

- a short lecture to explain key issues of consultation skills and motivational interviewing,
- a practical demonstration of a good consultation.

Pairs of students practiced consultations with each other using a 'dummy' patient script. Supervisory assistance was provided and students then practiced motivational interviewing in pairs, in order to either modify or initiate behaviours in their partner, to which they may be resistant. For pragmatic reasons and due to limited time, the duration of the motivational interviewing training session was only one hour.

### **2.5.2.5 Role-play session with actors**

All student participants in the study took part in a role-play session after the preparative training, but prior to meeting patients for the first time.

Professional role-players, or actors, were used as 'patients' during medication reviews to ensure good quality role-play.

Case studies for two patients were produced which mapped onto real life and attempted to provide a realistically long case history, similar to that seen in medical records at GP practices to include:

- demographics including age, BMI and latest data, eg BP,
- social history,
- drug history (including medications stopped), with dates started, dates of issues, dates stopped and allergies,
- medical history including all problems over the lifetime of the patient. Each case included T2DM, as the students will be meeting similar patients for real consultations,
- details of lifestyle such as smoking, alcohol use etc. but gaps were purposely left to allow students to gather information and provide an opportunity for practising motivational interviewing with respect to lifestyle,
- character details to include cases which tap into the emotions, e.g. fears, wants, expectations, force of character, to enable direction of actors.

Each student undertook a role-play medication review with two different actors, each of whom utilised one of the case studies.

#### **2.5.2.5 Delivery of role-play sessions**

To ensure realism and gain maximum benefit from the exercise:

- consultation rooms in the UEA clinical trials unit, which display great similarity to GP consultation rooms, were used for the session,
- six actors were used to take the role of patients, thus enabling three parallel groups. Scenarios were amended to accommodate age, sex and BMI to ensure that actors mirrored the scenario as closely as possible,
- scenarios were emailed to actors in advance to enable preparation,
- patient details taken from the scenarios and reflecting the data available in patients' records were emailed to students a week before the session to enable preparation (Appendix E),
- each session was facilitated by academic pharmacists and four PCT pharmacists,
- a general practitioner was present to receive recommendations from students and to provide feedback,
- administrative assistance was available for logistical support.

### **2.5.3 Intervention. Medication reviews**

#### **2.5.3.1 Level 2 medication review**

The researcher allocated students (with sight of student names) to medical practices using an Excel spreadsheet algorithm. Student names were visible to the researcher, for pragmatic reasons, but it was not expected that this randomisation would affect study results.

At each medical practice students, under the supervision of a PCT pharmacist, worked in pairs to undertake medication reviews for four recruited intervention patients who had provided consent. The review took the form of a level 2 medication review[85] ie, utilising the full medical records but without the patient present.

NB: Each student would later meet two patients for a level 3 medication review, but undertaking the level 2 medication review with another student provided practice with more patients i.e. four, whilst dual working provided student support.

For each medication, the student compared prescribing and monitoring with NICE guidance. They identified issues for recommendation to the patient's medical practitioner, or for further investigation in the subsequent medication review. In addition, the students identified, as far as possible from the records, issues relating to adherence, lifestyle, side effects, allergies and use of over-the-counter medicines. Gaps in information constituted a potential pharmaceutical care issue. All identified potential issues were checked and agreed after discussion with the PCT pharmacist and then recorded on a custom-designed form (Appendix G). The PCT pharmacist then, for safety reasons, checked the form prior to communication to the medical practice staff. Additionally, the PCT pharmacist recorded on the form if issues had been identified:

- by the students alone and accepted by the PCT pharmacist,
- by the students alone but rejected by the PCT pharmacist,
- by the students with assistance from the PCT pharmacist,
- by the PCT pharmacist.

Students completed a pharmaceutical care plan (Appendix G) using the forms previously utilised during the development training programme. Care plans were recorded and retained on laptops which were securely stored by the researcher. The care plan later acted as a reminder for students when meeting the patient during the face to face element

of the level 3 medication review process. It also acted as a tool for structuring both the level 2 and the level 3 medication reviews.

A PCT pharmacist moderated student questions for a one hour GP/specialist nurse practitioner feedback session. This was pre-arranged for the students at the end of their visit to enable discussion of identified medication issues. Agreed therapy changes were implemented, with GP consent, by the PCT pharmacist unless the GP preferred to implement them. Practices were offered a copy of the care plan and for that purpose the forms were produced in duplicate. Any changes recommended by the GP, nurse or pharmacist were recorded on the care plan.

It was deemed inappropriate for the students to undertake the level 2 medication review as a part of the face-to-face level 3 medication review, as they could potentially identify medication related problems which they were not in a position to implement or correct. This could have created difficulties when providing information to the patient, therefore, the level 2 medication review was undertaken first and was followed by a period of at least two weeks before the face-to-face level 3 medication review. This enabled recommendations to be implemented, by the medical practice, and for student reflection.

#### **2.5.3.2 Level 3 medication review**

The original protocol aimed to invite all intervention patients to attend a medication review at the UEA NHS clinical trials unit. During the development phase focus groups, it became clear that the intervention should be undertaken at the patient's medical practice. Therefore, an amendment was requested and approved by the Local Research Ethics Committee (LREC) to achieve this (Appendix D1).

A range of dates and times were offered for appointments and were planned, including some outside of normal working hours, to maximise participation. Patient appointments were made by telephone using administrative support at the UEA whilst attempting to achieve a balance between patient, GP practice and student needs.

Students were randomised to two intervention patients with whom they would undertake the level 3 medication review. One week prior to the medication review each student was provided with copies of the care plans relating to those patients. These had been produced by the same student when they had accessed patient records previously. The care plans were anonymised, i.e. patient identifiable information was removed for confidentiality reasons. The student was given the patient names on arrival at the medical

practice. Students were allowed a 45 minute appointment time to update their knowledge of the patient with access to the medical record (via computer in the medical practice); undertake the face-to-face medication review with the patient; and receive feedback from a pharmacist supervisor. The supervisors were present throughout the medication reviews to ensure patient safety, facilitate access to medical records, deal with any logistical problems and support the student. Supervisors also operated cameras and completed Medication Related Consultation Framework MRCF forms to provide student feedback. A summary of the MRCF is presented in section 2.5.4, with a full copy presented in Appendix G.

Early in the study one student, for personal reasons, left the study after undertaking the level 2 medication review utilising the records of patients. It was decided that the two patients randomised to participate in a level 3 medication review with the student would be removed from the study as their records had already been seen by the student. Later in the study similar situations arose when it was apparent that recruitment of patients would not reach the full target. The pragmatic decision was taken that a second student would be allowed to view those records and undertake the level 3 medication review.

Students were expected to discuss:

- each medication separately, including any 'over-the-counter' medicines identified.
- patient information needs relating to medicines, eg side effects, correct dose, actions, uses and indications, etc. The student was then expected to address the needs identified accordingly,
- adherence to prescribed regimens,
- disease states, with a particular emphasis on diabetes,
- relevant lifestyle issues and provide advice.

The care plan created from the level 3 review was updated and retained for later analysis.

All medication reviews undertaken by students were video recorded to facilitate feedback and self-reflection in addition to later evaluation of student performance. Patients provided verbal consent in addition to original written consent, although they were not visible in any recording. Video recordings obtained within this study were not analysed and discussed as part of this study, due to the lack of availability of researchers trained in this technique. However, training of a researcher in the Roter Interaction Analysis System (RIAS)[86] is planned and it has been decided that evaluation of the recordings using this technique should be undertaken within another research study, following ethical approval.

The protocol provided an opportunity for patients to provide verbal feedback on the medication review before leaving the medical practice. During the literature review it was identified that studies in USA and Australia had used short questionnaires to formalise this process. A questionnaire was produced (Appendix G) based on one used in a study by Boyatzis *et al.* in Australia (2004)[75]. The questionnaire consisted of a 5 point Likert scale in which patients could express their views on 7 questions, plus free text, after the medication review had ended. It was planned that the student should complete an almost identical questionnaire about their own performance. This questionnaire was discussed at a project steering group meeting consisting of patients with T2DM, last year's final year pharmacy students, a member of the academic staff and the researcher. This resulted in the addition of three questions: the first two related to student competence and confidence and would be answered by both student and patient, whilst the third question, provided to students only, related to students' self-assessed knowledge. Approval was sought and gained from the local Research Ethics Committee for this amendment. (Appendix D)

A PCT pharmacist or the researcher was present throughout each session when a student met a patient for medication review. Their role was to answer identified problems, provide supervision and safety, and to manage the logistics of the process. At the end of each session the supervising pharmacist evaluated student recommendations resulting from the medication review. They agreed with the students which of these recommendations should be forwarded to the GP/specialist nurse practitioner. This would be either face-to-face, or by a copy of the care plan if a doctor or nurse was not available.

#### **2.5.4 Medication Related Consultation Framework (MRCF)**

The Medicines Related Consultation Framework (MRCF)[87] (Figure 2.2) was chosen as the assessment tool for use during the medication reviews (including those involving role play) as a validated tool with which the research team have experience. (Appendix G).

During each medication review between a student and a patient in the study, scores were allocated by the researcher or a supervising PCT pharmacist, using the short form MRCF (Appendix G). In some cases two pharmacists (the researcher and a PCT pharmacist or two PCT pharmacists) evaluated performance of the student whilst the researcher trained the pharmacists in the use of the form. In addition, PCT pharmacists, when commencing supervision without the researcher, worked in pairs. These actions were designed to minimise variation in evaluation. Analysis was undertaken using an average of the two scores, in each case when two pharmacists completed the MRCF.

Figure 2.2 displays the content of the MRCF. Each section A to E is scored one to four, with four representing 'fully' able to effectively undertake the activity within that section. The form finishes with a 5 point scale represented by boxes ranging from poor to very good to represent overall impression. The MRCF was developed and validated by Abdel-Tawab *et al.*[87].

- (A) INTRODUCTION
  - A.1 Introduces self
  - A.2 Discusses purpose and structure of the consultation
  - A.3 Invites patient to discuss medication or health related issue
  - A.4 Negotiates shared agenda
- (B) DATA COLLECTION & PROBLEM IDENTIFICATION
  - B.1 Medication history, social history
  - B.2 Patient's understanding of the rationale for prescribed treatment
  - B.3 Patient's (lay) understanding of his/her illness
  - B.4 How often patient misses dose(s) of treatment
  - B.5 Reasons for missed dose(s) (unintentional or intentional)
  - B.6 Identifies and prioritises patient's pharmaceutical problems (summarizing)
- (C) ACTIONS & SOLUTIONS
  - C.1 Relates information to patient's illness & treatment beliefs (risk – benefit discussion)
  - C.2 Involves patient in designing a management plan
  - C.3 Gives advice on how & when to take medication, length of treatment & negotiates follow up
  - C.4 Checks patient's ability to follow plan (are any problems anticipated?)
  - C.5 Checks patient's understanding
  - C.6 Refers appropriately to other healthcare professional(s)
- (D) CLOSING
  - D.1 Explains what to do if patient has difficulties to follow plan and whom to contact
  - D.2 Provides further appointment or contact point
  - D.3 Offers opportunity to ask further questions
- (E) CONSULTATION BEHAVIOURS
  - E.1 Listens actively & allows patient to complete statements
  - E.2 Uses open & closed questions appropriately
  - E.3 Demonstrates empathy & supports patient

**Figure 2.2** Content of the medication related consultation framework.



### 2.5.5 Patient outcomes

Co-primary outcome measures:

- HbA1c,
- Cholesterol,
- Blood pressure.

Secondary outcome measures:

- health status measure (EuroQol EQ-5D)[88 89], which is a standardised measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as in population health surveys,
- patient satisfaction with information about medicines[90], comprises 17 items and provides a profile of patients satisfaction with the information they have received about prescribed medication. It has been shown to be valid and reliable in studies involving several illness groups,
- patient reported medication adherence[91] using the Medication Adherence Report Scale (MARS), which is a five item scale, which asks respondents to rate the frequency with which they engage in each of five aspects of non-adherent behaviour.
- patient reported autonomy[92 93] using Beliefs about Medicines Questionnaire (BMQ) which is an eleven item scale,
- Diabetes Treatment Satisfaction Questionnaire[88] (DTSQ) which is an eight item scale which asks respondents to rate their views about treatment. It includes hypoglycaemia and hyperglycaemia scores.

The Medical Research Council (MRC) guidance[48] states that inappropriate choice of outcome measures may result in negative outcomes by research studies.

Co-primary outcome measures of HbA1c and blood pressure were initially chosen as they are key measures which are known to reduce the risk of significant events[82 94]. They were also chosen because pharmacist-led medication review in patients with diabetes have demonstrated significant reductions in blood pressure[95 96] and HbA1c[94]. At the ethics committee review of the study it was requested that cholesterol should be added as

a co-primary outcome. Good control of cholesterol is also necessary to reduce long term morbidity[82] and this was accepted. Studies are only available outside the UK with respect to reduction of lipids following pharmacist-led medication review[97 98].

Co-primary outcome measures of HbA1c, BP and total cholesterol, rather than one primary outcome measure, were used to establish the most suitable outcome measure for a definitive study. This is accepted by MRC guidance[48] and was also recommended by the approving ethics committee.

## **2.6 Data collection – outcomes**

### **2.6.1 Patients**

#### **2.6.1 1 Baseline patient data**

##### **Questionnaire**

Both intervention and control patient participants were posted a copy of the baseline questionnaire, (Appendix G) with a covering letter and stamped addressed envelope. Experience from other studies showed that the questionnaires should take 20 minutes to complete.

The questionnaire was compiled from the following validated questionnaires:

- EQ5D health questionnaire (Euroqol)[89].
- SIMS – satisfaction with information about medicines[91].
- MARS – medication adherence report scale[99].
- BMQ – beliefs about medicines questionnaire[93].
- DTSQ – diabetes treatment satisfaction questionnaire[100].

A further non-validated question asked whether the participant used a medicine compliance aid.

Questionnaire analysis:

The sum of the seventeen SIMS[91] question responses produced a total score, with a score of one allocated if the patient rated the question ‘about right’ or ‘none needed’ or zero if the patient rated the question ‘too much’, ‘too little’ or ‘none received’ Sub-scale analysis was undertaken by generating a sum for the ‘actions and uses’ of medicines, or

'potential problems' of medication questions. In each case high scores indicated greater satisfaction with the amount of medicine information received. Comparison of intervention and control group data post intervention was undertaken for 'total', 'action and uses' and 'problems'.

For the five items of MARS[99] the score for each question which ranged from one to five was summed, with a maximum of 25. High scores indicated higher adherence to prescribed medication.

Use of medicine compliance aids was answered 'yes' or 'no' to give an indication of support obtained with taking medicines.

BMQ[91 93] questions 30-40 in the patient questionnaire, with each question scored one to five. The sum of the questions 31, 33, 35, 37 and 38 in the questionnaire produced a score of maximum twenty five where higher scores indicated high concern about potential adverse effects of prescribed medicines. The sum of the questions 30, 32, 34, 36 and 39 in the questionnaire produced a score of maximum twenty five where higher scores indicated strong belief in necessity and efficacy of prescribed medicines.

DTSQ[88 100] questions 41- 49 in the patient questionnaire with each question scored one to six. The sum of the questions 41 and 44-48 in the questionnaire produced a score of maximum of 36 where higher scores indicated greater satisfaction with each aspect of treatment for diabetes. DTSQ[88]Questions 42 and 43 in the questionnaire related to perceived frequency of hyperglycaemia and hypoglycaemia respectively with a score of zero to six for each. Low scores indicated blood glucose levels closer to the ideal whilst higher scores indicated problems.

### **Demographics**

Patients' age and gender was obtained from their medical records to enable comparison of control and intervention groups at baseline.

### **Follow up questionnaire for patients**

Both intervention and control patient participants were posted a copy of the follow-up questionnaire (Appendix D3) with a covering letter and stamped addressed envelope.

This questionnaire was identical to the baseline questionnaire apart from containing additional questions to identify frequency of contacts with pharmacists. Analysis followed

the same methods as at baseline, with the additional questions analysed by Mann-Whitney U.

The latest result after six months from the medication review for HbA1C, BP and serum cholesterol for each patient were obtained from the patients' medical records. Where BP, cholesterol and HbA1c had not been measured, medical practices were requested to undertake the test. Patients had given written consent for this, and a fee for these tests had been agreed with the practices. In cases where the medical practice had still not undertaken measurements one year after the student-led medication review, the result was marked as unavailable, as analysis would have been inaccurate due to the length of time following recruitment.

### **Clinical data**

Clinical results for both intervention and control patient participants were collected from the medical records of each patient.

Baseline data was collected post-intervention, for logistical reasons, with the most recent results for HbA1c, BP and total cholesterol recorded prior to the intervention collected.

Post intervention data was collected at the same time with the most recent results after six months post-intervention taken. Where results were not recorded, the medical records of those patients were searched at a later date for the first result. If a result was not available for one year after the intervention, no result was recorded, as beyond that date it would have no clinical relevance to the study due to other confounding factors. Control patients had no intervention and in order to decide on a suitable start point for the six months, discussions were undertaken with a researcher in the Norwich School of Medicine who was undertaking supervision with this study. It was agreed that data would be collected at a point six months from the mid-point between the first and last medication review at each medical practice. Where data was not collected, medical practices were requested to invite the patient to attend and have a blood test (ethics approval and patient consent obtained Appendix D). These tests were funded (time to make appointments and take blood plus the cost of the blood test) within the study and formed part of the agreement with medical practices.

When data was collected, it was established that data relating to LDL cholesterol in serum was not available for all patients. It was, therefore decided that total cholesterol would be

collected as the results would enable comparison between groups, whereas LDL cholesterol would present problems due to missing data.

## **2.6.2 Student and patient opinions**

### **Post level 3 medication review questionnaire**

Immediately post medication review both the student and the patient were asked to complete the questionnaire described in section 2.5.2.7 (Appendix G). Pens were provided and physical separation was ensured, with the patient assured that the results would be used for study analysis and not to judge the student.

No pressure was made to ensure completion of the survey as that may have affected results.

All statements were rated using a five point likert scale, with five = fully agree.

Statements for both patients and students were:

- The student was well organised.
- The student had a very professional attitude.
- The student communicated well.
- The student showed good confidence
- The student was an appropriate person to review my medicines.
- I learnt something useful about my medicines.
- The review of my medicines was interesting.
- The review of my medicines was important for my health.
- I would recommend this medication review to other people.

Students were also asked to rate an additional statement:

- I was comfortable with the level of knowledge that I had to carry out this review.

## **2.6.3 Students**

### **On-line survey of students' opinions of the training programme.**

All students commencing training for the study (n=47) were asked to complete two on-line surveys with requests sent by emails with each including a link to a survey with a request

to complete. These two surveys sent at approximately two week intervals. Students (n=15) leaving the study at any point were included as their views may show reasons for their action.

The surveys consisted of a mixture of questions, using 5-point Likert scales, which related to various aspects of the training were used. The use of free text in some sections was expected to elicit true feelings that may not be expressed in answer to other questions. Free text answers were subjected to simple content analysis.

Survey one sought the views of the students about the role-play session in which students undertook medication reviews with actors as patients (Appendix G).

A reminder regarding each survey was sent after two weeks.

Questions rated on a five point likert scale were used to ascertain student opinions on:

1. Timeliness and adequacy of preparation information.
2. The suitability and appropriateness of the location.
3. The use of actors as a learning tool.
4. The quality of the feedback provided.
5. The time allocated to different elements of the session.
6. The overall experience in particular with respect to personal feelings.

Survey two sought the views of the students about the whole course, which included preparative training, undertaking level 2 medication reviews at medical practices and undertaking level 3 medication reviews with patients at medical practices (Appendix G).

Questions were included about the preparative training to assess its effectiveness and sought their opinions on:

- Its effectiveness with respect to developing communication skills.
- Additional skills developed.
- The most and least rewarding aspects of the experience.
- How their feelings have changed during the process.
- Whether they would recommend this programme to another student.
- What changes could improve the process.
- The individual elements of the training.

Respondents were anonymous in order to gain the maximum response possible and unbiased answers. Therefore, results could not be distinguished between those students who continued and those who discontinued.

A reminder to complete each survey was sent by email after 2 weeks.

### **Interventions or care issues identified by students**

During both level 2 and level 3 medication reviews students utilised a care plan. The content and structure was devised by the researcher using the principles detailed in Pharmaceutical Care Practice[35] and an electronic pharmaceutical care plan obtained from Assurance System. The care plan was devised to be utilised electronically with drop-down boxes for ease of use.

Sections included are displayed in Table 2.1 (section 2.7.4.3) with a copy of the care plan included in Appendix G.

Students completed the care plan during the level 2 medication review, with recommendations or planned actions recorded in the relevant section. This plan was updated at the level 3 medication review.

Recommendations and planned actions recorded by students represented the data collected, as they each represented a care issue. Forms were collected from students after each medication review.

### **Students' academic attainment**

During the literature review it was identified that a criticism of some studies was that only the highest academically achieving students would have volunteered. However, no information was available of effect on overall academic attainment in literature reviewed. Therefore, a request was made to UEA ethics committee (Appendix D5) to collect the academic results obtained by all final year pharmacy students at the end of their third year (at the point of recruitment) and at the end of their fourth year (post intervention). The rationale for using the data of all the students in the year was that volunteers would represent intervention and non-volunteers would represent control. This request was approved by the ethics committee. Student names were anonymised to the researcher.

These were collected at the same time, after the final year examination results were announced. The rationale was that data could all be requested from administrative staff

as one set of data. Earlier collection could possibly have produced bias with respect to teaching within the curriculum or of study results. This was unlikely but was avoided.

Results requested included mean of exam results for year 3 and year 4 for both intervention (students participating in the study) and control (students not participating in the study). In addition, Objective Structured Clinical Evaluation (OSCE) results for year 4 were requested for the same groups.

OSCE stations, which assessed communication skills and which are, therefore part of the results shown include:-

- medication history taking,
- responding to symptoms,
- medicines information query taking,
- counselling.

(Appendix G - Objective Structured Clinical Evaluation marking forms OSCE).

Results were recorded as pass, distinction or fail. A pass required at least 70% within both skills and detail sections with no 'essential' items missed. If, in addition, the student attained over 90% in a section with no 'essential' items missed they attained a distinction. An OSCE station is recorded as a fail if the student fails any element of the OSCE deemed to be essential by academic staff, even if a distinction is achieved in any other element.

## **2.7 Review Focus Groups and Semi structured interviews**

Repeat focus groups and semi structured interviews were undertaken at the end of the study using the same methods as during the development phase. These occurred with four groups representing the stakeholders in the study:

- intervention patients who had received a medication review,
- members of the GP practices involved in the study,
- students who had participated in the study and met a patient at medication review,
- PCT pharmacists who had participated and provided supervision for students during MR.



Moderation of the students' focus group was undertaken by two independent people (PhD students with experience of this function) who were unknown to the students. This was to ensure that no bias resulted from the researcher undertaking the focus group as he was well known to the students.

Recruitment was identical to the previous focus groups with invitation letter, consent form and stamped addressed envelope being posted to the individuals (Appendix D3).

### **2.7.1 Questions**

Questions (Appendix H) were developed from information arising during the intervention in order to identify:

- intervention benefits,
- intervention problems,
- acceptability of the training method (relevant to students only),
- changes if the research was repeated.

Sessions were managed identically to those conducted in the development phase. Tapes were transcribed and thematic analysis undertaken to identify issues for possible follow-on studies or publication.

## **2.8 Data Analysis**

### **2.8.1 Development and Review Stage Focus Groups and Semi structured interviews.**

All interviews were recorded on an Olympus VN 510, transcribed verbatim by one secretary and then analysed for themes and categories by the researcher.

To provide structure, analysis followed the general principles proposed by Pope, Ziebland and Mays[101] as five stages of data analysis in the framework approach.

Initially this consisted of familiarisation, or 'immersion in the raw data' by searching for themes[102] related to the research question. As Krueger states "the research plan guides the analysis but is not carved in stone"[103] but must be practical and appropriate for the situation. The level of analysis was guided by researcher expectations, which in

this case was improvement of the research protocol. To achieve this, the recording was listened to once without making notes and then once more whilst checking the accuracy of the transcript. The transcript was then read by the researcher a number of times to ensure true familiarity or immersion in the data. Information was identified and relevant phrases or words marked up; what Ryan calls initial pawing and marking of text[102]. Re-reading the transcript a number of times enabled key ideas and recurrent themes to be identified[102]. Ryan[102] notes that the more the same concept appears in the text, the more likely it is a theme and also states that “the terms theme and expression more naturally connote the fundamental concepts we are trying to describe”; which in this case are issues relating to the study.

A thematic framework was then identified, with NVivo 10 software used to facilitate and record this. To achieve this, questions posed at the meetings and the aims and objectives of the research were explored. Issues raised by participants were noted. At the end of this stage a detailed index of the data, labelled into manageable chunks was achieved. NVivo enabled themes to be merged or deleted, when in some cases it became apparent that the initial designation of a theme was inappropriate. A theme was designated as significant after deciding if it had an impact on study design or to participants. It is possible to be too close to data, therefore, a space of a few days was left, before reanalysing, to identify major themes[103]. These generally resulted, naturally, from an accumulation of evidence, words or phrases.

An additional stage was implemented when an Excel spreadsheet was compiled to enable comparison of themes identified between each stakeholder group. This may be said to be a form of thematic framework. Following checking of this spreadsheet, a number of themes were renamed or changed when it became apparent that different descriptors had been utilised for the same, or similar, themes in different interview/focus groups. The spreadsheet was also used to identify missing data within stakeholder groups, with an example being the issue of confidentiality which was not discussed by nurses during interviews. The structure of the spreadsheet facilitated the researcher in ensuring that he was not simply finding what he was looking for[102]. Issues of missing data required considerable deliberation to ensure that they were truly missing. Ryan[102] points out that searching for missing data will produce the least number of new themes and deciding when participants are unwilling to discuss an issue or when they assume the researcher already knows about the topic requires a lot of familiarity with the subject”[102]. In addition to identification of themes, unusual and unique quotes, often referred to as deviant quotes, were identified as they are potentially important[50 103].

Indexing[101] did not totally follow the five stage analysis framework , as numerical codes were not assigned to the thematic framework.

Charting[101] followed, with sample text assigned to themes, or sub-themes. However, the principles of Pope, Ziebland and Mays[101] were not followed, as distilled summaries of views and experiences were not abstracted and synthesised. Instead, cutting and sorting, as recommended by Ryan[102] was employed, which he terms the most versatile technique.

Finally, interpretation was undertaken by reading the sample texts and checking the association with themes and interpretation. The prime aim was to identify issues applicable to the study design.

Review of the data by participants in the focus groups has been suggested as a method to provide greater meaning of data during analysis[102 103], however, this was not possible because of time constraints.

There was no independent analysis of the data, which may also have provided greater insight into meanings and a check for bias, however, a suitably trained colleague was not available.

Development and Review stage focus groups were analysed identically.

## **2.8.2 Statistical analysis**

SPSS version 16 was used for all statistical analysis.

Independent samples t test (or paired t test if comparing before and after results) were used for parametric data and Mann Whitney-U for ordinal or non-parametric data. Fisher's exact was used for comparing dichotomous data. All tests were performed on data provided post-intervention.

## **2.8.3 Patient Questionnaire Responses**

## **2.8.4 Student Measures**

### **2.8.4.1 Students' academic attainment**

The mean overall academic attainment at baseline, which was the examination score at the end of the 3<sup>rd</sup> year and post-intervention which was the final examination score, for control and intervention students' was compared using independent t test.

The mean OSCE score for control and intervention students' OSCEs at the final examination was compared using Mann-Whitney test.

As each student left the study, the mean of final year exam results of the remaining group of students was calculated, using comparison of mean using independent t test.

#### **2.8.4.2 Student Training**

An on-line survey tool utilising Likert scale questions and free text boxes was used to ascertain student opinions of the preparative training course and medication reviews (student assessment) within which the following topics were covered:

- preparative training course, including podcasts and three workshops
- role-play training session, including preparation, location, use of actors, feedback and the effect of stress,
- free text comments with the on-line survey relating to the preparative training course.

Simple content analysis was undertaken of free text responses to identify issues.

Presentation of percentage results of each answer option, with charts produced in excel,

#### **2.8.4.3 Student consultation (medication review) performance**

Results for the MRCF were used to evaluate the students' first and second consultations with a patient. Comparison of the mean score was undertaken (first v second medication review) using paired t test for each activity score, in addition to the mean of overall summed score (first v second medication review).

Post-medication review questionnaires were completed by both the student and the patient after the medication review. Comparison of mean was calculated using independent t test.

Care plan issues identified and recorded by students during level 2 and level 3 medication reviews undertaken for intervention patients were assessed and counted. Identification was undertaken of numbers of:

- level 2 and 3 care plan issues,
- level 2 and 3 issues by approval category,
- level 2 and 3 issues assessed against criteria stated in the care plan.

A full record of interventions identified and recorded by students on care plans devised for use within the study are available in Appendix G. Analysis of these was undertaken by grouping into intervention type. These were pragmatically identified as the individual sections within the care plan and are displayed in Table 2.1. Intervention types were not validated, therefore, identify a weakness in the analysis. Published versions were identified by literature search but it was decided that maintaining the same decision-making criteria as used by the students would be effective.

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1. Allergy status (including side effects).
2. Special needs including mobility, dexterity, swallowing, hearing, sight, literacy/reading.
3. Compliance aids used or needed.
4. Lifestyle-obtaining information includes alcohol, smoking, exercise, diet (general), diet special, eg vegetarian, lactose free.
5. Medical history.
6. Medication history.
7. General compliance issues.
8. Over the counter medicines, herbal preparations or homeopathic.
9. Issues related to use of a pharmacy.
10. Monitoring.
11. Specific patient advice recommended for use at level 3 medication review.
12. Questions to ask the patient at level 3 not stated elsewhere.
13. Patient education about medicines.
14. Patient education about disease or lifestyle.
15. Other issues.

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**Table 2.1** Descriptions of interventions displayed in Figures 5.1 and 5.2

## 2.9 Sample size calculation

Utilising clinical data collected at baseline and post-intervention for control and intervention patients, a sample size calculation was undertaken to identify the number of patients required in each group to enable the identification of an effect from a definitive study. Primary outcome measures of HbA1c, BP and total cholesterol were used separately to calculate a sample size, with subsequent choice of outcome based on clinical relevance, likelihood of achieving a target within an outcome and the practicality of recruitment of numbers required.

The mean difference displayed between intervention and control means for each primary outcome measure, and the standard error (SE) of mean difference were calculated by independent t test.

The Standard deviation (SD) of difference in mean was calculated using the formula:

$$\text{SD of difference in mean} = \frac{\text{SE of difference in mean}}{\sqrt{\frac{1}{A} + \frac{1}{B}}}$$

A = no. of patient results for control group and B= no. of results for intervention group.

Sample size was calculated by using the formula:

$$\text{Sample size} = x \times 2 \times \frac{c^2}{D^2}$$

Where x = a factor taken from tables provided by Campbell and Machin representing 5% significance and 80% power

$$= 7.849$$

Ref Campbell and Machin[104]

## 2.10 Health economics

Health economics data was analysed by the health economist funded within the study grant. This data included EQ5D, medicines use and costs, use of health resources and cost of providing the preparative training of students and the cost of providing the intervention.

Data was collected as part of this study for logistical reasons, but does not form part of this thesis and is reported elsewhere.



# **Chapter 3**

## **Development Stage Focus Groups and Semi Structured Interviews**

## **Chapter 3 Development Stage Focus Groups and Semi Structured Interviews**

### **3.0 Introduction**

In Chapter 1 it was recognised that there is limited evidence of effectiveness and cost-effectiveness for medication review by pharmacists in the community in the UK. Aspects of study design, including the choice of outcome measures, were demonstrated as contributing to the failure to provide this evidence. The MRC guidance on complex interventions[105] states that preparatory work in research is “often skimmed”, with evaluations often undermined by problems of acceptability of the study to potential participants. This leads to problems with recruitment and retention of participants, compliance with protocols and delivery of the intervention. To develop this intervention it was, therefore, thought to be necessary to obtain the views of potential participants in the study, to enhance the original protocol. Key areas to explore were acceptability and recruitment within the study, to ensure that recruitment met the target, whilst also maintaining retention of participants. Issues identified, which were able to improve the intervention, would be incorporated into the study design, if appropriate.

Bradburn *et al.*[106] recommended the use of focus groups to evaluate clinical trial protocols, whilst Kreuger[107] states that focus groups can be used at any stage of a study. Kreuger warns that the small numbers of participants in focus groups limits their ability to generalise findings to a population. Within this study participants in each focus group represented the characteristics or role of the proposed participants in the final study and, as far as possible, the proposed populations[106] to aid generalisation.

Powell and Single[108] define a focus group as a group of individuals selected and assembled by researchers to discuss and comment on, from personal experience, the topic that is the subject of the research. Morgan[109] states that focus groups are group interviews, in which a small group discusses questions raised by a moderator (or interviewer), whilst what the participants say forms the data. He recommends the use of focus groups by professionals who may think differently to those of the people with whom they need to work, resulting in “a powerful means of exposing the sponsors to the reality of those they need to understand”. In this study, the researcher needed to identify the views of potential participants in order to improve the protocol.

Focus groups offer a quick, cost-effective and convenient method of obtaining the views[50 106] of participants (stakeholders) who could provide easily accessible, detailed

information to help improve the design of a study[106] in situations where the outcome cannot be predicted. Additionally, focus groups potentially identify data which would not be identified via individual questionnaires or interviews[50 107 110]. Ethical approval was obtained for the focus groups. (Appendix D)

### **3.1.1 Aim**

The aim of this element of the research was to identify the views of stakeholder groups representing the overall participants in the study through focus group interviews and through semi structured interviews.

### **3.1.2 Objectives**

The objectives of this element of the research were to:

- determine the perceived value of participation to inform the design of information leaflets,
- identify changes required to improve the study,
- identify processes likely to improve recruitment and retention of potential participants,
- identify logistical issues which may be encountered by participants,
- optimise training of participating students,
- identify issues relating to the conduct of the student-led medication reviews,
- confirm elements within the existing protocol where appropriate,

## **3.2 Recruitment**

### **3.2.1 Medical Practitioners**

Recruitment of medical practitioners for focus groups yielded no response and contact with the medical practices confirmed that the reason for this was lack of time. After discussion with medical practice staff it was agreed that practice nurses, specialising in diabetes, would be recruited as they provide much of the diabetes-related care for these patients and could, therefore, answer the questions required. An ethical amendment was sought and approved (Appendix D) to enable this. Six nurses were recruited from four practices (3, 1, 1, 1), yet owing to pressure of work it proved impossible to agree a date and time for a focus group. Therefore, for practical and pragmatic reasons, individual

semi structured interviews were undertaken at the medical practices, resulting in a meeting for three nurses at one practice followed by three individual interviews at further practices. This approach potentially reduced the effectiveness of the focus group as a means of obtaining consensus views. One practice was unable to provide any member of staff for interview or focus group attendance due to staff shortages. Questions devised for the focus group were used throughout each interview.

### **3.2.2 Primary Care Trust (PCT) Pharmacists**

Ten PCT pharmacists were recruited, with one unable to attend on the agreed date because of previous arrangements.

### **3.2.3 Patients**

The researcher planned to recruit patients via Diabetes UK as this is an organisation providing support for diabetes research. However, this proved unsuccessful because there was no local network in Norwich. Recruitment via a local diabetes group also proved unsuccessful, as the majority of its members were already involved in other studies and unable to attend.

Three people from a local diabetes support group were recruited in addition to three people comprising two staff and one friend of a member of staff, via an advertisement in the staff online newsletter at the UEA. All had T2DM. One person was unable to attend on the agreed date because of work commitments.

### **3.2.4 Students**

Six final year pharmacy students were recruited after their final exam, with one unable to attend on the agreed date owing to sickness.

## **3.4 Results**

The themes identified were: acceptability of the study to potential participants, suitability of pharmacists for this new role, patients need for information about medicines, study process (with sub themes of recruitment, location of and travel to medication reviews, consultation), training and the questionnaire.

### **Acceptability**

Strong agreement existed within all stakeholder groups that the overall project concept was a good idea.

*“I think it’s good because it’s an opportunity to see some patients which is something we don’t really get.” (student)*

*“I think it’s a really good idea. I think trying to get the students to get more involved...” (practice nurse)*

Recruitment of the required numbers of participants for the study was described by all groups of stakeholders as being no problem, with a desire to help students with their training as a possible reason.

*“Most patients here are quite good in donating their time to help with the students, they quite like it.” (nurse)*

### **Suitability of pharmacists for this new role**

Nurses said that the different approach of the pharmacist would provide complementary support to healthcare. In addition to comments such as “a good idea”, patients expressed indirect support for pharmacists undertaking medicines reviews by discussing the relative knowledge of pharmacists, doctors and nurses with respect to medicines:

*“...a pharmacist would probably have more specific information on a drug regime than maybe a practice nurse or even a GP in some cases, because GPs are covering a wide gamut of people. If, for instance, the pharmacist I would imagine that he would be more in touch with the current medications, the side effects of medications and possibly long term effects with that type of thing.” (patient)*

Patient participants also gave opinions about gaps in the information provided to them by doctors and nurses, whilst saying that.

*“..it becomes harder and harder if you like for the GP to be on top of what is the best remedy for the patient given the other conditions they may have.” (patient)*

### **Patients’ need for information about medicines**

Statements displayed a perceived need for patients with long-term conditions to obtain information which may assist with self-management of their condition.

*“....so I think to have a good understanding, because I mean as a patient, I think it’s important that you’re at least offered, even if you don’t take on board, as much*

*education and understanding as you can about your condition which is going to help you to control that condition long term.” (patient)*

Patients also discussed a failure to fully resolve their own and other patients' information needs by the current system, through the provision of patient information leaflets supplied with medicines, as these were not accompanied by verbal explanation.

*“Quite worrying if their GP doesn't give them the advice which is on the paper, if you like. I worry about, the GP's busy.” (patient)*

*“...the number of times I've been a given drug by the doctor which when you read - of course one carefully reads the little bit of paper that comes with it - and it says this is contraindicated to people with diabetes and you think why have they given it to us?” (patient)*

The sources, other than healthcare professionals, that are said to be used by patients to obtain information about their medicines included newspapers and support groups such as local diabetes groups.

*“I personally like as much information as I can,...you'll often pick the paper up and read such and such a drug has been found to cause this, that or the other, ..... I found out at a meeting only a few weeks ago, which was one of the drugs that I was on, so I thought that's interesting so I shall be having a chat when I go back for my review over this...” (patient)*

Within a medication review the patient would normally be educated about their medicines if they desire, with a particular emphasis on the risks or side effects. Patients said that this information can be provided via a pharmacist if they display competence.

*“.....so I mean if we find that the pharmacists are more in touch with the medication regimes and that - I think and the patient can be educated in either the side effects or the risks involved in taking that particular medication, then I think it gives you a more informed choice.” (patient)*

Whilst endorsing the need for pharmacists to be more involved with patient education about medicines, one patient said that there may not be time available to do this as, in spite of supporting pharmacists' skills, they see this role as new.

*“But the question is I mean okay pharmacists will get training as part of their courses, will they then have time to actually interact with patients, I mean will the*

*system provide that flexibility if you like, that time, to do the job that they've been trained to do - or the additional job.” (patient)*

## **Process**

### *Recruitment*

Patients and students made numerous suggestions for changes to recruitment documentation to encourage participation. Both groups recommended “less dense” documentation, with an initial précis to explain the project, within which the importance of the potential participants to the study must be stated.

*“If you want somebody to participate, first of all you've got to get their attention; so your initial letter in effect sort of highlights what the thing is about and then let them have the information at a simple level and then still provide more information at a slightly higher level as they require it.” (patient)*

Views were expressed by patient participants that a potential participant should be encouraged to participate by the use of positive statements which also enhance their feelings of personal importance. Statements like this which are intended to enhance patient recruitment could be interpreted as further patient support for the study.

*“Saying how much you appreciate their help, and you know you've got to make them feel like you can't do it without them if you know what I mean and that particular respect in just a few words you know that they're partaking in a study which is going to benefit not only their self but the whole of the diabetic community long-term, but if you give people a bit of sense of self-importance as I said it's the whole traffic warden's hat sort of thing then they're more likely to take, certainly looking at the marketing thing, but that can help them sort of draw them in and they may take the trouble to read it.” (patient)*

Patients stated that the documentation within the patient information leaflet should say that the study would not result in the loss of a current service.

*“You might get some people who may think that it's some devious way of taking their treatment away from their GP.” (patient)*

Other recruitment documentation issues raised by patients related to comprehension of the wording in the patient information leaflet. Recommendations included the use of a glossary, a reduction in the use of abbreviations and proof-reading to ensure readability.

*“Did you include a glossary of terms? That would be quite useful, you know...”*  
(patient)

*“The invitation to patients I thought was pretty good, except my bug bear is things that are abbreviated...”* (patient)

*“...once you’ve got a package ready, you know say like a dummy package which is going out to a patient, you sit and read it, you personally...”* (patient)

A firm dislike of the terms ‘control’ and ‘intervention’ within documentation was stated, which was further supported by one patient participant displaying a misinterpretation of the terms during discussions. It was recommended that control and intervention should be replaced by terms which simply describe the role undertaken by a patient within a study.

*“Intervention is not a very good word. I think assessment or something...”* (patient)

Patient participants recommended that the importance of the role of patient controls in studies should be stressed in order to promote both recruitment and retention of patients.

*“I think they need to have a good understanding, the fact that their role in the study is just as important as the other, that’s got to be very much emphasised.”* (patient)

## **Process**

Location of and travel to medication review.

The topic of the medication review between the student and the patient generated considerable discussion within each stakeholder group, with strong opinions expressed about the proposed location of the medication review. All stakeholder groups agreed that this should take place at the medical practice at which each patient participant was registered. Reasons for this decision were generally that it was more convenient for the patient, but also that the patient would feel more relaxed as they know the location, rather than the UEA which they do not know, where they may get lost and also find intimidating. The students observed that the medical practice would provide more realistic experiential training.

*“They’re familiar with it, I mean to come up to a place like this (UEA) in some people it would be a little bit intimidating, if you know what I mean, it’s like you’re going to go on the slab in Dr Frankenstein or you could get lost like we did, so I think they’d feel under less pressure and they wouldn’t have all the rigmarole of*



*coming up to find the place, you've got to find them, and they'll just go to the surgery, they'll know where to park, they'll know who to ask for and they'll have a little room that they can go in and do what they normally do really. So they're doing exactly what they do, the only thing that's different is the student." (patient)*

*"I just feel like why? Why should they have to come here (to the UEA)? (student)*

*"That could be good for us as well because we're then going even more into a real life situation if we're going to be going back to the surgery where the patient's more comfortable they're probably, therefore, more likely to tell you honestly stuff and act more like they would in a proper consultation, whilst if they come here, they might feel more out of place and less likely to open up." (student)*

Students expressed strongly held and unexpected opinions about travel to medical practices, which were influenced by their previous experience during undergraduate training. They reported that travel to medical practices can be very long, particularly in a rural area like Norfolk. In addition to travel to the medical practices, they voiced concerns about arriving there in case they were not expected. It was said that groups of students arriving together may provide mutual support, thus relieving worry.

*"...when you got group transport you were a little bit less worried about it as well because you're all going, you're all going at the same time, you'll all talk to the same person whilst we had GPs where three or four of us would go to the place, but they wouldn't put any transport on for all of us so you'd go each separately, you'd then arrive all separately and then you'd stand there and someone would go to you oh is so and so coming and you're like I don't know if they're coming or and it's quite an awkward introduction plus if you're just there, you arrive there and you start off it's quite a nice way, it's a comforting way to start something which is unfamiliar if that makes sense (student)."*

## **Process**

Consultation (medication review)

Patients said that the consultation should be about the patient and that during a consultation students should appear confident and competent.

*"But if they come through as being very timid and not sure of their grounds then yes it could upset a few people." (patient)*

Safety was raised by all stakeholder groups, other than the students. Supervision by a trained pharmacist was perceived as essential, in order to ensure that the students did not provide incorrect advice to patients during a medication review.

A protocol, care plan or script to guide students during the medication review was said to be essential by all groups other than students. The students had not experienced a medication review with a patient and perhaps did not understand the issues.

*“I think it (a protocol) would clarify it for the students that would give them the limitations of where they should not step out of, the parameters would be actually marked out for them.” (patient)*

*“They’ve got to look at the care plan for the patient coming in before the patient comes in...” (pharmacist)*

Access of medical records by the students was discussed by both nurses and pharmacists. They said that students should be instructed to read the patients’ medical records to establish what actions or recommendations have already been made by healthcare professionals. Some nurses expressed strong views based on previous problems when student nurses had not referred to medical records. This had resulted in the student providing advice to patients which contradicted with that provided by qualified staff and, therefore, undermined the patient’s confidence in their treatment. Nurses in addition stated that training must prepare students to be aware of the consequences of their statements.

*“Well, she (student nurse) shouldn’t have said that, she hadn’t read the notes, she hadn’t seen the list of dressings he’d had previously, as a student she had no right to do that over an experienced nurse and she wasn’t in the good books, she found out when that patient had gone.....” (nurse)*

Strongly held views were voiced by practice nurses about another medical records issue: students must access patients’ records to gain an understanding of the rationale for previous decisions. This was to ensure that any advice offered to patients did not simply follow guidelines, as previous decisions by nurses or doctors may have followed a different course, for valid reasons.

*“...if you find your patient, being an individual, is not going to suit that particular one then you try a different drug, so it’s okay having the students coming in to say well you should go in there, step one, step two, step three, step four and then they*

*suddenly find we've gone a different way and there's a different thinking behind it as to why we've gone that way..." (nurse)*

Practice nurses expressed concern about pharmacy students' ability to interpret patients' medical records, particularly in relation to the interpretation of missing data. Not all actions undertaken by a healthcare professional are recorded which could result in students contradicting recommendations made by nurses to patients. The solution proposed was for pharmacy students to access medical records under the supervision of a qualified pharmacist, as previously planned.

*"...unless we've actually documented every single thing, because we normally know why we've done something, we can read between the lines, but you know if you've got students coming in that don't know these patients and aren't used to these treatment plans then they just may find they're in deep, deep water as to wondering why. And the other thing I'm worried about, in fact they say oh well you shouldn't be on that, you should be on this and that is another worry..."(practice 1 nurse)*

*"Read the notes." (practice 1 nurse)*

Following the theme of medical records, both practice nurses and PCT pharmacists stated that students should refresh their information immediately prior to the medication review by accessing the medical records. Both these groups are experienced in undertaking patient consultations including medication review, and, therefore, should know the value of last minute checks, which may explain these comments. In addition pharmacists recommended that the students should access records during consultations.

*"It would be good for them to look at the computer record just before, or in the five minutes before they saw them just to check whether there had been any consultations since they looked at the record last." (pharmacist)*

*"It would be good if they could access records while...they're talking to the patient." (pharmacist)*

All stakeholder groups, other than nurses, expressed concerns regarding confidentiality and wanted safeguards, such as student contracts which contain a requirement for confidentiality. A PCT pharmacist, though, noted that 'fitness to practice' guidance, which is imposed by the regulatory authority, already covers this situation for students.

*"...they know what confidential means and it's drilling it into to them what will happen to them, because there's fitness to practice, isn't there?" (PCT pharmacist)*

Students expressed concern that patient records transferred to laptops should be securely transported and stored.

Practice nurses did not raise the issue of confidentiality, and whilst it is impossible to know why, it may be because of their regular experience with medical and nursing students which means that they no longer see this as a problem, or simply that they focussed on activities within their sphere of work, i.e. the medical practice.

Practice nurses and PCT pharmacists raised the matter of care issues identified by students and information provided by them to patients during medication review. They said that these should be recorded in the patient's medical record, by a pharmacist for safety and logistical reasons.

*"It's always nice to know what somebody else has said, you know because one we're responsible for a treatment plan of any kind..." (practice nurse)*

*"...and somebody's advised them something differently and we don't know anything about it." (practice nurse)*

Recommendations made by practice nurses about the style and content of medication review conducted by students included:

- being polite and using Mr. and Mrs. until told that the patient is willing to be called by their first name,
- listening to patients,
- taking care with statements if patients are or have been shown to be intolerant of recommendations,
- ensuring recognition of side effects,
- inclusion of patient beliefs which also implies being able to recognise those beliefs,
- lifestyle advice must be included. This last issue was stated in strong terms as it was obviously a major issue.

*"I think it's (lifestyle) important that anybody who is in contact with people with type 2 diabetes, I think they do need, you know, need to go through it, it's so important I mean we know that it's the mainstay of the care really, they need to be looking after their health and I think any opportunity to promote that needs to be taken, doesn't it?" (nurse)*

Varying views were expressed regarding the duration of the medication review, although there was general agreement that at least 15 minutes should be allowed. Patients in particular differed, with some suggestions of unlimited time, whilst others stated that a time limit would focus the student on relevant issues. They appeared to base opinions on consultations with their GP which are time limited and result, according to some patients, in unresolved issues. Practical solutions were recommended which included an open-ended medication review which the supervisor could terminate if the student was not progressing.

*“...will it be like ten minutes, twenty minutes and then you’re out?” (patient)*

*“...as long as is reasonable I suppose, but if it’s twenty minutes and you’re out and someone’s got things they still want talk about.” (patient)*

*“...if you give them twenty minutes or half an hour even and if you see after fifteen minutes you conclude the student has completed all the information that they need to do so and all it’s going to be is fifteen minutes of waffle you could say oh well I think you’ve done very well there and we can bring the interview to an end.” (patient)*

PCT pharmacists did not suggest durations for medication review but recognised that they should be ‘longer’ than usual consultations with GPs or practice nurses, due to complexity of patient issues.

*“Students are going to face complicated patients, sometimes I know we run away from the really complicated ones...”(pharmacist)*

*“You just need more time.” (pharmacist)*

Students by contrast did not specify a time duration for medication review, possibly due to their lack of experience, or they may not have thought about the face-to-face time with patients. Practice nurses did not state an opinion about the duration of the medication review.

## **Training**

### **Need**

Evidence of the need for pharmacists to improve communications skills was expressed by practice nurses and patients. They said that there was uncertainty about the current

medicines use reviews (MUR). An MUR is a meeting between a patient and a pharmacist to explore medication issues but in less depth than a medication review. The uncertainty appears to be because pharmacists had not communicated the aims of an MUR to patients and nurses, or explained why they were undertaken by pharmacists. There were indications of possible patient concerns about the overlap of roles with GPs, with these concerns potentially resolved if the pharmacists had explained the MUR to the patient.

*“...they don’t quite understand why they’re (pharmacists) getting involved, that seems to be, you know why did the pharmacist want to talk to me because my doctor’s put me on this and they can’t, there seems to be a bit of gap.” (patient)*

## **Training**

### **Preparative training course**

Patient participants questioned the preparative training planned for the students prior to undertaking a medication review with a real patient.

*“How much training will they have had to consult with actual patients?” (patient)*

Further comments were made, in the form of questions, by patients in relation to preparative training, with one appearing to suggest that students should experience role-play before the patient medication review. Another patient developed this theme further by suggesting that group feedback during such a session would enhance students’ learning.

*“Would they do a dry run before they actually get on to a real patient?” (patient)*

*“...so they’re doing dry runs is there going to be a formal feedback within the group so that they can all experience what they’ve found, what the person felt, etc..” (patient)*

Practice nurses were supportive of the proposed preparative training, with a suggestion of ensuring that compliance issues and negotiation skills were included.

Patients and pharmacists agreed that we should ensure that students acknowledge gaps in their knowledge when undertaking a consultation. The inference is that this should be included in the preparative training.

*“...it would be much better for them to honestly say to the patient you know I’m afraid I don’t really know the answer to that at the moment, but I will find out for you and let you know or get back to you.” (pharmacist)*

Pharmacists made other recommendations including that conditions other than diabetes should be included in the preparative training of students. This was to enable discussion about those conditions during a medication review, because people with diabetes frequently have other conditions. One pharmacist also suggested that the use of insulin devices should be taught to the students. Pharmacists agreed that student participants should feedback to a GP after a medication review, as exposure to this activity would improve their confidence when meeting GPs in the future.

Level 2 medication reviews, when students would access the medical record of participant patients at the medical practice, was supported with practice nurses stating that it was practical and achievable. Pharmacists also noted that undertaking level 2 medication reviews would be good training for students

Students discussed at length the time that they would be required to spend if they took part in the training, and came to the conclusion that the amount stated in the information leaflet was appropriate and acceptable to them.

Feedback was an issue raised by all stakeholder groups but with a different emphasis. All agreed that feedback to students after training would be beneficial as it would enhance the training. Students debated the relative merits of group feedback versus individual feedback, with some saying that they found individual feedback to be uncomfortable in some situations.

*“I think individual feedback is better for reflection but group feedback helps everyone then.” (student)*

Students agreed that feedback to them would be beneficial after preparative training, including role-play sessions, and that they would be willing to receive feedback from patients after medication review in order to enhance learning.

*“...having a patient say that really makes you think about what the way you come across to people, and I think that’s probably quite good as long as it was positive.” (student)*

Students and PCT pharmacists said that the supervising pharmacist should check recommendations to GPs made by students following medication reviews with patients, to

ensure accuracy and correctness. Both practice nurses and PCT pharmacists agreed that feedback to a GP or nurse of recommendations resulting from the medication review would provide training opportunities for the students, whilst nurses also wanted the feedback in order to know what had happened during the medication review.

*“And they’ll feedback to us and it’ll be interesting to know what the students said so that we can either back-up what the student has said or you know say actually well we’re going to carry on with our previous plan, this is it, so it would be interesting just to have a knowledge of what they’re saying.” (nurse)*

One patient raised feedback to patients as an issue in the form of a question by asking:

*“Would it be beneficial to give a feedback sheet to the patient which the student could then keep as a record, as a reference, to his documentation. ....the patient’s actually got something to go home with..” (patient)*

The patient expanded the idea with the view that the patient would then have documentation of recommendations to take away and that this would also provide evidence to the GP.

*“That way if the GP starts complaining about what’s going on, you’ve actually got proof as well, you’ve got an audit trail basically of what actually went on in that particular consultation.” (patient)*

Nurses expressed the opinion that if pharmacy students were trained in the method proposed in the study, they should endeavour to become more integrated into the team with doctors and nurses when they qualify. This resulted from recognition that patients and healthcare professionals expect pharmacists to act independently.

*“ when you’re talking about an older group of people they are very used to dealing with nurses and more used to dealing with doctors even when it comes to medication reviews so it’s just a cultural, you know, shift to include, and also even with nurses and doctors we don’t work that closely with pharmacists generally so it would be, it needs to be more of a team.” (nurse)*

A nurse expressed concern about the security of her own role if pharmacists take on medication reviews with patients, yet also displayed support for the need for the role.

*“I think that that’s a concern because I think everyone’s worried about their job and somebody else taking over their job, but I think it’s complementary to what we do and I think it is, it’s another place for people to visit as well, isn’t it? We’re trying to*



*make healthcare etc accessible to people so going down to their dispensary and talking to their local pharmacist about the drugs that he dispenses or she dispenses to them all the time, no I think it's complementary and it's all for the patient benefit to be honest.” (practice nurse)*

Further comments by participating patients supported the development of additional training of pharmacy students with recognition that pharmacists have unique skills which need enhancing.

*“I just think it's one of those, utilising the skills that somebody has got, I mean I know you're teaching these to become, so I do, I think it's a, I also think that pharmacists probably come at things from a different angle to doctors and nurses that patients are used to getting so I think that, yeah, I think it's a very good idea. Utilising the skills that you're trained to use really.” (patient)*

Practice nurses raised logistical issues which could contribute to the effective introduction of medication review training with patients for pharmacy students in medical practices. One suggestion involved pharmacy students booking patients on the same day as the nurse review in order that patients could move straight between appointments, therefore, increasing efficiency and possibly patient recruitment. Another practice nurse commented that undergraduate medical students work in pairs to undertake training with patients, which might provide a scenario for future roll out of the pharmacy student led medication reviews. However, it was added that medical students are not supervised and it has already been established that supervision of pharmacy students within a medication review is required. A practice nurse expressed views that if the training within this study was repeated in the future, supervision by a qualified pharmacist should still be undertaken.

*Nurse“... if we were to roll this out in the future that the final year pharmacy students would do the consultations, I'm not sure if that's appropriate ..“*

*Researcher: Would you have a different opinion if they were supervised?*

*Nurse: Yes, rightly or wrongly, yeah, but that's my personal view.*

The group of three practice nurses discussed the existing training of medical and nursing students, where a 'building' or iterative approach is utilised, and recommended the use of this approach with pharmacy students in the future.

*“...medical students come out and we would get patients to come in with specific problems for that specific group, so say for instance, in a couple of weeks I’m doing a vaccination morning and I will have students coming in and out and they just will be observing me consulting and vaccinating so it’s all dependent on their level, but they, in general they aren’t actually making any decisions, it’s kind of basic learning that they’re doing really...” (nurse)*

*“The UEA are trying to sort of build-up with the nursing students where they will actually, they’re hoping that they will get placements within general practice and that those placements as they go through their training will become more independent so at the end of their course they could perhaps do certain clinics..” (nurse)*

Students, within their focus group, commented that this form of training, if implemented in the future, would encourage more of them to apply for positions in the community, as currently many students apply for jobs in secondary care because of its clinical focus.

Both final year pharmacy students and PCT pharmacists said that the preparative training will potentially ‘fill a gap’ in the current training of pharmacy students. They also stated that they would have wanted to take part in this training if the opportunity had presented itself. Students suggested that we should check the knowledge of participating students, with respect to the podcasts, to ensure comprehension. They also aired various views relating to the scheduling of sessions but with no conclusion reached.

## **Questionnaire**

Lastly, significant discussion took place amongst the patient participants about the questionnaire which was designed to be completed both at baseline and after the intervention to identify potential changes. Patients expressed critical views about wording of questions and their interpretation, with discussion of individual words. They did agree that it could be completed easily in the stated time, with one patient suggesting that the researcher should sit down and read it themselves to check comprehension.

*“I think you’ll find that once you’ve actually tried it yourself you will find things yourself which may need tweaking.” (patient)*

Another patient recommended asking volunteers to read and assess the questionnaire.

*“The thing that again may be beneficial to you is to sample the forms and then just send them out random to a few, half a dozen people, a dozen people, get them*

*back and have a look, just analyse them before you actually include them into a main study.” (patient)*

### **3.5 Discussion**

The purpose of this chapter was to obtain stakeholder views on the perceived value of participation to enable better design of information leaflets, the design of the study to improve recruitment and logistics, proposed student training and conduct of the student-led medication reviews. The rich data obtained demonstrates the benefit of undertaking focus groups and semi structured interviews with participants representing the stakeholders within the study. The process enabled the identification of previously unidentified issues, which improved all of the elements stated and, therefore, improved the conduct of the research.

Stakeholders stated that the project is a good idea, with good acceptance by medical practice staff. Universal support was provided within focus groups and there was agreement that the study should proceed. There was recognition that pharmacy students require training to improve their consultation skills and undertake medication reviews with patients.

Patients showed a trust in the knowledge of pharmacists, and supported their provision of medicines information to patients. This was due in part to their perception that pharmacists show competence in this respect in reality and that they provided more up-to-date information than that provided by doctors or nurses.

Participants reported that recruitment of all stakeholder groups to the study would be “no problem”, although this could not guarantee that the rate of recruitment was sufficient. A significant number of useful issues were also raised by patients and students about acceptability of recruitment documentation. Patient participants also made considerable, yet constructive, criticism of the wording of the questionnaire.

The major change to the protocol was for the location of medication reviews to be undertaken at the medical practice used by each patient rather than the university. Due to the distance travelled it was requested that students should travel in groups by taxi or with a supervisor.

Training to prepare students for the medication reviews with patients should include role-play medication review, compliance with medication, lifestyle issues and negotiation skills, whilst feedback was recommended.

Recommendations were made to improve the conduct of the student-led medication reviews, including access to records, content of the review, and the disease on which to focus. Specific requests were made concerning the time allowed for the medication review, supervision, use of care plans or protocols, and feedback.

Some issues raised at focus groups did not result in changes and mainly involved the wording of the baseline questionnaire which could not be changed due to the use of validated tools.

The themes or issues were identified from the data obtained and were not pre-determined in advance of analysis, which reduces the likelihood of bias in the findings. It could be argued though that these were unintentionally pre-determined, as the objective of the focus groups and semi structured interviews was to identify issues which may result in changes to the protocol in order to improve the research.

Focus groups and semi structured interviews comprised participants whom were representative of each stakeholder group in the research and, therefore, possessed a similarity which was important to the research. They also displayed a homogeneity which facilitated recruitment and ensured that participants were comfortable with each other which potentially helps the process, although it may mean that diverse opinions may be lost[107 110]. The focus groups were undertaken in the manner recommended by researchers in the field by being composed of five to ten people[107], and in a neutral location[110].

Analysis followed a structured approach utilised by researchers in this field[102 103] with results presented in a manner which allows the reader to, as far as possible, distinguish the data, analytical methods and the interpretation[111]. Minority or deviant data were included which added to the strength of results[50]. Due to the small numbers of participants, it is not possible to generalise the results obtained to the whole population; however, it has been stated that results can be transferred by the researcher to another environment, if appropriate[107]. The use of small numbers of participants in focus groups is an accepted technique[50].

Whilst the process demonstrated strengths it was also apparent that focus groups and semi structured interviews undertaken earlier would have enabled more changes to be made, as in some cases timescales precluded inclusion of recommendations. A more experienced researcher may have obtained data representing a wider understanding of the answers to questions under consideration, although the experience he obtained during early meetings enabled development and subsequent improvement of this skill. An example of omissions in early meetings is that the researcher occasionally failed to ask follow up questions to identify the reason for opinions and to establish if they were based on experience or supposition.

Results were not reviewed by another researcher reading and analysing the transcripts, which may have identified additional themes or interpretations of them[111]. This would have reduced the potential impact of “limited perceptions and introspections of the investigator”[111 112]. Returning the transcripts to participants of focus groups and semi structured interviews was not undertaken, which may have also resulted in additional data[103 112]. Participants may have provided greater understanding of meaning rather than simply content. Ryan[102], however, observes that ‘some investigators also recommend that respondents be given the opportunity to examine and comment on themes’. The wording of ‘some’ implies that this step is not essential. Following analysis of the data there was not sufficient time to involve participants and, in addition, a suitably trained researcher was not available to undertake second analysis to provide inter-rater reliability.

Focus groups with practice nurses proved impossible to organise, which resulted in undertaking separate semi structured interviews with three nurses and the organisation of a further meeting at an individual practice for three nurses. The data obtained may be different to that obtained by groups due to the interactions which are enabled by focus groups[50].

The need to provide preparative training to undergraduate pharmacy students prior to undertaking medication reviews is in agreement with published research. In a study in Australia Boyatzis and Batty[75] provided lectures and workshops about communication skills, medicines, ethical issues, the principles of medication review and communication with general practitioners. O’Neill *et al.*[76], in a study in the USA provided in-depth preparative training for the students prior to meeting patients. The protocol in the current study included preparative training for participating students in addition to that provided within the undergraduate course. This was planned because previous experience by the

researcher and colleagues suggested that it would be necessary. The information provided by focus group and semi structured interview participants, in addition to published research, provides strong evidence that this was the correct view and therefore the additional training was retained in the study.

Nurses displayed a poor understanding of the role of pharmacists within Medicine Use Reviews (MURs) and this affected the nurses' perceptions of the potential impact and value of this service. These comments support the need for improved and effective communication of the rationale and content of the service to healthcare staff.

Evidence was provided by patient statements that the pharmacy students need to ensure the use of additional and effective methods to educate patients with diabetes about their medicines. The gap in patient medicines information knowledge had prompted them to seek alternative non-professional sources. The need for information about medicines has been widely researched and is a key component of a level 3 medication review[28] which should include 'full and accurate information' about the 'pros and cons' of treatment options, including side effects. Dickinson and Raynor[113] identified that patients require four aspects of information about drugs (what it does and what it's for, side effects, do's and don'ts, how to take it). Consequently the training must ensure that students are aware of these needs and address them during consultations. Participants in the patients' focus group did, however, report valuing the knowledge of pharmacists, which was perceived as being up to date.

The recruitment of stakeholders for the research study was identified as 'no problem'; however, whilst this provided support for the protocol it provides no insight into the anticipated rate of recruitment.

Patients identified a number of very interesting issues relating to the documentation designed to recruit patients for studies, and these were included in this study. Comprehensive guidance is provided by the National Research Ethics Service[114], however, the use of a patient focus group here shows that improvements can still be made which have the potential to optimise recruitment and retention of subjects. The National Research Ethics Service guidance already recommends an invitation paragraph. This is shorter than that recommended by the focus group, who suggested a précis of the document to encourage further reading of it. In addition, the National Research Ethics Service guidance also warns against the use of longer complex information and suggests the use of short easily read sentences or areas of text. This concurs with the focus group suggestions, but does not take account of the concerns with respect to the terms control

and intervention. In describing the dislike of them one participant muddled up the two groups, thus proving the point. The suggestion of using a simple description of each group is sensible. Stakeholders also reported that documentation should clearly state that patients would not lose their current service, unless this is planned.

Possibly the most important issue identified was the location of the patient medication review: this was expressed in strong terms by all groups as being wrong. They did not want this to be at the university, but at the medical practice of each patient. The original location was chosen because undergraduate students in other disciplines, such as optometry[73] and dentistry[71], routinely offer care to patients in university-based clinics. It is possible, however, that patients are accustomed to attending a more distant location for services such as these. Most patients, however, expect to receive medical services, other than hospital-based ones, at their GP's medical practice. Pharmacy in England recommended[115] that specialist services can be provided in convenient locations.

The other key issue identified was student travel to medical practices. The number and strength of the comments in the focus group was unexpected. As students' participation in the study was voluntary and also essential for the implementation of the study, changes were made to the protocol. Instead of leaving students to travel by bus or their own car, taxis were arranged for them. This enabled up to four students to travel together, thus solving both the logistical problem and, in addition, it provided group support when they arrived, therefore, addressing the concern expressed about arriving alone at a practice.

The issues identified by focus groups and semi structured interviews which required changes to the study were sometimes unexpected, but useful. A number of these related to preparative training of participating students. Other issues, including appearing confident and competent; admitting to a lack of knowledge; patients' beliefs, and care with statements form part of consultation skills requested. These issues were included in the preparative workshop dealing with consultation skills.

The use of role-play medication review to train students had been planned as part of the protocol, and focus group and semi structured interview support for this was encouraging. Most published research relating to role-play has been conducted with medical students. However, the scenarios encountered by medical students and pharmacy students often have great similarities, with one such scenario being the undertaking of medication reviews. Nestel[116] (2007) investigated the use of simulated patients with pre-registration pharmacists (PRP), with this being an alternative terminology for role-play. The situations encountered by PRPs are similar to those of undergraduate pharmacy

students. This study identified that the use of role-play provided effective training, although they were unable to state that this would provide lasting benefit. In our scenario, however, the benefits were only required for a short period to provide practice and feedback for the students prior to meeting a real patient. Joyner[117] in providing guidance for undertaking role-play training with medical students, provides evidence that the use of role-play is a widely used technique. Undertaking medication review is a role that is taught to medical students and, therefore, the evidence is relevant to this study which utilises pharmacy students. Bokken *et al.*[118] (2009) conducted focus groups with medical students who had experienced role-play, and found that it provided good preparation for real patient interactions. In addition, it provided an opportunity for giving constructive feedback on communication skills.

Feedback to a GP during the role-play session had been recognised as important, due to the widely recognised benefits of feedback during this form of teaching[116-118] and this was retained in the protocol following comments by stakeholders.

It was recommended that students must access patient records with supervision prior to a patient medication review and must use a protocol or care plan during the medication review. Access of patient records is also regarded as an important element in studies which investigated the teaching of undergraduate students with patients[81].

Other changes required the inclusion of conditions other than diabetes in preparative training and ensuring that during medication reviews students appear confident and competent. Preparative training should include recognition of side effects, patient beliefs, and care with statements (especially if patients have previously shown intolerance or non-acceptance of advice). It was stated as important that feedback should be ensured during training and that this should take the form of group feedback, if possible.

During medication reviews, it was recommended that students must admit to lack of knowledge. Medication reviews should not be time-limited, although they should have a nominal time of 20 minutes, and that patient feedback should be obtained at the end. After the medication review (level 2 or level 3) it was recommended that students should feedback issues identified to a GP to increase student confidence, and that written records should be provided to the GP of the medication review. Patients should also be provided with a written record of the medication review.

Stakeholders stated that supervisors must ensure confidentiality and prevent students providing contradictory advice. Confidentiality and the need to supervise students are



issues recognised and dealt with on a regular basis by academic staff in the School of Pharmacy at the UEA. Issues of confidentiality are a requirement of all registered pharmacists and pharmacy students in the UK[119 120], and are taught as part of the undergraduate course. In addition, all participating students were to apply for honorary contracts for the PCT which would ensure further confidentiality control. Therefore, it was already decided to leave the teaching of confidentiality unchanged as part of the protocol.

Consensus on time allocation for student-led medication review within the study was not achieved. Research has focussed on the needs of patients for time during consultations. A study in the UK (2004) Ogden *et al.*[121] identified interesting results. They found that the majority of patients underestimated how long the consultation took, whilst a large minority would have preferred more time. A key finding was that a preference for more time was correlated with dissatisfaction with the emotional aspects of the consultation and a lower intention to comply with doctors' decisions. They suggested that more time could be given, but stated that a doctor who listens and tries to understand their patient may make the patient feel more satisfied with the consultation length. It was decided that, with the current study, consultations would not be limited, but that supervisors were advised to stop the consultation if it went on for too long. A nominal duration of 45 minutes was allocated for the student to access the patient's medical record and update records, undertake the consultation, write a record of the issues raised for feedback to the medical practice and obtain feedback from the patient. This incorporated two other issues raised: accessing the records and feedback.

It was decided that the supervising pharmacist would check recommendations made by students following a medication review, before forwarding them to the GP. By taking professional responsibility, the pharmacists ensured accuracy, as the students are not qualified. A similar suggestion asked that recommendations and observations from student-led medication reviews were recorded in the patients' medical record. Supervising pharmacists were asked to undertake this role as they are qualified and also know how to make such records.

Finally, two issues raised were not implemented. The first was a series of disagreements by patients with the wording of questions in the baseline questionnaire. These comments may have been very relevant and useful, but the questionnaires were developed from validated tools. It was not, therefore, possible to make changes without the permission of the author(s) and this, if implemented, could adversely affect interpretation of results. The second issue was that undergraduate pharmacy students should receive training with

patients earlier in their training. In particular, nurses in one practice recommended this following their experience with nursing and medical students. Their recommendation, that students should start in year one with simple tasks and develop in complexity each year until undertaking medication reviews in year four, is sensible. However, this is a pilot study with the aim of identifying effects, so this issue could not be implemented at this stage. The perceived need for early training of undergraduate pharmacy students with patients is one of the drivers for the integrated model of education being proposed for pharmacy in the UK. Pharmacy students said that if roles in the primary care sector, involving medication review were available, then more pharmacists would apply for such posts as it involved clinical work. This demonstrates evidence that pharmacists who have received training in consultation skills within medication reviews during their undergraduate course could be recruited to these roles. Support, therefore, is provided for the future sustainability of the model of training if the study proves to be successful.

The use of focus groups and semi structured interviews comprised of stakeholders representing participants groups within this study proved to be very useful. The data generated enabled confirmation of some aspects of the protocol, whilst important changes were made which potentially improved the evaluation which follows recommendations by the MRC[48] to evaluate protocols using potential users of the service.

# **Chapter 4**

**Training**

**undergraduate**

**pharmacy students in**

**medication review.**

## **Chapter 4 Education: training undergraduate pharmacy students in medication review**

### **4.0 Background**

This chapter seeks to define the educational approach undertaken and to provide an evaluation of its effectiveness and appropriateness to prepare pharmacy students to undertake medication reviews.

In earlier chapters it has been demonstrated that not only is there a need for pharmacists to undertake medication reviews with patients, but that pharmacists in the UK are lacking in the consultation skills required to effectively undertake them. Leikola[122] reported that society's increasing expectations of pharmacists' involvement in assuring rational drug therapy and appropriate medication review creates pressure to maintain current and develop new competencies. Kassam[123] recognised that pharmaceutical care, which encompasses roles such as medication review, 'takes the profession beyond simple drug distributing and counselling responsibilities to a broader mandate of patient-centred care to maximize the positive outcomes of patients' drug therapies'. This was reported to have resulted in the Canadian authorities requiring pharmacy schools to ensure that students are provided with these skills. Owen and Stupans[124], in a report on quality standards in pharmacy placements in Australia stated that universities provide the underpinning skills, whilst the supervisor provides guidance and facilitates learning during experiential placements. In the UK, the modernising pharmacy careers programme[74] states that their proposals will not result in the teaching of less science, but that students will be applying their knowledge, largely in the context of a patient-facing setting.

Skledar (2006)[125] when discussing the development of a pharmacy internship stated that experiential learning is the application of classroom learning in a real-life interactive environment and is a teaching strategy commonly used by schools of pharmacy. When discussing the need to develop pharmacists for new roles, Hall *et al.*(2012 Canada)[126] stated that patient-centred care requires a different set of skills and training including collaborative interpersonal practice skills. They also recognised that experiential training is an essential requirement for the development of these skills.

Dewey[127] provided support for undertaking education in the real world by stating that "there is an intimate and necessary relation between the processes of actual experience and education.". Kolb[128] later developed this further by defining experiential learning theory as "the process whereby knowledge is created through the transformation of

experience". This could be related to the current study, as students undertaking medication reviews with real patients. Schon[69] discussed reflective practice as an important tool in practice-based professional learning settings, with people learning from professional experiences, rather than from formal teaching. He writes that this may be the most important source of personal professional development and improvement, as it brings together theory and practice. However, Dewey[127] also recognised that individual students obtain different experiences from these experiences and that, therefore, not all experiences "are genuinely or equally educative". He suggests that in progressive education, the quality of the experience is essential. This, therefore, must require the evaluation of experiential education.

Kimberlin *et al.*[129] (Florida 2006) reviewed the assessment of communication skills by US schools of pharmacy. They stated that communication skills are essential to establish effective therapeutic relationships with patients and that these cannot effectively be improved simply by practice, thus requiring education and training. This provides support for training and evaluating communication skills rather than relying on work experience. The measurement or assessment of communication skills by student pharmacists was not undertaken in a consistent or unified manner across the universities. This resulted in a call from the author for a consensus conference to establish the best methods for teaching and evaluating communication and personal skills. This provides evidence that until a consensus is agreed within the pharmacy teaching community, including the UK, we are justified in choosing available validated assessment tools.

Silverman *et al.*[70] state that experience alone is a "poor teacher", and that knowledge is required in addition, which provides support for the provision of underpinning knowledge in the at the university prior to the experiential element. Kolb[128] states that the focus of experiential placements differs from the structured university and that the experiences of each student varies and is dependent on the particular site and supervisor's knowledge and skills. It, therefore, follows that, as training pharmacy undergraduates with real patients in the UK is a new approach and as both Kolb and Dewey identify possible variation in resulting outcomes, that evaluation of this form of training must be undertaken.

The Department of Health[115] recognised that pharmacists' clinical skills and expertise are an important part of delivering better care to patients, which must require consultation skills. Silverman, Kurtz and Draper in 'Skills for communicating with Patients'[70] state that " the prize on offer from communication skills training is improved clinical performance.

The process for effectively developing consultation skills in pharmacists from undergraduate to postgraduate level in the UK is yet to be defined. Within other professional groups this is undertaken by initial class-based training, usually with actors followed by students providing simple services to real patients. Development of the requisite skills is traditionally assessed by OSCE within the undergraduate programme and by tutor observation within real practice.

This project is designed to test the translation of a new model of education and training into the pharmacy setting. This chapter, therefore, considers the effectiveness of a new preparative training course; the suitability of using actors and artificial scenarios to prepare students for real patients; and then the provision of a structured service to the patients under close supervision. The optionality of this research project is one factor which requires evaluation as this may bias selection, resulting in a non-generalisable sample. Delivering this training programme and experience alongside a traditional programme also provides an opportunity for determining its effect on student performance within those elements of the degree which are potentially enhanced by this experience. Consequently, an opportunity to triangulate observation of practice and its development, alongside student experiences and student performance, measured by an independent means, is provided. Due to the small numbers of students involved, however, it may be difficult to draw many conclusions as there will be limited power within any quantitative comparisons.

## **4.1 Aims and Objectives**

### **Aim**

The aim of this section of the thesis is an evaluation of a novel training course designed to prepare students to undertake medication reviews.

### **Objective**

The objectives of this element of the research were:

- to assess the suitability of the training course for developing consultation skills in pharmacy students,
- to assess the academic status of participant and non-participant pharmacy students to enable evaluation of the generalizability of student cohorts who self-

select for participation in a study which is designed to provide and evaluate education,

- to describe recruitment and retention rates and provide reasons for non-retention,
- to determine the participant students' perceived effectiveness of the delivered training programme after its delivery.
- to assess and describe the effect of the training on student consultation skills within medication reviews,
- to describe participant student opinions regarding the experience of undertaking medication reviews with real patients;
- to describe the opinions of patients regarding the value of the medication review service with final year pharmacy students.

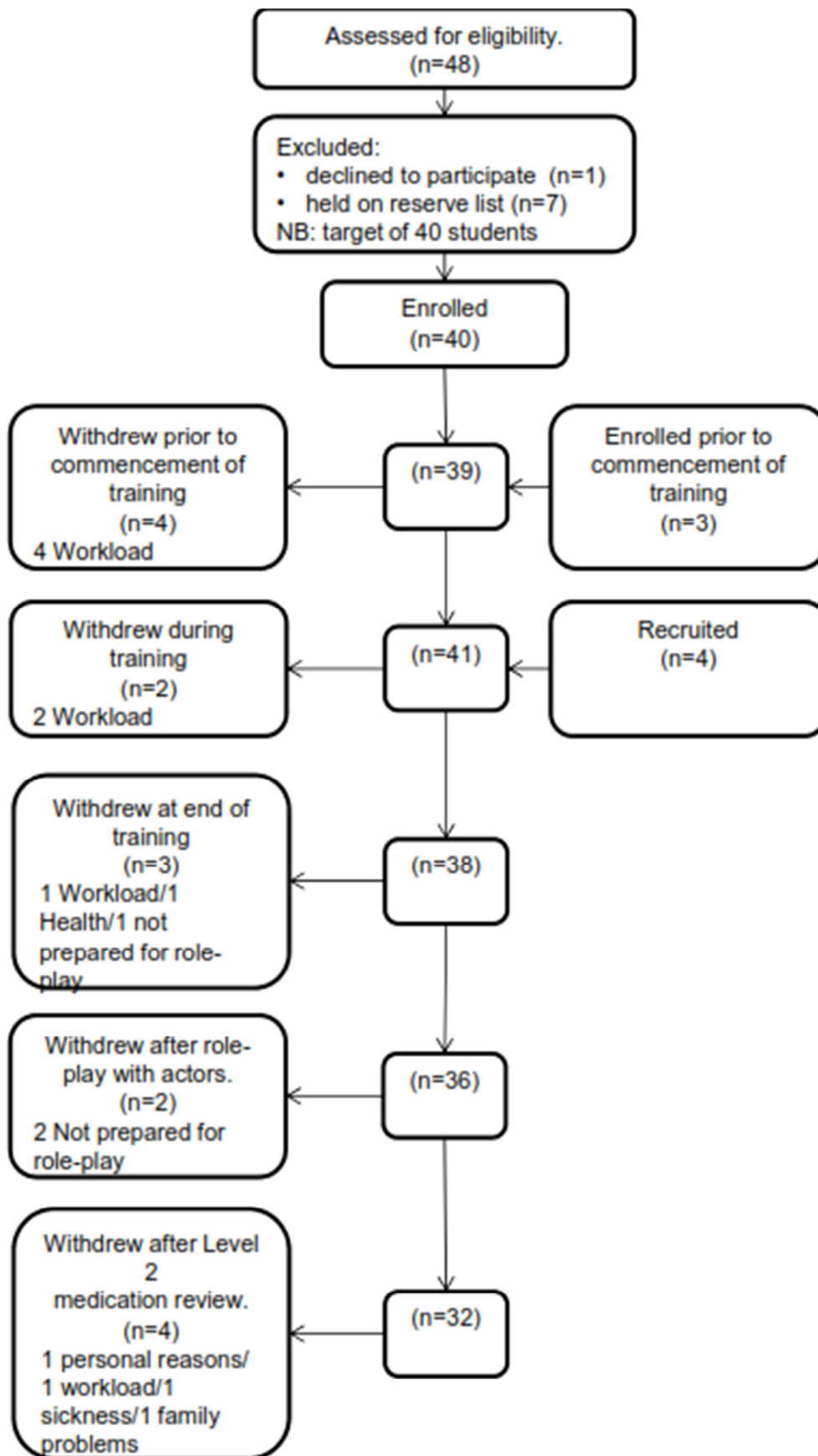
## **4.2 Results**

Forty-seven undergraduate pharmacy students were recruited to participate in the study. Six (12.75%) were male. Seven volunteers were placed on a waiting list, whilst forty students were enrolled into the study. As volunteer students left the study, students from the reserve list were included.

Thirty-two students completed the project. The principal reasons for students not completing the project were workload (n=3) and inability to cope with the difficulty or complexity of the tasks involved in undertaking a role-play medication review (n=3).

### **4.2.1 Student Participants**

The CONSORT flow diagram (Figure 4.1) describes the numbers of students joining and/or leaving the study at each stage. Reasons for students leaving the study are provided to enable evaluation.



**Figure 4.1** Flow diagram for student recruitment, attrition and replacement



#### 4.2.2 Academic ability of students volunteering to participate in a study

Data in Table 4.1 demonstrate the mean of exam results at the end of year 3 (at recruitment) and at the end of year four (post-intervention) for both control (non-participating) and intervention (participating) students, with volunteers displaying academic superiority and therefore self-selection bias.

	<b>Non-participant students, i.e. the remainder of year 4 students. (Control)</b>	<b>Participant students n = 40, i.e. all those recruited and enrolled at the beginning of the course. (Intervention)</b>	<b>p value (Independent samples t-test)</b>
	Mean (SD)	Mean (SD)	
<b>Year 3 average mark</b>	58.91 (7.91)	62.80 (7.98)	0.035
<b>Year 4 average mark</b>	66.89 (4.87)	69.26 (4.77)	0.032

**Table 4.1** Mean exam results year 3 and 4.

### 4.2.3 Individual students leaving the study

Data in Table 4.2 describe the academic ability of students leaving the study in addition to timing and reasons for leaving. Students informed the researcher of their decision to leave either verbally or by email.

Student leaving the study	Mean mark year 3	Mean mark Year 4	Stage at which student left the study	Reason stated by student for leaving the study
Student A	70.88	71.84	During initial training	Workload
Student B	70.58	67.77	During initial training	Workload
Student C	57.67	64.96	Before role play	Health
Student D	57.21	70.88	Before role play	Too busy/workload
Student E	59.38	66.93	Before role play	Not ready for consultation
Student F	59.89	61.35	After role play	Too difficult
Student G	56.03	66.90	After role play	Too stressful as not competent or confident
Student H	67.78	71.02	After review of patient's medical record	Personal reasons
Student I	76.54	84.25	After review of patient's medical record	To concentrate on exams
Student J	46.63	57.97	On the day of the consultation with patients. Last session so no later sessions to fit into	Health
Student K	45.87	75.94	On the day of the consultation with patients. Last session so no later sessions to fit into	Personal reasons

**Table 4.2:** Student leavers' mean exam results and leaving information.

#### 4.2.4 Objective Structured Clinical Evaluation (OSCE) results

Data in Table 4.3 display comparison of final year summative OSCE results between participating students and non-participating students. Distinctions are assessed independently of passes.

Intervention group refers to all those students completing preparative training and medication reviews with patients.

Control group refers to all students not volunteering or completing preparative training and medication reviews with patients

Scores are zero to four which equals the number of OSCE stations, with four representing the highest possible. Scores are presented as the mean of combined pass and distinction.

OSCE status	Intervention (n=32) Mean (SD)	Control (n=48) Mean (SD)	p value Independent samplest-test
Pass + Distinction	3.53 (0.76)	3.49 (0.67)	0.769

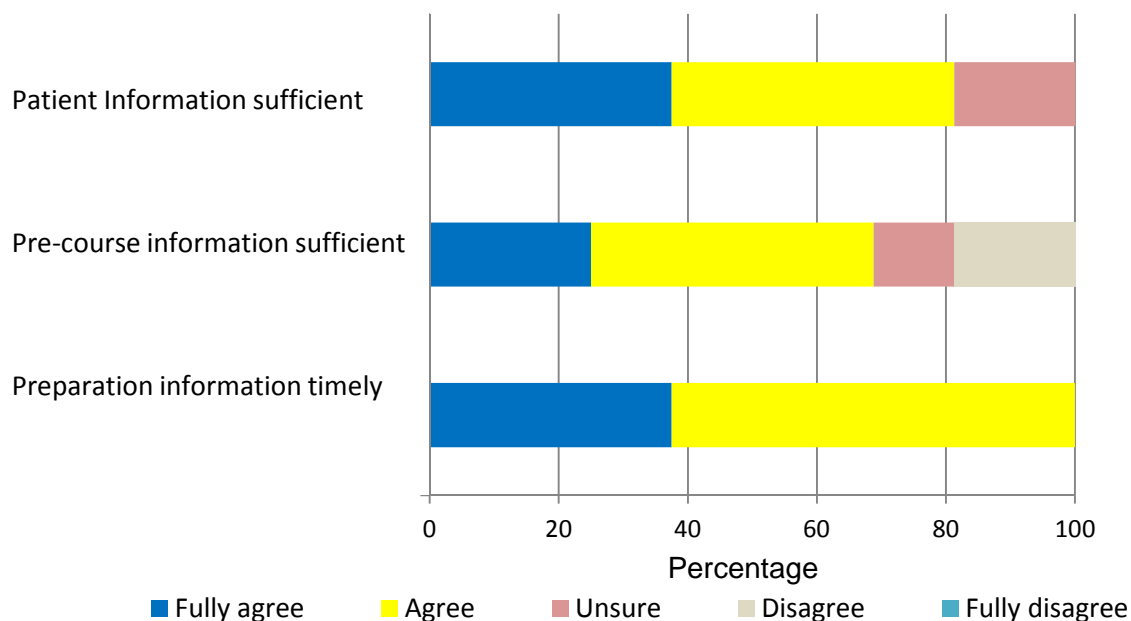
**Table 4.3** Final year Objective Structured Clinical Evaluation results for intervention and control students.

#### 4.2.5 Online student surveys

##### 4.2.5.1 Role-play session

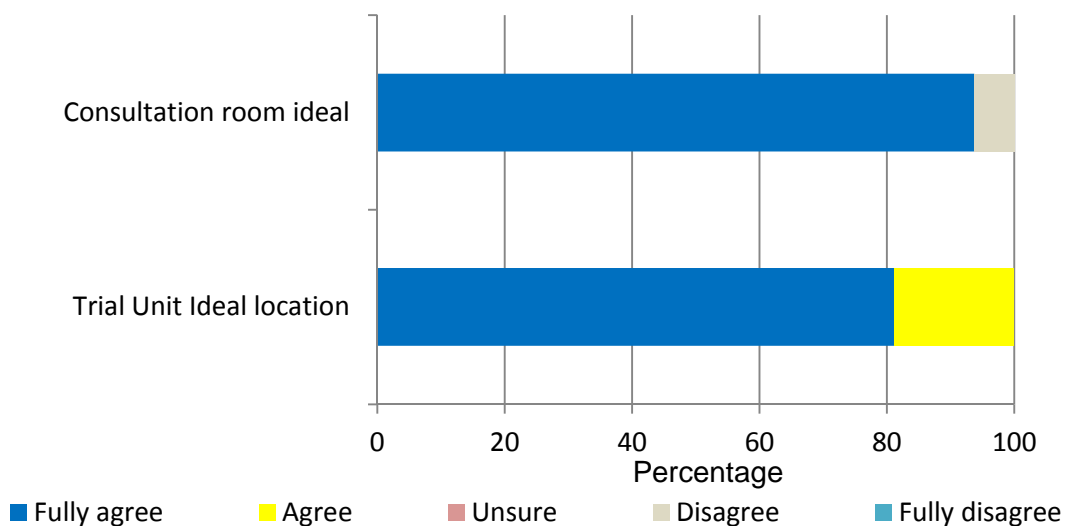
Seventeen (40.5%) out of 42 students who completed the preparative training completed the survey. Twelve (70.8%) students fully agreed and four (23.7%) agreed that practising consultation skills with professional actors is an ideal way to learn consultation skills, whilst 1 (5.8%) was unsure.

Data in Figure 4.2 represents student's opinions in response to questions seeking to establish the usefulness and timeliness of information sent to students prior to the role-play session. (n = 17)



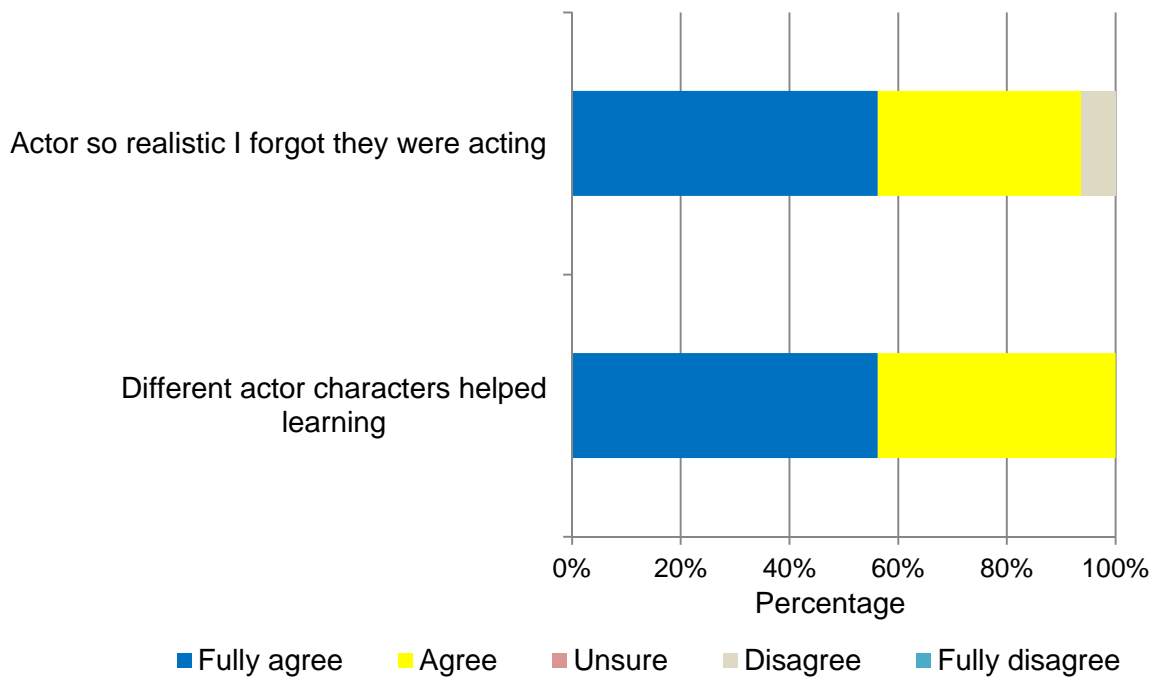
**Figure 4.2** Preparative information sent prior to the role-play session.

Data in Figure 4.3 represents students' opinions of the suitability or effectiveness of the location when undertaking the role-play session. (n = 17)



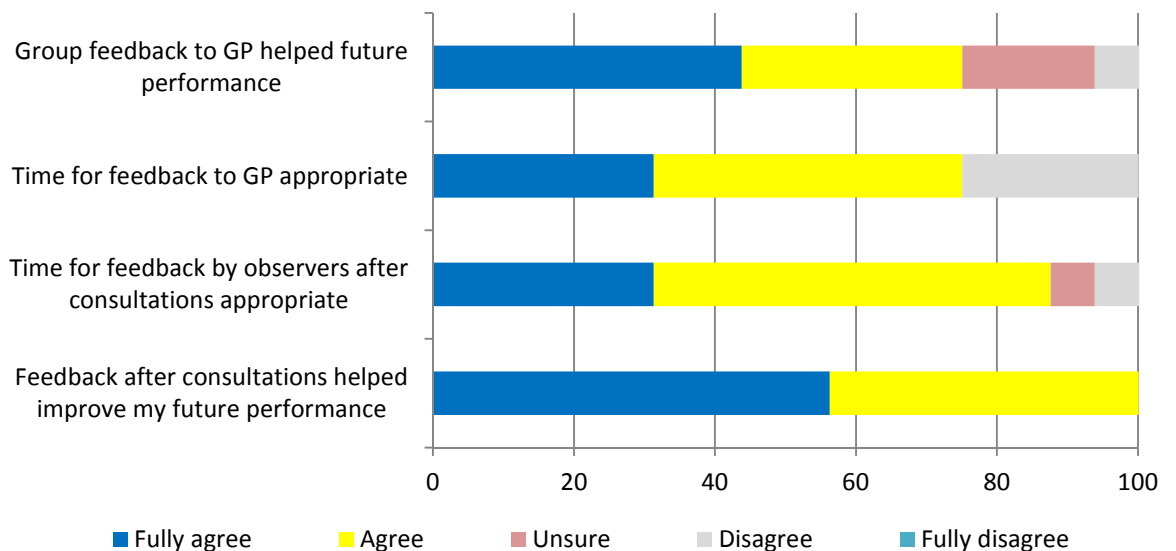
**Figure 4.3** Effect of the location for role-play training.

Data in Figure 4.4 represents students' opinions of the value and possibly the effectiveness of the actors in training them for consultation skills during role-play. (n = 17)



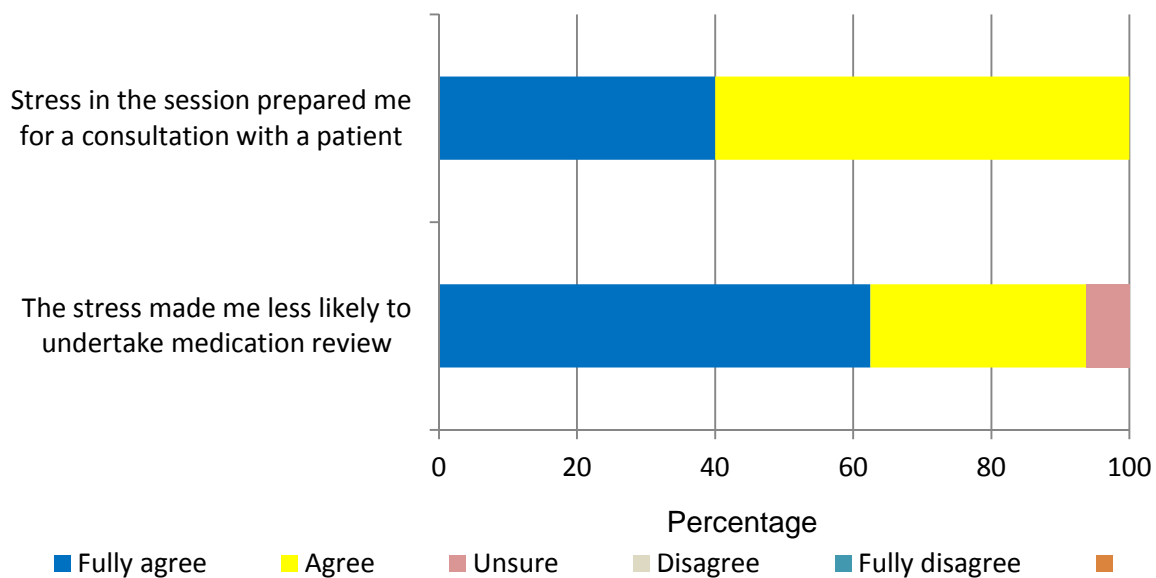
**Figure 4.4** Effectiveness of using professional actors for role-play training.

Figure 4.5 displays student opinions presented about feedback provided after each consultation within the role-play session and also the GP feedback session which followed the two student/actor consultations. (n = 17)



**Figure 4.5** Effectiveness and time allocation for role-play feedback

Data displayed in Figure 4.6 presents students' opinions relating to the effect of stress within the role-play session on future actions. (n = 17)



**Figure 4.6** Effect of stress during the role-play session

Data presented in Table 4.4 display free text words used by students to describe the role-play session. The words are collated according to perceived meaning. Simple content analysis identified three groups of words, planning and delivery, effectiveness or outcome and the effect.

Where a word has been used by more than one student the number of occasions in which it was used is stated.

<b>Words relating to the planning and delivery of the role play session</b>	<b>Words relating to the effectiveness or outcome of the role play session</b>	<b>Words relating to the effect of the role play session on the students</b>
Good preparation	Interesting	Apprehensive
Well organised	Helpful (4)	Motivating
Organised (4)	Useful (2)	Challenging
Practical	Relevant	Fun
Realistic (9)	Effective	Reflective
Informative (6)	Constructive	
	Unique	
	Invaluable	

**Table 4.4** Free text words by students describing the role-play session

Table 4.5 presents free text comments made by participating students in relation to the role-play training session. Comments were subjected to simple content analysis to answer the question posed by the research plan[103]. Objective was identifying issues requiring changes to improve the role-play session if repeated.

<b>Content identified</b>	<b>Student's text (unedited)</b>
<b>Information supplied to students prior to the role play</b>	I wasn't sure about what I was going to do whether it was medicine use review or a pharmaceutical care plan-this information was not disseminated explicitly prior to the mock consultation
<b>Reality of the scenario</b>	I think the set-up of the consultation was a very real environment and this helped for me to get into my role
<b>Location – effect</b>	Obviously it does make it more realistic to practice consultation skills in a consultation room, but I think valuable gains can be achieved outside of this setting.
<b>Characters</b>	Not every patient will be the same. You need to learn how to adapt your skills to different types of people.
<b>Actors - script and its use</b>	Even though these actors had a lot more detailed information to give then perhaps in a regular counselling or responding to symptoms workshop, there was still an element of them only having a limited number of things to say unlike a real patient, who can respond to any question you may ask.
<b>Feedback - by academic staff and/or PCT pharmacists</b>	The feedback by observers was fantastic, especially getting feedback after the first session, which then allowed me to improve in my performance the second time and then receive even more helpful feedback after this.
<b>Feedback time allowance with the GP</b>	Not enough time to feedback to GP. I feel this adversely affected how useful the GP feedback session was.
<b>Feedback - GP style</b>	I found the GP's manner rather abrupt and critical which didn't give students enough confidence to feedback as much.
<b>Stress - effect</b>	I was really nervous before this as I knew we were being assessed at the same time but it was good in increasing my confidence for the real thing and giving me ideas for improvement

**Table 4.5** Student free text responses regarding the role-play session.



#### **4.2.5.2 Overall course survey**

This data presents views and opinions of student participant views of the overall training programme, including preparative training, medication review (level 2) at a medical practice and a medication review with patients. Data presented includes the effectiveness of aspects of the course, students' feelings about undertaking a medication review with a patient and opinions about repeating the exercise.

All forty seven students who provided consent to join the study, irrespective of whether the student completed the study, were requested to complete the survey. The response rate was twenty four (51%).

#### **4.2.5.3 General comments**

All seventeen participating students replying to this question stated that they would recommend the programme to another student. Sixteen students (66.7%) students strongly agreed, and seven (29.2%) students agreed that the course helped them to communicate with patients in a medication review.

#### **4.2.5.4 Podcasts**

Podcasts posted on the university intranet and which were designed to improve background knowledge were accessed as follows:

- fifteen students stated that they accessed Podcast 1 Blood Glucose,
- five students stated that they accessed Podcast 2 Cardiovascular,
- fourteen students stated that they accessed Podcast 3 Consultation skills.

Of those students replying:

- nine students stated that they strongly agreed or agreed that podcast one was useful,
- five students strongly agreed or agreed that podcast two was useful,
- nine students strongly agreed or agreed that podcast three was useful.

No students stated that they strongly disagreed that any of the podcasts were useful.

#### 4.2.5.5 Skills learned (as stated by students in the on-line survey)

Table 4.6 represents free text comments made by participating students about skills that they may have learned during the preparative training course. Themes identified were communication, mainly within consultations such as medication reviews, use of medical records, confidence, clinical knowledge and the role of healthcare professionals.

<b>Skill learnt</b>	<b>No. of students stating that they learnt or improved this skill</b>
<b>A. Communication - mainly within consultations</b>	18
<ul style="list-style-type: none"><li>• Listening skills</li><li>• Questioning including use of open questions</li><li>• Controlling a conversation</li><li>• Patient focussed</li><li>• Counselling</li><li>• Clarity in expression</li><li>• Types of patient</li></ul>	
<b>B. Use of medical records</b>	9
<ul style="list-style-type: none"><li>• Accessing information</li><li>• Interpretation of records</li></ul>	
<b>C. Confidence</b>	3
<b>D. Clinical knowledge</b>	4
<ul style="list-style-type: none"><li>• Diabetes</li><li>• Monitoring</li><li>• General</li></ul>	
<b>E. Role of healthcare professionals</b>	1

**Table 4.6** Skills students stated that they learned during the course

#### 4.2.5.6 Most rewarding aspects

Data presented demonstrate the opinions of students about the most rewarding aspects of participation in the study. These were expressed through free text comments in the on-line survey.

Thematic analysis was undertaken to identify issues important to participating students and the design of the training course. Themes and sub-themes identified include a theme, quoted throughout, of improvement in consultation skills; consultation skills learned (controlling the conversation, patients as individuals, open questions, listening skills);

feedback; provision of benefit to patients; improved confidence due to demonstration of competence; use of medical records; clinical knowledge of diabetes and the role of healthcare professionals within a medical practice.

### **Consultation skills learned**

#### **Controlling the conversation**

Students stated that due to the study their consultation skills improved, and that this was partly due to the interaction with real patients rather than actors, and that real patients act differently.

*“I feel my ability to adapt during a consultation was improved. By that I mean that real life patients will communicate in certain ways, go off on tangents and have varying degrees of knowledge on their own condition and it is very difficult to replicate this with actors.”*

The theme of controlling the conversation or consultation was expanded by other students, with comments which show the difficulty of talking to real patients.

*“Getting the required information out of patients, while staying within the time and not hearing their life story!! This was more difficult than many of us thought.”*

#### **Use of open questions within consultations**

Other students repeated the theme of improving consultation skills and in this case there was recognition that the use of open questions is an effective method of conducting a consultation.

*“My consultation skills were improved greatly after completing the course and I was able to use more open questions to gain large volumes of information from the patient compared to one word answers when closed questions are used.”*

Recognition of several of these issues was displayed within one statement when the theme of keeping the patient on track and the use of open questions was once more highlighted.

*“Consultation skills - before this course i would have found it very difficult to be able to lead a consultation as it is often difficult to allow the patient to talk throughout whilst staying on track. I feel I have developed this skill to be able to do this rather than asking lots of closed questions.”*

## **Patients as individuals**

This was developed further, with recognition that patients are individuals and that, therefore, a consultation must be adapted to the patient rather than relying on a formulaic approach.

*“I felt the course help me to appreciate the patient as an individual and thus led me to rely on adapting as the conversation progressed rather than relying on a planned routine.”*

## **Feedback**

Feedback provided to students by supervising pharmacists or medical practice staff was quoted as providing guidance for students' consultation performance.

*“Feedback gave us pointers on what we did well and what we could improve when we have conversations with patients.”*

One statement by a student displayed the positive feelings resulting from patient feedback.

*“Hearing the patients say they enjoyed working with the students and that they thought we were good at what we were doing. This made it all feel worthwhile as it was a real patient and not somebody who was acting.”*

## **Provision of patient benefit.**

The issue of working with real patients was further expanded to show recognition that a student had found that providing benefit to patients was rewarding to themselves.

*“Hopefully making a difference in one of the patients' lives, or at least helped them to understand their medication/condition more.”*

Another student further developed this idea to state that the consultation skills practice within a medication review provided benefit to the student because they perceived that they helped the patient.

*“Being able to make a contribution to the care of the patient while learning invaluable skills.”*

## **Improved confidence due to demonstration of competence.**

Students stated that their confidence improved after they had undertaken medication review with patients due to demonstrating competence in a real scenario.

*“Actually being able to have contact with real patients! I think in the MPharm degree it is essential to have contact with patients in order to be able to build confidence when talking to them, but it also allows yourself to gain confidence that the information you give them is correct and you begin to understand that you know more than you thought you did.”*

### **Use of medical records**

There was recognition that due to the need to access and interpret patients' medical records as part of the training programme this was, therefore, one of the rewarding aspects of the study training programme.

*“...the opportunity to use patient records as part of the learning process.”*

This study involved patients with T2DM as the group receiving the medication review and students stated they were able to learn more about the management of that long-term condition. This included practical aspects of the management of diabetes for a patient such as monitoring and lifestyle advice.

*“Clinical knowledge about diabetes and what should be given first line, safe ranges of blood glucose level to be in, also a bit about dietary and lifestyle advice.”*

### **Role of healthcare professionals in the medical practices**

Students experienced professional contacts with healthcare professionals during the study and in response to the question “what was the most rewarding part of the study”, one student stated:

*“More about the roles of diabetic nurses at doctors' surgery.”*

#### **4.2.5.7 Least rewarding aspects**

The on-line survey provided students with the opportunity to include free text comments relating to the least rewarding aspects of the study, and themes identified related primarily to preparative training and included content, delivery and usefulness.

## **Preparative training**

Some students expressed dissatisfaction with aspects of the preparative training, with mention that some training sessions, such as care planning or the use of IT medical records were too long.

*“Some of the sessions at the start of the year. Although relevant I think they could have been reduced into less time as we had a very busy year work-wise.”*

Time allocation was further discussed, with one student stating that all the preparative training should have been an integrated part of the undergraduate pharmacy course.

*“A large amount of time was taken up spending time on aspects that we have or should have already covered in the Masters course.”*

Another important issue of time allocation was highlighted with students stating that because this training was undertaken as outside their undergraduate course they experienced problems managing their time.

*“The stress and fitting these long sessions into the already packed 4th year schedule.”*

*“..... having to manage my time for the study and other university commitments..”*

A student quote suggests that the solution may be to incorporate the training into the undergraduate curriculum.

*“It could be very time consuming at times as it was not timetabled as such.”*

## **Positive comments**

A number of student respondents stated that there was nothing wrong with the training in answer to the question which sought to identify the least rewarding or useful aspects of the students' experience.

*“I think all aspects were useful.”*

### **4.2.5.8 Feelings of students at the start of the study**

The on-line survey provided students with the opportunity to include free text comments about their feelings at the start of the study. Themes and sub-themes identified included nervousness, real patient consultation, lack of previous patient contact, uncertainty of what a consultation would involve, lack of consultation skills; positive anticipation of the project; uncertain expectation if course would improve consultation skills; helping patients.

## **Nervousness**

Students reported feeling nervous at this stage about what they were about to undertake.

*“.....really nervous....”*

## **Real patient consultation**

Another student explained that the reason for their nervousness was due to undertaking a real consultation (medication review), thereby requiring a level of responsibility for displaying competence.

*“Perhaps a little apprehensive about talking to real patients in a consultation environment. It felt daunting to be responsible for obtaining information from them and giving them advice.”*

## **Lack of previous patient contact**

One student explicitly stated that they were nervous (or apprehensive) about talking to patients.

*“Also I was apprehensive about talking to patients.”*

## **Uncertainty of what a medication review would involve**

Quotes showed that whilst students stated that they were unsure of what the study involved; in reality, in some cases, they may have been unsure about how to conduct a medication review. This is demonstrated because the preparation training helped to resolve the problem.

*“That I was not really sure what was expected of me. The practice with the actors helped a lot with this.”*

## **Lack of consultation skills**

The students' lack of confidence in their own skills or knowledge at that stage may also have contributed to the nervousness.

*“....possibly being unsure about how to answer a question if the patient had asked one.”*

## **Positive anticipation of the project**

Some students, however, recognised their lack of skills and reported positive feelings whilst looking forward to the experience, particularly to improving their consultation skills.

*“I feel like my communication skills with patients is poor and expecting to become more competent in giving medication reviews at the end.”*

The use of the word exciting was used by more than one student. In addition, a currently unmet need with respect to student expectation of training is mentioned.

*“Excited that I was going to build on consultation skills as don't have much of an opportunity to do this on the course.”*

### **Expectations of the course to improve consultation skills**

There is not universal assurance that the course would succeed in the stated aim of improving students' consultation skills.

*“Excited. It was interesting to find out whether pharmacy students could actually master the skill of consulting patients.”*

### **Helping patients**

One student reported positive feelings in relation to a desire to help patients.

*“Curious if I would be able to make any significant interventions.”*

### **4.2.5.9 Feelings of students at the end of the study**

The on-line survey provided students with the opportunity to include free text comments about their feelings at the end of the study and provides a comparison to feelings at the beginning of the study. Themes identified include improved confidence and knowledge through patient contact; reflection and self-assessment; supervision; patients as volunteers; knowledge of disease states; and support for the course.

### **Confidence and knowledge through patient contact**

The issue of confidence which was highlighted at the start of the programme was raised again at this stage by many students, but more positively and related to consultation skills. Comments demonstrated that improved confidence was due to the patient contact, enabled by the study. Knowledge and confidence were highlighted.



*“I feel the interaction with the patients has made me more confident in myself and my knowledge.”*

Further evidence was presented that improvement in skills and, therefore, confidence was due to meeting real patients rather than classroom teaching. A specific issue was stated as the technique of consultation involving open and closed questions.

*“Developed a more realistic approach when speaking with patients as in the past it was all theory that we had learnt and practiced with our colleagues. I feel more confident in speaking with patients and have also learnt how to ask particular questions in an open manner and closed questions when it is necessary.”*

### **Reflection and self-assessment**

Comments were made which show students being able to make valued reflective judgements of their ability to develop consultation skills.

*“Although competency in consultation skill has grown, the awareness of my incompetence was more important.”*

One student showed an understanding that a medication review is more than just the skill of communication: it also required utilisation of knowledge to evaluate the effectiveness of therapy which is another skill.

*“I enjoyed it because I learnt a lot and it was not just about talking to the patient but going through their medical history and investigating if their therapy was effective.”*

There was recognition that not all input to patients during medication review has to be major in order to be effective.

*“Little changes also matter, does not have to be really significant.”*

### **Supervision**

Recognition was displayed, of the significant part played by supervision in effectively training students, as it provided them with confidence that supervisors would correct errors.

*“I feel more confident. Having observers in the consultation room with me, although initially a little apprehensive, helped me to feel more confident as I knew if I did say anything that was incorrect or gave inappropriate advice they would be*

*able to step in and correct. The fact that this did not happen made me feel more confident that I understood what I was talking about.”*

### **Patients as volunteers**

There was recognition by a student that because the patients were volunteers, they did not totally represent the real world. This, however, was quoted in a positive manner: the issue raised was that the use of volunteers enabled the student to show gaps in knowledge or training.

*“I think that because the patients knew we were students they didn't mind if sometimes there were pauses while looking at notes and checking, and although real patients in practice possibly wouldn't have this patience, it was an invaluable experience.”*

### **Knowledge of disease states**

Comments showed that students had improved knowledge of a disease state in addition to consultation skills, as the patient group within this study were patients with T2DM.

*“I have more confidence and increased understanding of diabetes. “*

### **Support for the course**

Students' comments demonstrated that the course was received positively, and in one case would result in recommendation of the course to other students.

*“I am very glad I took part in the programme.”*

*“I learnt a lot more than I thought I would from the experience and would recommend the opportunity to all pharmacy students.”*

This is stated in a more explicit manner by another student.

*“After completing the whole course I think pharmacy students can indeed carry out consultations with patients and I think it should be a regular part of the pharmacy degree.”*

#### **4.2.5.10 Recommended course changes**

Data presented represents the views and opinions of students about changes that they would recommend to the training programme. A number of issues replicate those raised earlier.

Themes identified included, content, scheduling, medication review with patients; feedback and student training cohort.

##### **Content**

More demonstration of, and practice of, consultation skills was requested even before the role-play session with actors.

*“More realistic demonstrations on examples of consultations skills rather than just theories and simple role-play, before the practice session with the actors.”*

Sessions undertaking role-play consultations with actors received strong support, with requests for more of these due to their effectiveness.

*“I feel another session with the actors would have been helpful as I feel I learnt a lot from that experience.”*

##### **Scheduling**

Because the study was undertaken by volunteer students, in addition to their undergraduate course, the frequent comments by students which relate to scheduling or duration of training sessions could be expected.

*“The time-frame between the training courses and medication review - closer together.”*

Another student’s comment about scheduling, sought to identify a solution.

*“The time schedule can be changed but since it will be part of the course, I believe it will be on the timetable and safeguarded.”*

Disagreement was displayed by statements about scheduling of the training session designed to provide training to students about the IT medical record system (Systmone®).

*“Some training sessions may have been too long, for example when using the system on the computer, students are able to pick things up quickly.”*

*“Perhaps more training on the SystmOne® programme “*

### **Medication review with patients**

The study protocol provided for each student to meet two patients for a medication review. Patients were volunteers recruited via medical practices, with consent provided. Students stated that they would wish to meet more patients.

*“I would have liked to see more patients - although I know recruitment would be difficult.”*

An alternative view of increasing the number of medication review was raised with a recognition that meeting the patient(s) again would be desirable.

*“... and perhaps seen the patient again a few months later to follow-up.”*

### **Feedback**

The protocol included the opportunity for students to feedback issues identified during the level 2 or level 3 medication reviews to the patients' GP. Comments received from students included:

*“At the final session it would have been nice to be able to talk to the patient's GP about the issues raised with them and the information gathered so it could be discussed properly.”*

### **Student training cohort**

One student identified that not only was this course of value, but that it should be offered to undergraduates in their third year.

*“Suggest you run this with the third years as part of the PP3 course.”*

#### **4.2.5.11 Additional free text comments by students**

Students were invited to add any comment that they wanted at the end of the on-line survey which resulted in three comments received, all of which were very supportive of the training course.

*“It was a precious training opportunity that was enjoyable and educational. I sincerely appreciate the time and hard work to arrange this training for us. Thank you very much.”*

*I think this was a great experience and am glad I participated in it.*

The final comment, whilst supportive, suggests that the preparative training requires improvement.

*Extremely advantageous and a learnt a lot. With more structured training sessions would be hugely beneficial to our course to go out into practice.*

#### 4.2.6 Medication Related Consultation Framework (MRCF)

Data in Table 4.7 presents results obtained by students after undertaking their first and second consultations with patients (medication review). N.B. each element of the MRCF short form is scored on a scale of 1 to 4 where 1 = not able to undertake the activity and 4 = fully able to undertake the activity.

Order of consultation	MRCF: activity measured	N	Mean (sd) score (range 0 to 4)	P value (paired samples t-test )
1 <sup>st</sup>	Introduction	17	2.80 (0.58)	0.134
2 <sup>nd</sup>			3.02 (0.43)	
1 <sup>st</sup>	Data collection and problem solving	21	2.68 (0.68)	0.289
2 <sup>nd</sup>			2.80 (0.40)	
1 <sup>st</sup>	Actions and solutions	14	2.46 (0.77)	0.159
2 <sup>nd</sup>			2.86 (0.57)	
1 <sup>st</sup>	Closing	14	2.60 (0.14)	0.655
2 <sup>nd</sup>			2.70 (0.46)	
1 <sup>st</sup>	Consultation behaviours	18	2.67 (0.51)	0.003
2 <sup>nd</sup>			3.08 (0.39)	
1 <sup>st</sup>	Total of scores	14	13.64 (1.30)	0.084
2 <sup>nd</sup>			14.83 (2.94)	

**Table 4.7** MRCF mean scores for first and second patient consultation.

#### 4.2.7 Post level 3 medication review questionnaire

Fifty eight patients received a medication review from one of thirty two students. Twenty six students reviewed two patients whilst eight only reviewed one patient, due to a shortfall in recruiting patients.

Fifty five patients (95%) completed post-medication review questionnaires. Three patients declined to complete the questionnaire: two gave no reason, whilst the other had completed the baseline questionnaire (approximately 20 minutes) prior to the medication review, as he had previously forgotten, and stated that he had completed enough forms for the day. Students completed fifty two questionnaires (89.5%) out of a possible 58. Table 4.8 displays a comparison of patient and student questionnaires completed immediately after the student-led level 3 medication review.

Question	Mean (sd) patient score of student n=55	Mean (sd) student self-assessment score N=52	p value Independent samples t-test
The student was well organised	4.84 (0.37)	3.61 (0.70)	<0.001
The student had a very professional attitude	4.80 (0.40)	4.08 (0.61)	<0.001
The student communicated well	4.84 (0.37)	3.84 (0.69)	<0.001
The student showed good confidence	4.66 (0.56)	3.63 (0.76)	<0.001
I was comfortable with the level of knowledge I had to carry out this review		3.65 (0.63)	N/A
The student was an appropriate person to review my medicines	4.70 (0.57)	3.76 (0.63)	<0.001
I learnt something useful about my medicines	4.20 (1.00)	3.47 (0.94)	<0.001
The review of my medicines was interesting	4.60 (0.70)	3.52 (0.70)	0.001
The review of my medicines was important for my health	4.60 (0.73)	4.07 (0.83)	0.001
I would recommend this medication review to other people	4.90 (0.30)	4.02 (0.86)	<0.001

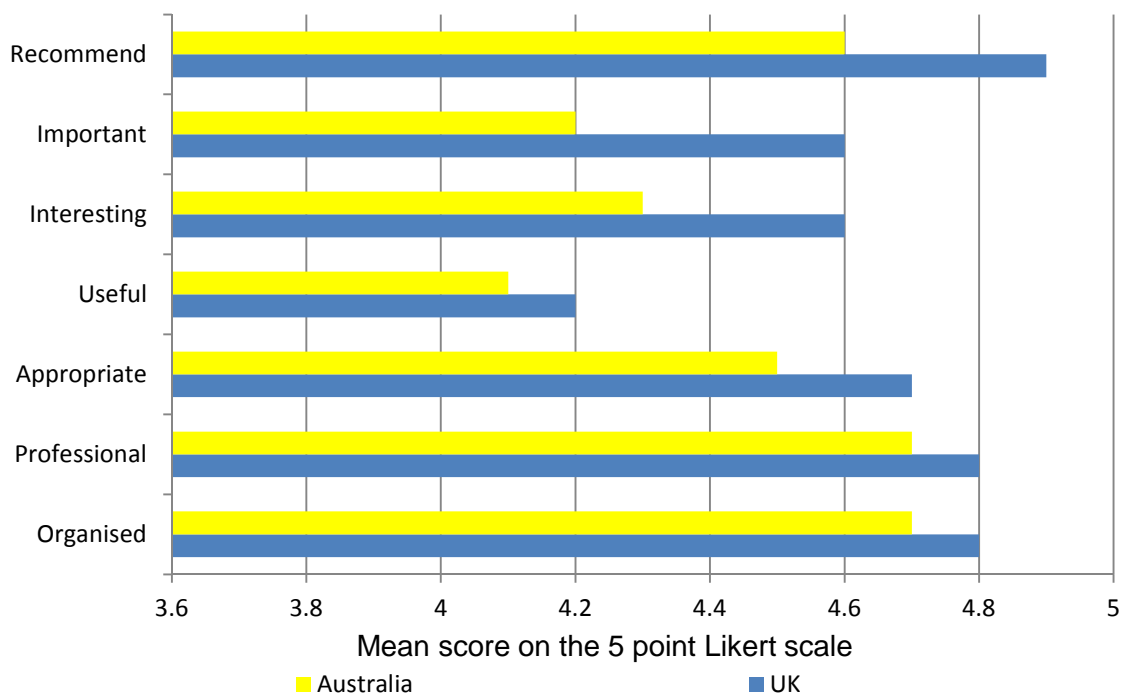
**Table 4.8** Patient and student questionnaires post consultation

Only 4 patients chose to add free text comments :

1. *“It was a good opportunity to ask questions.”*
2. *“Very good.”*

3. *“Too many colloquialisms in student’s speech such as ‘cool’. Other than that a positive experience.”*
4. *“I hope this has proved useful for the student.”*

Figure 4.7 provides a comparison between the mean scores provided by patients to questions asked after a student led medication review in this study and in a similar study using an almost identical questionnaire in Australia 2004[75]. UK results show a higher mean for all questions.



**Figure 4.7** UK versus Australian patient provided scores of student consultations.

### 4.3 Discussion

This chapter evaluates an education intervention which consists of distinct phases, the development of underpinning knowledge and ability to apply it, skill development in an artificial setting and, finally, further development of skills and application of knowledge with real patients.

Those students who completed all three phases were very positive about the experience with 100% of them recommending the course to other students. The main benefits were improvement in consultation skills and self-confidence.

The first phase of the training was the least well received as some elements were too long and some were not accessed. This element which was designed to develop knowledge needed to better consider what had already been previously taught within the undergraduate course and should be provided closer to the initial practice with actors.

The role play of medication reviews with actors was very well received, with students reporting improvement in consultation skills, assisted by feedback after the first consultation. Students provided useful data regarding the actor scenarios, including a recommendation that these should not include full details and not always include a need to resolve problems, in order to mirror the real world with patients. However, the time available for feedback by the GP, in addition to the style of presentation was criticised. A small number of students left the study at this stage, with stress of undertaking the session identified as a cause. In common with other timescale issues, students stated that this session must be closer to the medication reviews with real patients

Following the final phase, when students met real patients for a medication review, the students reported good development of their consultation skills and a better understanding of the processes within a medication review and GP practices.

A high rate of completion was demonstrated for post-medication review questionnaires. Inviting all participating students, including those who had left the study, to complete the on-line survey increases the strength of the data, as those views may provide fuller explanations. However, because the surveys were anonymous it was not possible to identify if any students who had left the study had participated. Triangulation of data from different sources enhances confidence in findings[111]. Mays and Pope[111] describe triangulation as referring to 'an approach to data collection in which evidence is deliberately sought from a wide range of different, independent sources and often by



different means'. In this case, different sources (students) were used, in addition to different methods of data collection. Students volunteering to join the study were self-selected and demonstrated academic superiority over non-volunteers.

MRCF forms were used within the role play session to provide feedback to students on their performance, and were given to students. Retention of a copy by the researcher during the role play session would have enabled further evaluation of the effectiveness of that session. Similarly, the forms were used to provide feedback following each medication review with a real patient, but in this case forms were retained. Evaluation of the study using MRCF forms was not initially planned and this provides a lack of potential bias in scoring of the forms.

Response rate, of the students' on-line survey was low, possibly due to their course workload at the time, which would represent their key priority, and reduces the generalisability of results and conclusions. However, those results obtained displayed strong evidence that students valued the course (podcasts, preparative training workshops, role-play, level 2 medication review at a medical practice and a patient medication review at their medical practice).

Almost one third of students who initially consented to participate left the study, with the main reason stated to be workload created by undertaking this course alongside their undergraduate studies. Those leaving for health, personal or family reasons cannot be adequately discussed as no details are available. Of concern were those students who left due to the stress or not being prepared, as these demonstrate a failing of the preparative training. Inclusion of the whole course into the undergraduate curriculum would enable management of workload issues and provide better preparation for students, therefore, potentially resolve stress issues.

The information provided in podcasts was primarily revision of knowledge provided within the undergraduate curriculum and this may explain why these were poorly accessed. Additionally, this work was expected to be undertaken in the students' free time and motivation was probably lacking to undertake additional learning over the summer. A student in a development focus group suggested subjecting students in the study to a multi-choice question test after the vacation to increase uptake of learning within the podcasts. This was considered but it was decided not to use multi-choice questions because this may have increased drop-out rates of volunteers.

Students requested changes to the structure of the preparative training with more practical demonstrations on how to carry out consultations, rather than theory, to aid learning of consultation skills. Whilst students may wish to commence practice of consultation skills straight away, knowledge of the underlying structure and theory is believed to be important. Silverman[70] *et al.* state that knowledge and communication skills are two of the four essential components of clinical competence, and 'experience alone can be a poor teacher'.

Disagreement was displayed regarding the duration of the training in the use of the IT medical record system, which may demonstrate variation in underlying students' IT skills. This may require pre-assessment to establish skills levels, with more intensive training for those reporting greater learning needs. The teaching of care planning was stated as being too long and this was possibly due to extensive teaching of this subject within the current curriculum.

A key comment made by students, related to scheduling of preparative training, was the need to ensure shorter timescales between completion of training and undertaking medication reviews. Whilst students displayed criticism of the delivery of the preparative teaching, they recognised its value and want such teaching to be part of the undergraduate curriculum.

The students all believed that role-play training with professional actors is an 'ideal' way to teach consultation skills, resulting in requests for more role-play opportunities. Agreement was shown that pre-training information of organisation of the session and the 'patients' was sent in a timely manner, however, students wanted more information about both factors. Better information to fully inform students of what they are about to undertake would enable improved student preparation, resulting in reduced stress or concern. This could improve performance and, therefore, increase the benefit of teaching. Joyner[117] recommends good preparation for role-play sessions. Full agreement was demonstrated that using real consultation rooms was a good location to undertake role-play.

Students provided support for the use of actors, rather than other students or university staff to role-play, is a good way to learn consultation skills in preparation for real life medication reviews. Joyner[117] and Nestel[130] utilise students as patients, although Nestel[131] also suggests the use of actors. Students reported that different characters given to the actors within their scripts added to the experience. In most cases students forgot that they were talking to an actor, which adds to the effectiveness of the experience. Joyner[117], suggests the creation of challenging cases, including conditions, emotions,

opportunities for motivational interviewing and raising ethical issues. There is not an explicit recommendation that actors should learn the full script but it is stated that actors should provide information in 'challenging cases' on demand. Student comments demonstrate actors' responses being limited compared to patients' responses, showing the need to ensure that actors know and utilise the script fully. This important issue, which must be addressed in future role-play, is supported by Nestel[130] who identified that good acting of the role is essential for realism and effectiveness. Student questionnaire responses about the role-play display proactive and supportive words such as organised, realistic and informative appearing several times and demonstrate that the role-play session was well planned and organised, which would have facilitated effective training.

Comparing first and second medication reviews with patients demonstrated no significant improvement in the combined scores of the individual elements of the MRCF, or in any of the individual elements other than that a significant improvement for 'consultation skills' scores was observed. 'Data collection and problem solving' and 'actions and solutions' whilst essential parts of consultation skills, represent more technical rationalist functions which had been practiced extensively during the undergraduate course. Students would have developed those skills, therefore, providing less room for improvement within a medication review. 'Closing the consultation' demonstrated lowest improvement; however, the MRCF scoring system 'closing': explains what to do if patient has difficulties to follow plan, whom to contact, provides further appointment or contact; offers opportunity to ask further questions. Silverman, Kurtz and Draper[70] state that closure is partly a reflection of the consultation skills throughout the medication review; however, the students met each patient once and, therefore, it is possible that they would not know what to do about future appointments, or follow-up. Interim analysis after the first cohort of participating students may have identified the issue of poor performance during closure of the consultation thus enabling identification of the cause, which should have resulted in feedback to later students to resolve the issue.

It is impossible to predict if meeting more than two patients for a medication review would have improved the skills of the students further, although students did request that they should meet more patients. Research including Boyatzis *et al.*[75] and O'Neill *et al.*[76] demonstrates pharmacy students' education benefitting from meeting more than two patients for medication review and for repeat consultations. Janson *et al.*[81] undertook a study of interprofessional learners including medical, pharmacy and nursing students, during which repeated consultations with patients demonstrated improved consultation

skills by the students. A student suggested in the on-line survey that there should be repeat meetings to undertake medication reviews with patients. Nuffer *et al.*[132] reported a study of pharmacy student facilitated diabetes clinics, in which students stated a positive perception of their experiences when providing self-management education about diabetes to multiple patients.

Data show patients scoring student-led medication reviews significantly higher than students' self-assessments and may demonstrate a desire by patients to help the students, whilst students' previous self-assessment experience may have led to increased self-criticism. Even the lowest score provided, for the question "I learnt something useful about my medicines", shows patients receiving benefit from students during a medication review. Patients reported finding the experience acceptable, would recommend it to others and report some benefit, which suggests that such training may be sustainable.

Data demonstrates a clear relationship between the Australian study[75] mean scores and the UK study mean scores, with a slight superiority of scores recorded by patients in the UK study. Interpretation by Boyatzis and Batty of the Australian study[75] was that "feedback indicated that students had demonstrated a professional approach and that there was general approval of the process of DMR (Domiciliary Medication Review) by this group of patients". It is reasonable to propose the same conclusion for this study, whilst the close relationship between scores indicates an effective questionnaire.

Australian study patients were given the evaluation form to complete and post anonymously, directly to the investigators, whereas in this study patients were asked to complete the questionnaire immediately post-medication review. Within this study patients were told that results would not be used against any student and would remain confidential. An area separated from the student to ensure privacy, but in the same room was allocated to complete the form; however, results may still have been affected by the student's presence. Response rate in Australia was 70% compared to 96.5% in this study. An immediate response may produce a more accurate score, as time elapsed may affect recollection of events and it is also not known what effect non-responders in the Australian study would have on mean scores.

Communication skills, essential for effective implementation of medication reviews, were the most commonly reported improvement by students. All but one of those skills stated as learned by students are included in the Calgary-Cambridge guide[70]. The one not included is 'controlling a conversation' which, as worded in student responses, is not in the guide. However, the definition of 'agenda setting' includes the healthcare professional

taking into account their own needs, including managing limited time. A degree of 'control' may be required to focus discussion on patients' problems to ensure effective patient outcomes, which may explain the use of the term controlling a conversation. Other skills stated by students: use of medical records; clinical knowledge and the role of healthcare professionals, all represent knowledge required to support the use of consultation skills. Because students stated that they learned skills during the study, evidence is displayed of effectiveness of the training.

The most rewarding part of the course was 'working with real patients' which formed a repeated theme in student responses. This is not surprising as it was the first opportunity for those students to undertake medication review with patients. Students stated that they partly enjoyed working with patients because contributing to patient care is rewarding and this provides support for a repeat of the study. A student recognised that healthcare time is limited and that medication reviews cannot be open-ended. Knowledge and skills learned, including clinical, use of medical records and the role of healthcare professionals, is highlighted again, providing further evidence of the need to provide teaching in medical practices to support the teaching of consultation skills. The modernising pharmacy careers programme[74] states that skills are required to enable utilisation of knowledge. In this case, the process of skills acquisition enabled an increase not only of skills but also of knowledge, such as diabetes care. Students' wanted further experiential learning opportunities within the undergraduate course.

Students volunteering to participate in this study demonstrated academic superiority over those not volunteering. There is increasing evidence, mainly from USA and Australia, in which pharmacy students have undertaken activities similar to those in this study, including practising consultation skills within a medication review. In the majority of cases students were volunteers and a potential criticism of their research is that, because students were self-selecting the probability is that those with a higher academic ability and/or achievement would volunteer. The effect could be that the students were more effective at learning consultation skills and, therefore, results generated would not be generalisable. In a study in Vancouver (2008)[123], in which pharmacy students participated in an experiential programme, a stated limitation was that student participants were volunteers, and therefore, self-selected. This potentially resulted in a "Hawthorne-like upward drift in both interest and performance". They also suggest that it is not known if "more mainstream" participants would generate similar results.

No conclusive evidence is provided by data for an effect by the study on students' grades in final year exams. This study was undertaken with volunteer students, thus requiring them to undertake activities in addition to their undergraduate course. This further compounds the difficulty in interpretation, as the extra workload could have exerted a negative effect on participating students. It is also possible that a ceiling effect applied to exam results, in which both groups reached their limit of improvement, potentially enabling the controls to reduce the academic gap. This may be supported by the smaller standard deviation in both groups in the final year, which demonstrates a smaller spread of means of grades, which may indicate 'bunching' at a 'ceiling' or limit.

The academic status of students leaving the study potentially affects self-selection bias of remaining students. It is, therefore, justifiable to identify the academic status of students choosing to leave the course. Data shows that as each leaving student departed the study, until student G, a general trend was observed of increase in the mean of remaining intervention students' scores in the final year exam. However, the increase in mean of final year exam results of students leaving the study is only 0.41% and does not represent a significant change. Students leaving the study due to workload could be predicted, as this study was undertaken in addition to students' undergraduate course. Statements of 'not being prepared' or 'competent to undertake consultations' are concerning as this could be evidence of a failure to effectively prepare students for the medication reviews. The data shows a number of possible reasons, including skills, language and confidence, all of which could be resolved by more effective training, therefore, provision of the preparative training as part of the undergraduate curriculum would present considerable academic and logistical benefits.

The OSCE stations which were evaluated were medication history taking, responding to symptoms, medicines information (taking a request: not answering) and counselling about a medicine. Through additional training, participating students had learnt to undertake fully interactive medication reviews with patients. It could be anticipated that they would perform better than non-participating students in an OSCE, but only a very small non-significant superiority was observed. Possible interpretations include: OSCEs test simple actions rather than complex medication reviews; the assessment method used within OSCEs is not effective at testing consultation skills; the scenarios used do not reflect that of a medication review; or simply that the small numbers of students did not enable the identification of a statistical effect.

An OSCE is defined as “an approach to the assessment of clinical competence in which the components of the competence are assessed in a planned or structured way with attention being paid to the objectivity of the examiner”[133]. Hodges[134] (2003) and Brannick *et al.*[135] (2011), in a systematic review of OSCEs in the medical field, both discuss problems with OSCE scenarios. Assessment in an artificial environment, such as a university room, is more difficult with this not reflecting true ability in a real situation. The Cambridge-Calgary guide[136] lists 70 skills to employ in consultations, therefore, requiring adaptation by the practitioner. It may be effective to utilise an alternative OSCE scoring tool, which focuses on consultation skills. The Medication Related Consultation Framework (MRCF)[87], assesses a range of skills, rather than actions, and has been used in a variety of scenarios and is, therefore, appropriate.

It was appropriate to use the MRCF to evaluate student performance in medication reviews, however, it was incorporated into the study to enable structured feedback to students on their performance in medication reviews. It was only during analysis of the study that it was decided to include evaluation of this potentially useful data, which reduces the likelihood of marking bias. Support for modifying or adapting research methods is provided by the guidance from the Medical Research Council[48] on developing and evaluating complex interventions: this allows changes to data use during a study of a complex intervention.

Supervision during medication reviews and feedback at all stages of the training to enhance student learning was fully supported due to enabling students to identify weaknesses and strengths in their consultation skills. This resulted in improvement in students’ performance, with particular comment being made of the benefit of feedback by academics or supervisors between medication reviews in the role-play and real patient sessions.

Responses regarding the GP (medical practitioner) feedback after the role-play session display far less agreement. The GP was seen as abrupt and critical and this may represent a failure to undertake the role required effectively, or difficulty by students to adapt to meeting a GP. The GP had previously provided medical clinical training and may have expected a similar standard of student performance. Any repeat of the session requires better preparation of students and better briefing of the GP about their role. Students wanted more time for this feedback as they stated that it would improve performance, which is also support for retaining the session.

It was planned that students should present recommendations to a GP or nurse following each medication review session; however, this did not always occur due to availability of staff. Students reported this to be a failing which affected their effective learning. Schon[69] provides support for feedback through discussion of thinking in action which entails 'thinking on your feet'. In this scenario, a practitioner draws on previous experience or experiences to enable them to resolve problems encountered. Schon, however, also refers to reflection on action, or 'retrospective thinking', which occurs after the unexpected event and has particular relevance to feedback. Discussion of what has taken place, feedback, can help the practitioner to improve subsequent performance(s) and to add to effective experience, which may be used in future reflection in action. Feedback facilitated by observers or more experienced practitioners enables improvement and learning. Nestel and Tierney[130] (2007) support the use of feedback to medical students after role-play to improve subsequent student performance. However, they advise caution, as students report disliking 'unstructured, vague, non-specific feedback' which they considered unhelpful. Evidence exists that feedback is useful and effective and should, therefore, be retained within role-play sessions and medication reviews.

Stress and nervousness was displayed at the start of the study, partly due to a previous lack of patient contact, knowledge of conducting a consultation or specifically how to answer patients' questions. Students referred to needing to know how to apply knowledge, which is a key recommendation in the modernising pharmacy careers programme[74]. Students' stress may, therefore, result from a lack of knowledge and experience. Students also reported being excited and looking forward to the study, whilst displaying a desire to improve consultation skills and resolve their unmet need to undertake learning with patients. Research with pharmacy students undertaking patients consultations, e.g. O'Neil *et al.*[76] (2007 USA) reported that students were nervous prior to meeting patients, with their confidence, competence and 'preparedness' subsequently improving.

Students recognised that whilst role-play is stressful, it provides benefit as preparation for medication reviews with real patients. One student reported leaving the study due to the stress of role-play and the aim of teaching must be to provide an effective outcome for every student, with the stress they encounter managed. Hodges[134] states that students can fail OSCEs due to 'examination nerves', yet may perform that role competently and regularly in practice. Students reported experiencing stress during the role-play session due to assessment.



Student performance was observed and scored as recommended in Joyner and Young's guide[117], and was to enable effective feedback, which was supported by students. After meeting patients for medication reviews students stated that the experience had provided confidence for future contact with patients, thus relieving stress through experience.

Students' comments about beneficial aspects of the study are supported by Kassam *et al* (2008 Canada)[123] who reports good indicators 'that direct interaction with patients is a most powerful learning tool'. When reflecting on feelings at the end of the study, students displayed overwhelmingly positive opinions. They reported being more prepared and confident about planning and undertaking medication reviews. Comments display an understanding of individual aspects of undertaking medication reviews.

# **Chapter 5**

## **Feasibility and Pilot Study**

## Chapter 5 Feasibility/Pilot Study

### 5.0 Background

The purpose of this chapter is to describe the feasibility testing of the intervention and the piloting of the trial. This study is a pilot study to test the training of undergraduate pharmacy students within the context of providing medication reviews to patients. The National Institute for Health Research[137] states that a feasibility study is a piece of research undertaken before a main study to answer the question “can this study be done?” They enable the estimation of important parameters required for study design including standard deviation (to enable sample size calculation), recruitment and retention of subjects and acceptability of the intervention. However, the NIHR also states that pilot studies, similar to this study, are smaller versions of full studies, designed to test the working together of the main study components. These include many of the elements within a feasibility study.

In line with MRC guidance[48] on complex interventions, feasibility and pilot studies are performed to test procedures for their acceptability; estimate rates of recruitment and retention of subjects; identify the most suitable outcome measures, the effect of randomisation and to provide the parameters required to enable the calculation of appropriate sample sizes. In evaluating the process, part of the rationale is to test the feasibility of experimental design. Importantly this is stated by MRC to be an essential step in the development and testing of an intervention in addition to the use of theory and existing evidence from systematic reviews or literature reviews.

Specifically it was stated by Arian, Campbell and Cooper[138] that the definition of a feasibility study is a piece of research done before a main study used to estimate important parameters that are needed to design the main study, which include standard deviation of the outcome measure in order to estimate sample size. In addition to elements stated in MRC guidance, they refer to the willingness of patients to be randomised, willingness of clinicians to recruit participants and responses to questionnaires. They also state that a pilot study is a version of the main study that is run in miniature, to test whether the components of the main study can all work together and is focused on the processes of the main study, and this must, therefore, be analysed. They agree that a pilot will resemble the main study in many respects.

MRC states that a crucial aspect of the design evaluations is the choice of outcome measures, recommending that they are evaluated to assess importance and that whilst

single primary outcomes are preferable, more may be used in such a study. Within this study co-primary measures were used to establish the most appropriate for use in a full trial. Co-primary outcome measures were utilised as allowed within pilot studies by MRC guidance[48] and represented best practice. Patients' questionnaires provided additional secondary measures which MRC states should be evaluated.

## **5.1 Aims and Objectives**

The aim of this study was to identify the feasibility of repeating this study as a full study.

The objectives of this study were to:

- describe the recruitment rates and retention rates for patients,
- describe the response rates for questionnaires,
- observe effects on the primary outcome measures,
- explore the potential effect of student medication review on a range of outcome measures,
- describe and characterise student interventions,
- describe the interventions made by the supervisor with student care issues during the medication review process,
- calculate the standard deviation of the outcome measures and then calculate the sample size required for a full RCT,
- identify the most appropriate outcome measure.

## **5.2 Results**

### **5.2.0 Patient Recruitment and Retention.**

All medical practices were in market towns in Norfolk apart from one practice which is situated in a city suburb of Norwich.

Table 5.1 displays characteristics of the participating medical practices. It demonstrates that no major differences existed, other than the lower level of people in Costessey who were classed as healthy.

The source of data was Norfolk insights (available at <http://www.norfolkinsight.org.uk/>). Data collected 2011.

Area	% of people over 65 years of age	% of people classed as healthy	% of people with pre-existing health problem	% of people with adult obesity	% of people over 17 years of age with type 1 or 2 diabetes
Wymondham	20.5	53	15	25	5
East Dereham	22.0	41	22	27	6
North Walsham	25.1	47	16	25	6
Costessey	21.0	33	13	23	5
Hoveton & Wroxham	24.0	49	13	24	6
Norfolk average	21.4	45	18	24	6

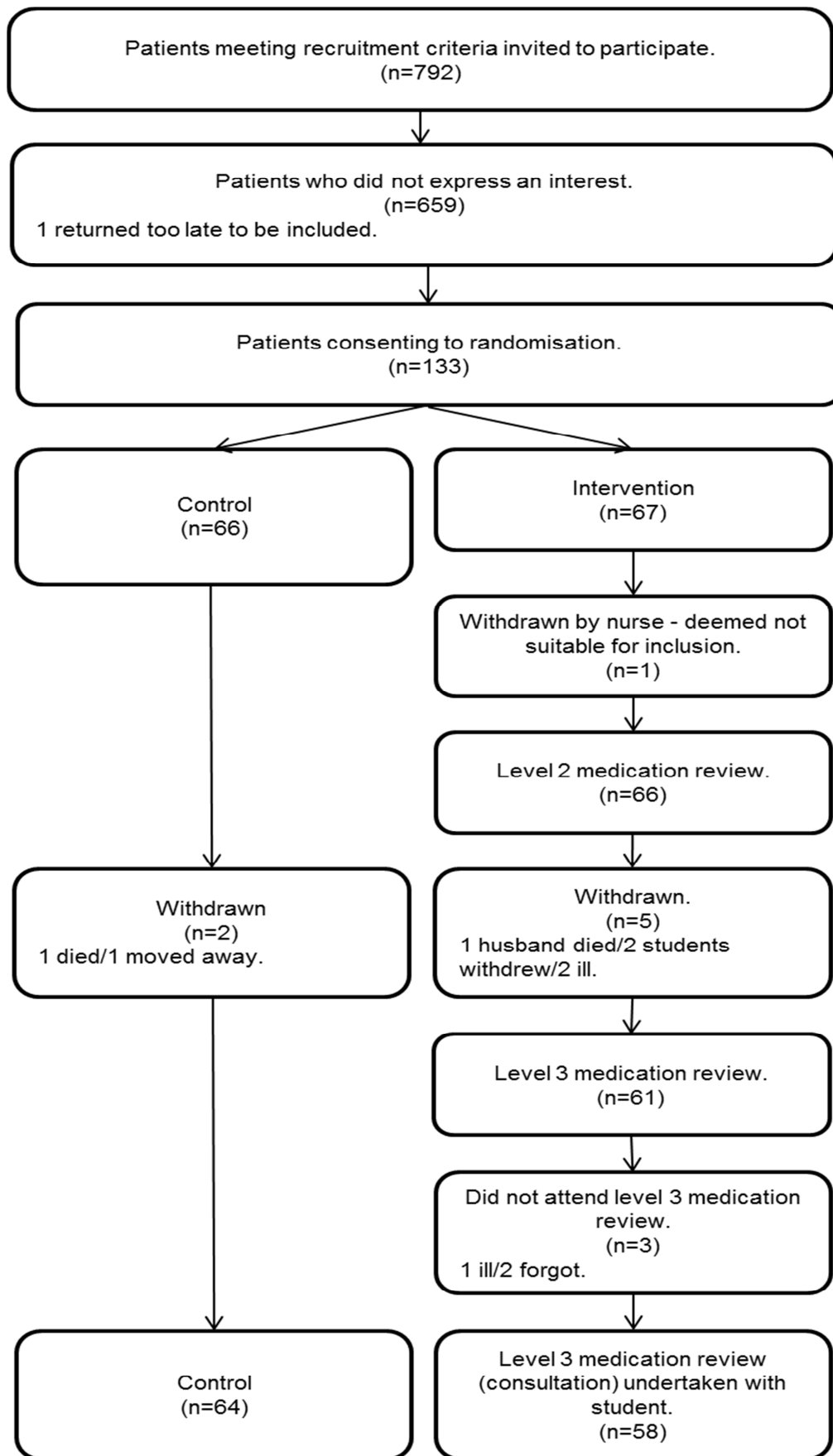
**Table 5.1** Characteristics of areas in which medical practices situated

Table 5.2 demonstrates the patient recruitment rates for each of the five medical practices within the study. Expected rates of recruitment predicted by medical practice staff were approximately achieved in all but one practice. One practice (Wymondham) telephoned 30 non-responding patients but recruited no additional patients. On their advice no further telephone calls were made. The researcher received three comments from patients at Hoveton & Wroxham medical practice about postal charges. They had been asked to pay additional postal fees in order to receive letters with insufficient postage paid, which transpired to be recruitment letters. It was later found that the practice had used second class stamps for those patients which was insufficient. It is not known if other letters were similar.

<b>Medical Practice location</b>	<b>No. of registered patients</b>	<b>No. of GPs</b>	<b>No. of letters posted</b>	<b>No. of patients recruited</b>	<b>Recruitment rate (%) demonstrated</b>
<b>Wymondham</b>	18,238	13	151	26	17.2
<b>East Dereham</b>	9,500	6	163	32	19.6
<b>North Walsham</b>	7,198	6	174	35	20.1
<b>Costessey</b>	11,938	9	124	23	18.5
<b>Hoveton</b>	8,231	6	180	17	9.4
<b>Totals</b>			792	133	16.8

**Table 5.2** Patient recruitment statistics.

Figure 5.1 displays a summary of patient recruitment and retention. Of 792 patients approached by unsolicited letter via their medical practice (Appendix D), 133 were recruited and randomised to control or intervention (n=67, i.e. 83.75% of target number of 160). The overall recruitment rate was 16.8%.



**Figure 5.1** Patient recruitment process.

### **5.2.1 Patient baseline clinical, questionnaire and demographic data**

Table 5.3 presents baseline data (at recruitment) for control and intervention patients. This includes demographic and clinical data in addition to results of patient completed questionnaires. Data demonstrates that randomisation resulted in reasonably comparable groups.



Characteristic	Measure	Intervention patients (n=67)	Control Patients (n=66)
<b>Age</b>	Mean (SD)	69.18 (10.46)	68.31 (9.46)
<b>Male</b>	No. (%)	45 (68%)	38 (58.5%)
<b>HbA1C</b> mmol/mol	Mean (SD)	56.81 (11.12)	59.71 (13.92)
<b>Total Cholesterol</b> mmol/L	Mean (SD)	4.14 (0.99)	4.19 (0.91)
<b>Blood pressure</b> mm Hg			
Systolic	Mean (SD)	132.48 (11.98)	131.65 (10.90)
Diastolic	Mean (SD)	73.22 (8.15)	72.13 (9.54)
<b>Euroqol QOL</b> scale		(n=45)	(n=48)
	Median (IQ)	80 (70,90)	80 (70,90)
<b>SIMS</b>		(n=43)	(n=47)
Total	Median (IQ)	12 (7,17)	12 (8,15.5)
Action and use	Median (IQ)	7 (4.75,9)	7 (5,9)
Potential problems	Median (IQ)	5.5 (2.25,8)	5 (2,8)
<b>BMQ</b>		(n=43)	(n=47)
Necessary	Median (IQ)	18 (16,21)	19 (17,21)
Concerns	Median (IQ)	11.5 (10,14)	13 (10,16)
<b>MARS</b>		(n=43)	(n=47)
	Median (IQ)	24 (23,24)	24 (23,24)
<b>DTSQ</b>		(n=45)	(n=48)
Treatment satisfaction	Median (IQ)	30 (26,35)	31 (26,34)
Problem-hyperglycaemia	Median (IQ)	1 (0,3)	2 (0,3)
Problem-hypoglycaemia	Median (IQ)s	0 (0,1)	0 (0,3)
Using a <b>Medicine Compliance Aid (MCA)</b>	No. (%)	44 (47.7%)	48(43.8%)

**Table 5.3** Baseline data for control and intervention patients.

### **5.2.2 Patient Six Month Follow-up Data (Clinical and Questionnaire)**

Table 5.4 presents a comparison of follow-up data (six months post-intervention) including clinical data and results of patient completed questionnaires. Completed questionnaires were returned by 101 (85.6%) of patients. Not all questions were answered by all patients. Data demonstrates significant differences existing between intervention and control groups only for change in quality of life and some elements of SIMS.

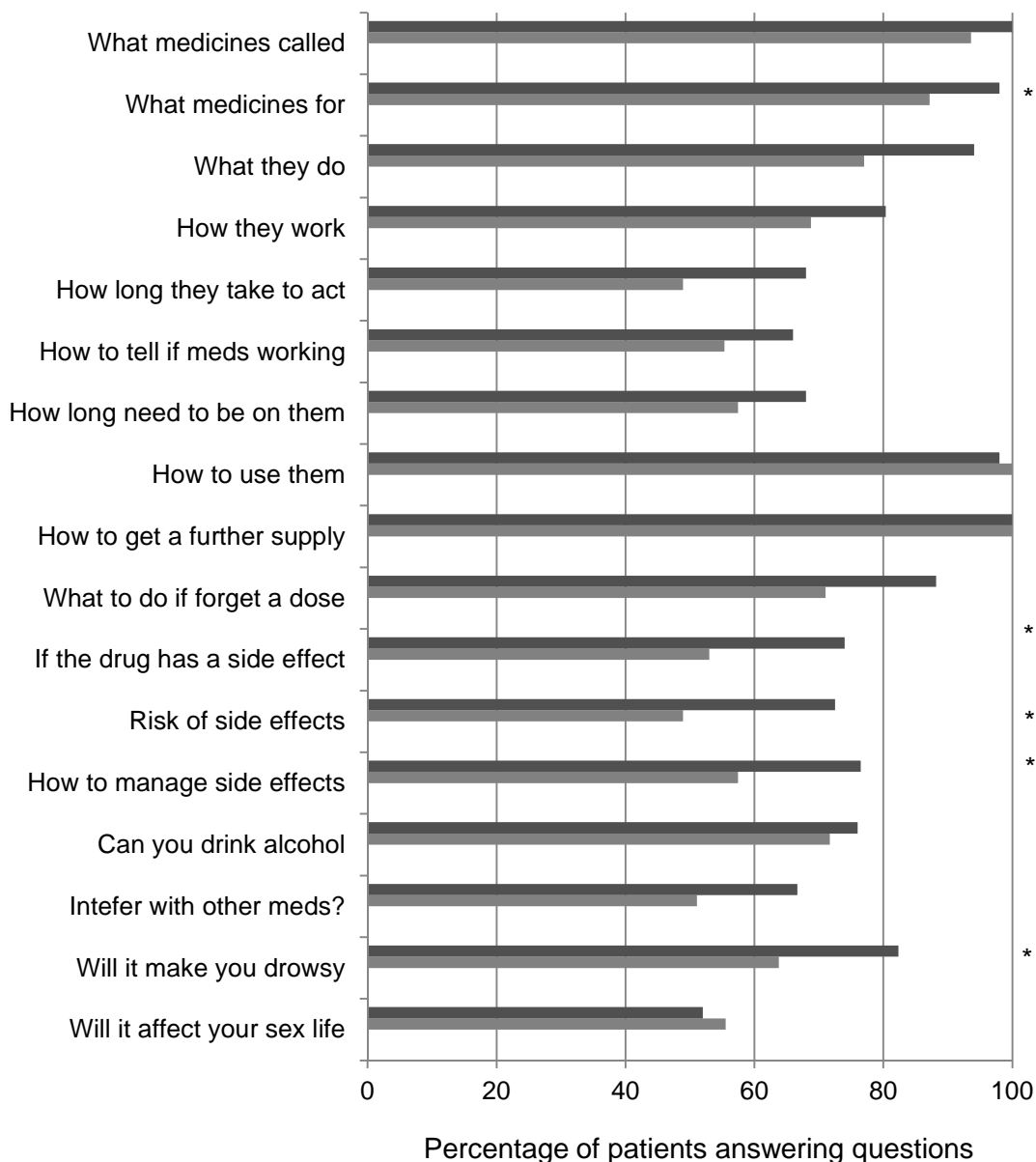
Within the results the test used to identify the p value is indicated by # Independent samples t test, \* Mann Whitney U, \$ Fisher's exact test

Characteristic	Measure	Intervention patients (n=68)	Control patients (n=66)	P test value
<b>HbA1C</b> mmol/mol		(n=59)	(n=59)	
	Mean (SD)	56.32(11.5)	59.68(13.2)	0.14#
<b>Total Cholesterol</b> mmol/L		(n=61)	(n=53)	
	Mean (SD)	4.22(1.0)	4.01(0.8)	0.47#
<b>Blood pressure</b> mm Hg		(n=61)	(n=60)	
Systolic	Mean (SD)	132.26(12.9)	127.98(11.9)	0.06#
Diastolic	Mean (SD)	73.38(6.8)	70.97(9.5)	0.11#
<b>Euroqol QOL</b>		(n=51)	(n=48)	
	Median (IQ)	80(70,85)	72.5(61.3,85)	0.182*
<b>Change</b>		(n=37)	(n=40)	
	Mean (SD)	+2.00(8.73)	-6.24(18.28)	0.015#
<b>SIMS</b>		(n=50)	(n=47)	
Total	Median (IQ)	14(9.2,17)	10(6,15)	0.073*
Action and use	Median(IQ)	8(7,9)	8(6,9)	0.078*
Potential problems	Median (IQ)	5(3,8)	3.5(2,7.7)	0.037*
<b>BMQ</b>		(n=48)	(n=49)	
Necessary	Median (IQ)	20(18,22.5)	20(19,22)	0.925*
Concerns	Median (IQ)	14(12,16)	14(12,15)	0.825*
<b>MARS</b>		(n=50)	(n=48)	
	Median (IQ)	24(23,24)	24(23,24)	0.843*
<b>DTSQ</b>		(n=49)	(n=48)	
Treatment satisfaction	Median (IQ)	32(26.5,35)	30.5(27.7,33.2)	0.413*
Problem-hyperglycaemia	Median (IQ)	1(0,3)	1(0,2)	0.360*
Problem-hypoglycaemia	Median (IQ)	1(0,1)	0(0,2)	0.929*
<b>Using a Medicine Compliance Aid (MCA)</b>		(n=50)	(n=46)	
	No. (%)	23 (46.0%)	25 (54.3%)	0.540\$

**Table 5.4** Follow-up data for control and intervention patients.

Figure 5.2 presents the results of SIMS questionnaire at follow up (six months post intervention) comparing intervention and control group patients' responses and demonstrates that patients in the intervention group were significantly more satisfied with five parameters (one action and uses, four concerns)

Control n= 34 Intervention n= 36



\* denotes p value < 0.05,

■ Intervention ■ Control

Figure 5.2 presents a comparison of individual SIMS questions

Data in Table 5.5 provides a comparison of control and intervention patients' responses to additional questions asked in the follow up questionnaire at six months post-intervention. No significant difference exists between control and intervention. The data demonstrates that during the previous three months very few patients in either group spoke to their pharmacist regarding any issue.

Question regarding previous 3 months	No.	Median (IQ)	No.	Median (IQ)	P value. Mann Whitney
	Intervention		Control		
No. times spoke to pharmacist	50	0(0,1.25)	48	0(0,1)	0.738
No. times asked pharmacist about extra information	38	0(0,0.25)	34	0(0,0)	0.634
No. times asked pharmacist how to use medicines (MUR)	40	0(0,0.75)	35	0(0,0)	0.742
No. times asked pharmacist about minor condition	39	0(0,1)	36	0(0,0.25)	0.415
No. times asked pharmacist about whether to see doctor	38	0(0,1)	36	0(0,0)	0.225
No. times asked pharmacist about other things	35	0(0,0)	33	0(0,0)	0.110

**Table 5.5** Additional question responses (follow-up questionnaire)

Twenty five (55.5%) patients who had met a student for a level 3 medication review agreed or strongly agreed that they were far more likely to speak to a pharmacist about their medicines or their health following the medication review, whilst 11 (24.5%) were unsure.

### 5.2.3 Intervention approval

Table 5.6 displays the category, number and percentage of pharmacist approvals of student interventions at level 2 and 3 medication review (where recorded). This demonstrates that the majority of interventions were identified by students unaided, and approved by a pharmacist without changes. In a very small number of cases additional advice was required by the student. Very small numbers of intervention were rejected by the supervising pharmacist or raised by them because student had not identified the issue.

Pharmacist approval category	Level 2	Level 3
	No.	No.
<b>A. Issue identified by student and approved by pharmacist.</b>	420 (92.4%)	40 (90.9%)
<b>B. Issue identified by student and accepted but with pharmacist input.</b>	18 (4.0%)	1 (2.3%)
<b>C. Identified by student but rejected by pharmacist</b>	2 (0.4%)	0
<b>D. Issue identified by supervising pharmacist.</b>	15 (3.3%)	3 (6.8%)
<b>Total</b>	455	44

**Table 5.6** Summary of intervention approvals

### 5.2.3 Intervention examples

To aid interpretation examples of interventions identified by students during level 2 medication reviews are provided in Appendix F, with pharmacist approval status and intervention type displayed. The issues displayed demonstrate a wide range of intervention type.

Full data is also presented in Appendix F.

#### **5.2.4 Supervisor Observations.**

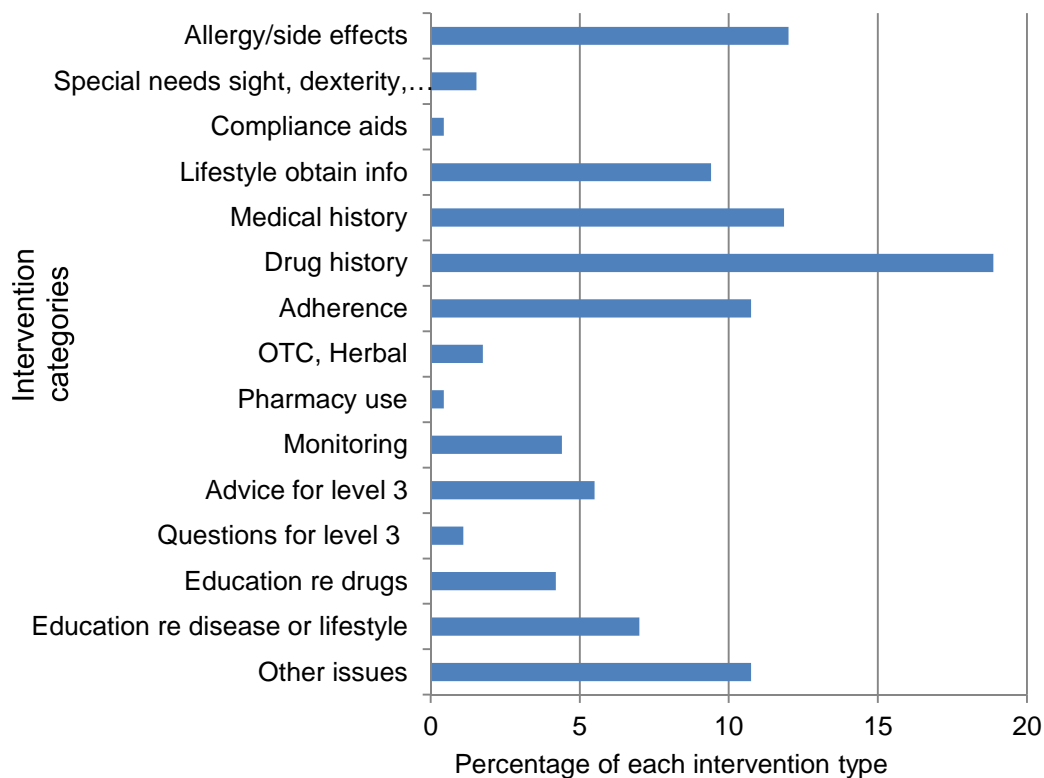
Pharmacists supervising medication review observed that, on a regular basis, students failed to record all care issues identified during level 3 medication reviews. Observation identified that the most likely reason was concentration on the patient and general consultation issues, with time constraints creating pressure.

Whilst an electronic care plan utilising drop down boxes of options and formatting to enable easy data entry was devised and tested with students the pharmacists undertaking supervision of medication review observed that students preferred to use a paper version of the care plan during medication reviews. Care plans were printed and used by the students during both level 2 and level 3 medication reviews to record issues and data, and as a reference source.

It was planned to have a GP available after each level 2 or level 3 medication review for students to present any recommendations arrived at during the process, and for the GP to then provide feedback. Due to the availability of GPs, this was only possible on one occasion. Specialist diabetes practice nurses undertook this function, but were unavailable on ten out of twenty seven occasions. In addition, nurses stated that, whilst students identified care issues for all conditions exhibited by patients, they could only respond to issues related to diabetes.

### 5.2.5 Student identified care issues

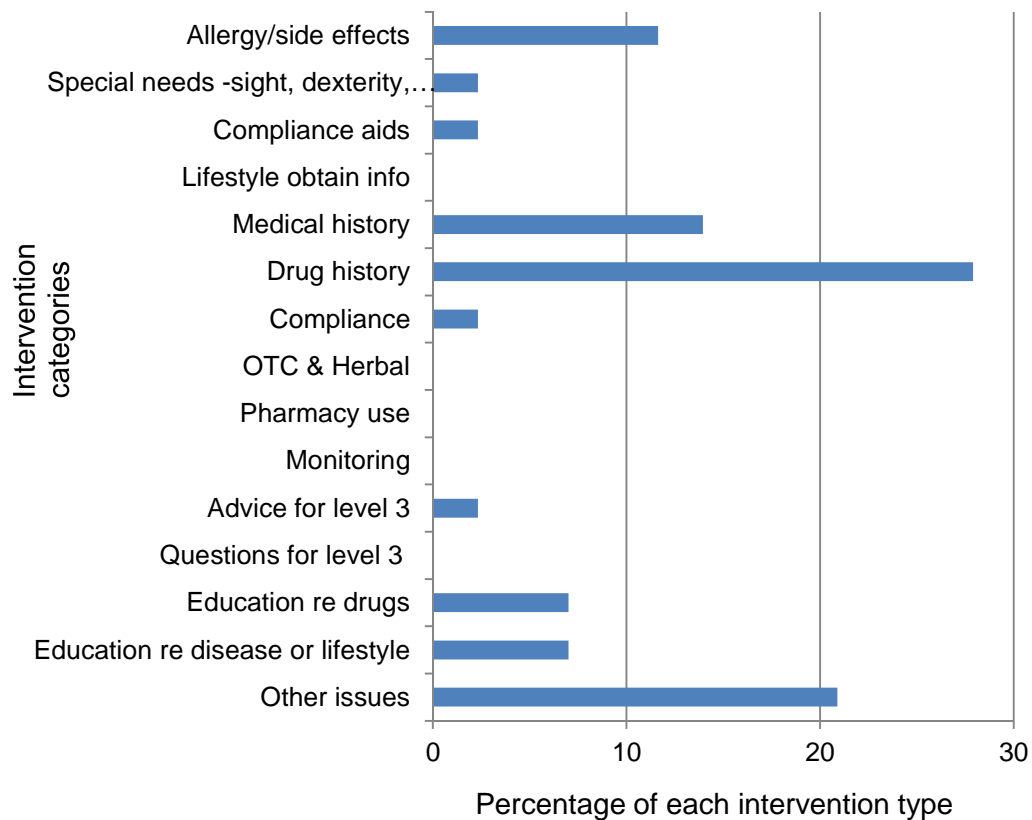
455 interventions (range 2 – 12 per patient) were recorded during the level 2 medication reviews for 64 patients. These were classified as in Chapter 2. Figure 5.3 shows the reasons for the different types of intervention recorded by students at level 2 medication review. The most frequent interventions identified were allergy or side effect status, obtaining and providing information about lifestyle issues, issues related to medical or medication history, and adherence with prescribed medication regimes.



**Figure 5.3** Summary of level 2 medication review interventions.

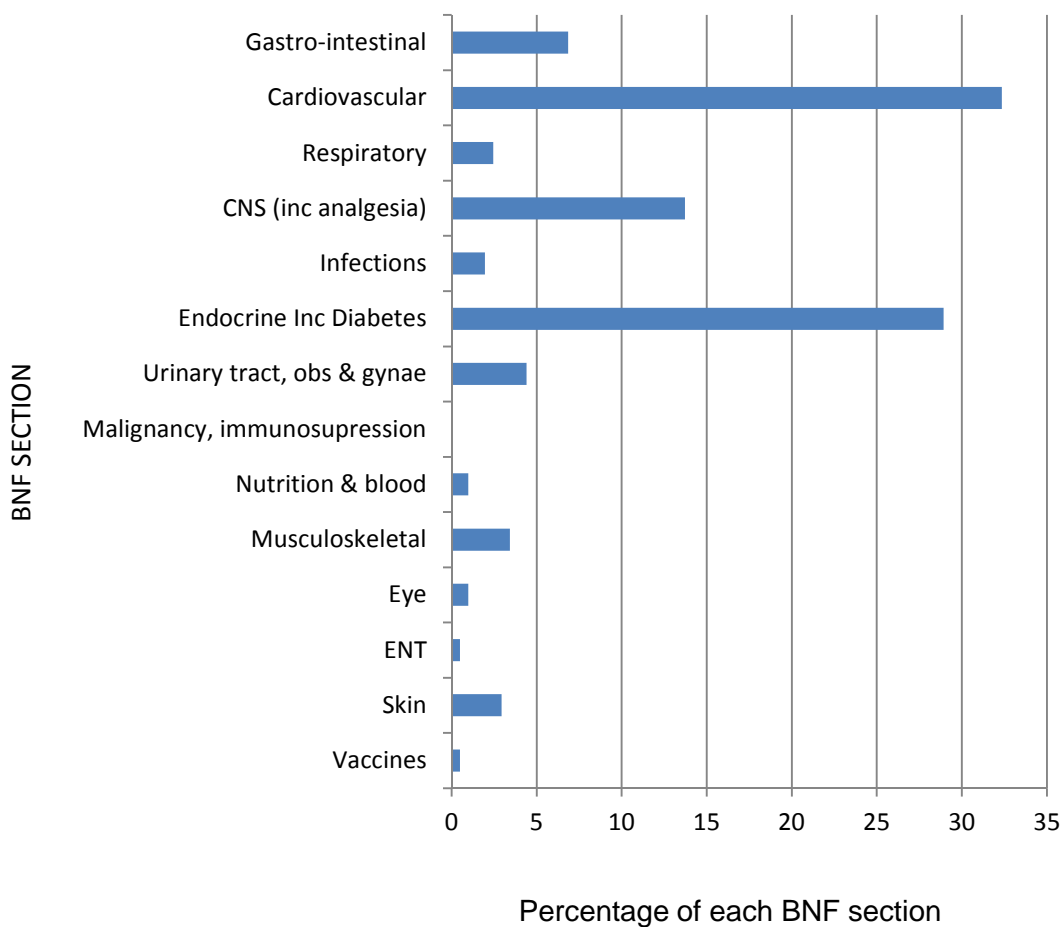


44 interventions were recorded for 18 patients by 15 students during level 3 reviews and these are summarised in Figure 5.4. The most frequent interventions identified were allergy or side effect status, issues related to medication history or medical history in addition to education of the patient regarding their medication, disease or lifestyle.



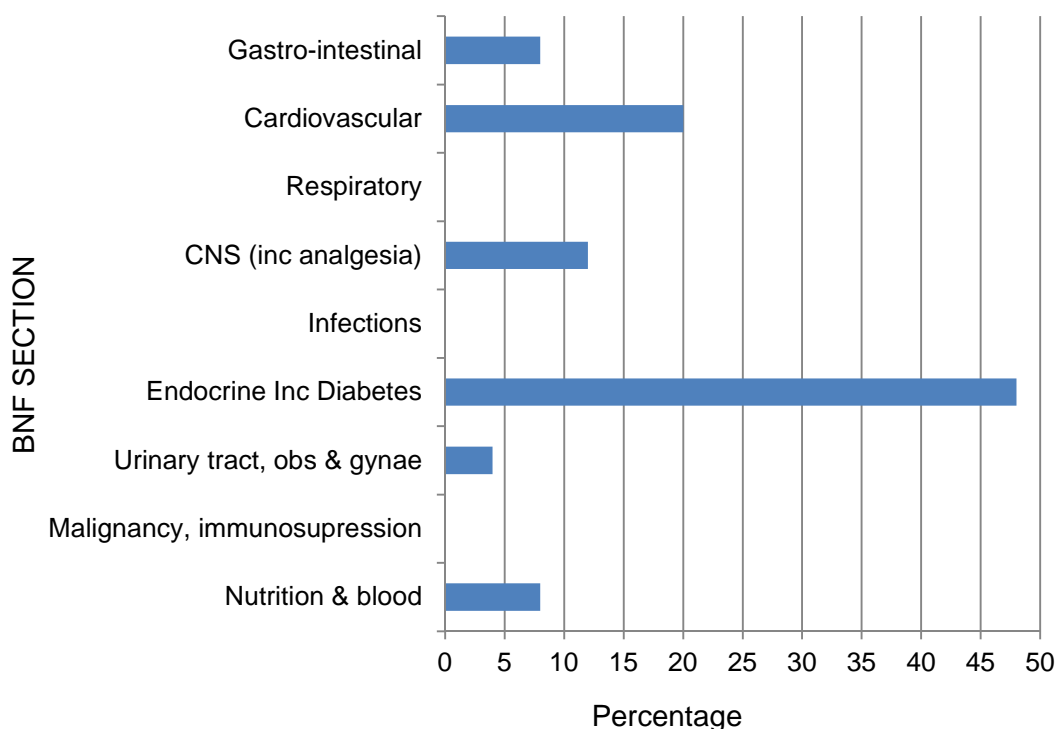
**Figure 5.4** Summary of interventions identified during level 3 medication reviews.

Figure 5.5 displays the 204 medication related interventions recorded by students at level 2 medication review by BNF section. This demonstrates that Gastro intestinal, cardiovascular and endocrine and central nervous system medications represent the majority of interventions recorded by participating students.



**Figure 5.5** Summary of level 2 medication review interventions coded by BNF.

Figure 5.6 displays the 25 medication-related care issues recorded by students at level 3 medication review, coded as percentage by BNF section. This demonstrates that Gastro intestinal, cardiovascular and endocrine, and central nervous system medications represent the majority of interventions recorded by participating students.



**Figure 5.6** Summary of level 3 medication review interventions coded by BNF.

### 5.3 Sample size calculation

The target level of HbA1c reduction used for the calculation of the sample size required for a definitive study was 0.5% (5.5mmol/mol), which is the level generally accepted to be of clinical relevance[139].

The target level of systolic blood pressure reduction used for calculation was 3.3mmHg which was the level calculated in a study by Lee(2006)[140]. In this study a pharmacist intervention programme produced a reduction in SBP of 3.3mmHg which was claimed to be significant. This is in accordance with the greatest significant SBP reduction in the trials reported by Staessen(2005)[141], of 3.2mmHg, where new versus old medications were tested.

Total cholesterol was collected because data relating to LDL and HDL cholesterol in serum was not available from all participating GP practices. This prevented comparative

analysis. However, publications such as that by the Cholesterol Treatment Trialists[142] and NICE guidance[143] recommend that LDL cholesterol in serum is used to guide research and treatment, in addition to overall reduction in cardiac risk calculated by Qrisk. No clinically important reduction quantities in relation to total cholesterol are provided. It is not appropriate to calculate the sample size, as this would entail using non-evidence based data. With no target reductions published by regulatory authorities, a reliance on target levels would not enable calculation of sample size. It is recommended that Total cholesterol is not used as the primary outcome measure for a full study

Table 5.7 displays the sample sizes which data provided from the study would suggest would be required for a future definitive study based on clinically important differences. The numbers of patients required in each group to provide 80% power are stated.

Utilising clinical data collected from patient participants in this study it was calculated that 159 patients would be required in each group (intervention and control) to demonstrate a clinically significant effect by the intervention if HbA1c is used as the primary outcome measure. If the current level of student intervention (two medication reviews per student) is maintained then, using a figure of 160 patients per arm, 80 students would need to be recruited to enable each student to undertake two medication reviews.

Only 3 of 67 (4.47%) intervention arm patients left the study for unavoidable reasons. Other patients leaving the intervention arm could be avoided following observation of reasons documented in this study. Therefore, to allow for losses to the study an additional 7 patients would be required in each group.

Output measure	Standard error of mean difference #	Standard deviation of mean difference	Clinically important difference	Unit of clinical measure	No. of patients required in each group
HbA1c	2.28	17.5	5.5	mmol/mol	159
Systolic blood pressure	2.27	12.47	3.3	mm Hg	224

**Table 5.7** Sample size calculation for future definitive study

# = calculation by independent samples t test in SPSS

## 5.4 Discussion

The study identified that approximately 20% of patients approached by their GP would consent to participate in student-led medication review clinics. Questionnaire response rates were high, both at baseline and at follow-up, for both control and intervention groups and drop-out rates were minimal. Consequently a cohort of 100 students would be sufficient to provide the intervention to 159 patients in a definitive trial utilising HbA1C as its primary outcome measure with a desire to demonstrate a clinically important difference.

Randomisation resulted in comparable groups; however, clinical parameters before intervention were largely within normal treatment ranges resulting in limited opportunities for students to demonstrate a positive effect.

Whilst there were no significant differences observed for clinical parameters after intervention, patients in the intervention group demonstrated significant superiority with respect to change in quality of life at follow-up.

Scores relating to information about medicines, measured by SIMS, displayed statistical significance for intervention patients for subjects which would be expected to improve adherence, however, adherence was not identified to be improved by the intervention. The high reported multi-compartment device use and good level of control may explain this.

The number and range of care issues identified by students demonstrates that they possess and can utilise, in a patient-focussed manner, the technical skills required within medication reviews. Data suggest some students conducted effective medication reviews, as illustrated by the issues identified and accepted during patient medication reviews. Data recording by students after level 3 medication reviews was poor and this must be addressed if an RCT is undertaken, as it prevents a full analysis of consultation competence.

Lack of GP availability for meetings to review care issues must be addressed in a full RCT. It is unsurprising that GPs failed to implement care issues, as some may not have been passed to them by specialist nurses, but this may have reduced the potential clinical effect of the student-led medication review. Utilising the medical supervisors working with the study to negotiate with the GPs may prove more effective if a full study is undertaken.

The data obtained enabled the calculation of a sample size and definition of the most appropriate primary outcome measure for a full trial.

This is a feasibility and pilot study which is recommended by MRC guidance[48] to evaluate interventions prior to implementation of larger studies. The range of outcome measures represented sensible measures which could be readily and accurately obtained and which provide a good means of measuring the effects. Recruitment and retention of participants, in particular patients, demonstrated very good rates, with the majority of loss of retention due to external factors such as illness. The data obtained are of a quality and quantity to enable the effective design and implementation of a future study.

Relatively large numbers of patients were recruited to the feasibility/pilot study thus enabling some significant differences to be identified, although this was not the aim of the study. Data collection was demonstrated to be effective with accurate data recorded for recruitment and retention rates thus enabling the effective design of a future full study. The response rate for completion of patient questionnaires was high. Students demonstrated technical competence and consultation skills which is evidence of success in a number of elements of this trial. The quality of life data obtained will enable the estimation of cost-effectiveness.

However not all care issues identified at medication review were recorded, making analysis difficult. A meeting between a student and a GP only occurred on only one occasion, and it is not known if issues presented to specialist nurses were passed to the GPs for implementation. Intervention codes used to evaluate care issues identified by students were not validated.

Data demonstrate that whilst patient recruitment for this pilot study was possible it did not achieve the full target. It is noteworthy that the overall rate was reduced because one medical practice achieved only approximately 50% of the recruitment rate of the others. Evidence is, therefore, presented that, as a pilot study, success was achieved in establishing the likely recruitment rate for a full study which was 83.75% of anticipated rates. The low rate in one practice may have resulted from a clerical error when posting recruitment documentation. A sensible solution may be for documentation to be put into envelopes and stamped at the university and delivered to medical practices for posting. If that practice had recruited at the same rate as other practices the overall recruitment rate would have been approximately 94% of target (160). Telephone follow-up of non-responding patients in one medical practice resulted in no additional recruitment, suggesting that reliance on the initial posting may be sufficient.

This study sought to recruit patients with T2DM, due to the availability of national guidelines for prescribing and the potential population size. In a full study, it may prove

useful to consider widening the potential pool of patients for recruitment by including other medical conditions. MRC guidance[48] recommends that pilot studies establish recruitment rates[82 144 145], and that these should relate to the wider community. However, recruitment was designed to achieve maximum achievable rates for the desired patient group of patients with T2DM and changing the target medical condition may require further piloting to ensure recruitment reaches desired rates.

Baseline data show the mean age of recruited patients was over 68 years with approximately 10 years standard deviation in each group. In 2011, 56.5% of people with T2DM in England were over 65 years of age[146]. The recruitment of a greater number of younger patients may have presented more opportunities for improving patient care. Younger patients with diabetes present a greater potential for preventable long-term complications due to their greater potential lifespan. If a full study is undertaken in another part of the country, a different demographic profile may be recruited.

Retention rates were high, with only one patient lost prior to the first intervention (level 2 medication review), due to inappropriate inclusion by the medical practice. Early in the study, two patients were removed from the study after their records were accessed by a student who then left the study. On reflection, they could have been retained in the study for a medication review with another student, and this was the case with a small number of other patients. In those cases, the student taking on the case was given access to the patient's medical records as preparation for the medication review. The remaining withdrawal of intervention group patients included four unavoidable ones due to health and two people who forgot to attend for their appointment. These last people indicate that patients should be provided with written appointments, rather than the verbal ones employed in this trial.

The high response rate to questionnaires demonstrated by patients, both at baseline and follow-up enabled a greater confidence in results. In addition, high response rate to questionnaire data show a large commitment to participation in this form of research and provides further confidence that a full trial may be successful in recruiting patients and obtaining reliable results. During the development phase focus groups it was recommended that the need for control patients must be stated in recruitment documentation. These results demonstrate further, that this was achieved.

Intervention and control groups of patients did not display significant differences at baseline (recruitment) which provides confidence that any effects seen at follow-up are due to the intervention.

Follow-up was undertaken at six months post-intervention to allow any effects to stabilise, Individual clinical measures, such as HbA1c, would not normally be measured before this time-point (certainly not before three months[82]) because it is a long-term measure of glucose control. No significant clinical effect was observed, with both intervention and control patients displaying a mean BP within targets[82] for patients with type 2 diabetes. The large standard deviation indicates a potential for optimisation of some individuals. The desired target for patients with T2DM who also exhibit cerebrovascular disease or microalbuminuria is lower (130/80). Data were not collected to establish the incidence of those patients, although a small number being diagnosed with these conditions and aggressively treated could exert a large effect on a group mean. It, therefore, appears sensible to collect this data for a full study.

Total cholesterol for both groups was within generally accepted targets, and guidance[82] suggests focussing on overall cardiovascular risk, rather than absolute cholesterol levels unless new cardiovascular disease or increased albumin excretion, is observed, when the target is <4.0mmol/l. Levels observed are close to 4mmol/l, and a similar situation exists to that with BP, i.e. it is recommended that albuminuria and new cardiovascular conditions should be recorded in a full study to allow for required tight control. In routine clinical practice total cholesterol of approximately 4mmol/l is generally accepted.

Whilst many studies state the importance of BP in the control of micro and macrovascular events[94], diabetes is a condition characterised by raised blood glucose, the control of which is still important[82 147]. It is acceptable to recommend that HbA1c is utilised as the primary outcome measure in a future full trial, however, HbA1c results indicate that no significant change occurred for either group. Guidance[82] recommends a target HbA1c of 6.5% (48mmol/mol), with acceptance that negotiation may be undertaken with individual patients for a higher level of up to 7.5% (58mmol/mol). It is agreed that lower HbA1c levels predispose patients to hypoglycaemia[147] and, in some cases, to weight gain due to the medicines required to achieve this. This has led to the commonly accepted scenario of higher HbA1c levels. It is not, therefore, surprising to see the levels identified in clinical practice.

Within the scenarios displayed above it would have been difficult for a pharmacy student to make a significant change to the intervention group patients. There may have been opportunities for individual patients, but the utilisation of group means as outcome measure makes individual changes harder to detect. It is possible that inclusion of patients nearer to diagnosis would have presented more opportunities for improvement.



With the uncertainty demonstrated and with the acceptance that HbA1c may be negotiated for individual patients, the use of HbA1c as a sole outcome measure may present an insuperable barrier for students. Therefore, the inclusion criteria for participating patients should ideally be amended. Whilst this may affect recruitment rates, the process in this study was to randomly select sufficient patients to approach from the pool available. It therefore may have been more appropriate to only select from those with raised HBA1C levels.

The lack of available GPs for all but one session for students to discuss care issues reduced the likelihood of implementation. This would have prevented students from exerting a direct effect on patient outcome measures, other than via changes in patient behaviour. Recommendations were provided to nurses in paper form or sent by email, but again did not appear to result in implementation. McCollum[80] identified that only 32% of issues sent to a medical practitioner by a pharmacy student were accepted with a range of zero to 60%. Studies by Lindquist[148] and Pound[149] both identified that care issues which are presented to a medical practitioner orally result in a higher acceptance rate. Further evidence, therefore, exists that a repeat of this study should seek to ensure oral presentation of recommendations to GPs by students.

Few significant effects were demonstrated within the results from patient completed questionnaires (baseline and at six months post-intervention). However, a significant positive effect was demonstrated for change in patient reported quality of life (QOL) for the intervention group. It was stated above that improvements in clinical outcomes were not demonstrated for the group mean. Individual patients may have benefitted clinically but without data this cannot be discussed effectively. Therefore, the improvement in QOL may be assumed to be due to an appreciation of the medication review; changes to lifestyle resulting from the medication review; improvements in medicine taking; a reduction in concerns about medicines; or at this stage could be a type 1 error.

Little[64] (2001), in contrast to Pilnick[150], observed doctor:patient consultations and concluded that patients prefer a patient-centred consultation and that "if doctors don't provide a positive, patient-centred approach, patients will be less satisfied, less enabled, and may have a greater symptom burden and higher rates of referral". This provides support for the student-led consultations being of a good quality and resulting in improved QOL. However, a Royal College of General Practitioners (RCGP) report[151] recommends research into medication reviews by non-medical professions (including pharmacy) as they may help adherence, because some patients are reluctant to express

doubts or concerns about medicines due to a fear of displeasing the doctor. It is possible that patients enjoyed simply talking about their medicines to a student who did not represent an authority figure.

Significant intervention group superiority was observed in some elements of SIMS[91] which demonstrates improvement in satisfaction with information about medicines. The majority of significantly superior results for questions relate to 'potential problems' rather than 'actions uses', where many items would already be known by patients who had taken medicine for an extended period. Patients in this study had a diagnosis of diabetes for at least two years, which can be described as an extended period. Horne *et al.*[91] (2001) state that higher levels of satisfaction with medicines information were associated with higher levels of reported adherence. The current study demonstrates that patients who had received a student-led medication displayed lower concern about potential problems with their medicine than patients who had not received a consultation. The improvement in reported SIMS by participating patients did not result in an improvement in adherence as reported by MARS. This displayed no significant difference between control and intervention patients, which is potentially unexpected[91]. It has been stated, however, that MARS should not be used as an exact measure of medicine-taking behaviour, but rather to provide an indication of their overall standing with regard to adherence[152]. Additionally, doubt has been cast on the accuracy of self-reported scales of adherence including MARS[153 154], due to a desire by patients to be viewed in a good light and maintain self-esteem through socially acceptable responses. However, the use of postal questionnaires and confidentiality, as undertaken in this study, has been stated to reduce this risk[154]. Farmer[154] also discusses the wording of MARS in which the questions refer to 'not taking medicine' rather than 'taking medicine', which could conflict with the theories of Ajzen and Fishbein[155].

Ajzen in his theory of planned behaviour[156], states that the dispositional prediction of behaviour is problematic, with poor predictive validity of attitudes to predict behaviour. However, aggregation of specific behaviours across occasions, situations and forms of action has more validity. Planned behaviour is stated to be an extension of reasoned action in which a central factor is the individual's intention to perform a behaviour such as taking a medicine. A strong intention will result in positive action, but requires, amongst other things, resources, which in this case would include skills and knowledge. By providing a patient with information about medicines, they have gained knowledge and possibly skills. A central element of planned behaviour is perceived behavioural control[156], which again relates to resources and opportunities, which dictate the

likelihood of behavioural achievement (medicine taking in this case) through reduction of barriers. Ajzen reports that perceived behavioural control refers to people's perception of the ease or difficulty of performing a task, with expectancy of success being a major factor. With effective consultation with a patient during a medication review, a pharmacy student could be expected to provide information (knowledge) and reduce barriers through reduction in fears about side effects or provision of information of how to manage side effects. These factors would all reduce concerns if undertaken correctly and the students could provide patients with an expectancy of success with medication taking. It is surprising, therefore, that the positive effects in SIMS did not result in a significant effect displayed in MARS, especially as the students used recommended techniques and endeavoured to provide assistance rather than treat non-adherence as a failure[157].

Both groups of patients displayed a high use of multicompartiment aids to assist with medicines taking. It is probable that this would have exerted a considerable positive effect on adherence prior to participation in the study, thus reducing any possible effect from the student-led medication review. The inclusion of patients closer to diagnosis may present further opportunities for students to influence factors such as adherence or medicines information as, at that stage, patients will have a greater need for education about their medicines. Returning to Ajzen's[156] theory, an early provision of support and information may enable greater adherence and satisfaction through the provision of resources, which in this case would be represented by information.

A systematic review by Cramer[158] (2004) in patients with type 1 and 2 diabetes reported that adherence to oral hypoglycaemic agents ranged from 36-93%. Cramer, when discussing information provided to patients, only states that information should be provided to the patient about what to do if they miss a dose or if adverse effects are 'bothersome'. The questions in SIMS which display a statistically significant effect, related to side effects, drowsiness and what the medicines are for. A report by the Royal College of GPs[151] states that patient concerns, including side effects, should be addressed as they can affect adherence to medication. The failure to influence adherence, therefore, cannot fully be explained.

An alternative tool to test adherence would be the Morisky Medication Adherence Scale (MMAS-4)[159 160], which provides a 'reasonably accurate' estimate of adherence[159]. The scale is also short and easy to complete for patients, which is important to ensure completion. Collection and evaluation of the frequency and amount of issues of patients' prescriptions, as an alternative method of adherence testing, would only provide an

indication of adherence, as in reality it would only inform us how many unit doses of medications the patient potentially received. This would take no account of collection of the medicine or of subsequent administration, and therefore, the MMAS-4 is recommended.

No significant difference was observed between the intervention group or control group results for DTSQ or BMQ at the six month follow-up, as reported by self-completed questionnaire. This included self-reported incidence of hypo or hyperglycaemia, which displayed good glucose control at both baseline and post-intervention. With low incidence of these problems at baseline, there was little potential for students to make any significant positive impact on outcomes for patients seen at medication review.

To provide more opportunities for students to demonstrate effectiveness and patient benefit, other patient recruitment strategies may be recommended. The recruitment of patients with known, or suspected non-adherence, would meet the requirements. In order to achieve this, the patient criteria of T2DM may require amending to include a range of conditions, in order to provide a suitable pool of patients for recruitment. In addition, researchers would need to ensure effective identification of suitable patients at participating medical practices. An alternative recruitment approach would be to recruit patients with a recent diagnosis, rather than greater than two years. These patients would have a greater requirement for education about medicines and, therefore, provide greater opportunities for students to provide patient benefit and effectiveness.

The data demonstrate that fourth year pharmacy students are capable of identifying pharmaceutical care issues, during level 2 medication reviews, which in the opinion of the experienced supervising pharmacists, are appropriate for use in patient care. Participating students identified a wide range of issues, as coded against intervention criteria, during both level 2 and level 3 medication reviews. Fewer care issues were identified for intervention criteria of 'special needs', 'compliance aids' and 'pharmacy use' at level 2. 'Special needs' is surprising, as this is taught and included as a key care planning issue within the undergraduate course. The reason is not known, but it may be that the issues were recorded already in the medical records or that they were forgotten by the students. As the students do not yet work on a regular basis in practice, they would not be used to advising on compliance aids or use of a pharmacy. Results show allergy status, obtaining lifestyle information, medical and drug histories and compliance as the majority of issues identified. These factors are practiced by undergraduate pharmacy students and, therefore, would be expected to perform well. The small number

of issues related to over-the-counter medicines and herbal products, as well as education about medications, is surprising as these factors are well practiced at the university and may show a need for additional preparative training. Issues identified at level 3 medication review are harder to interpret due to the lack of recording. However, there is some evidence of a concern to ensure checking of allergy status and obtain good drug history data, whilst educating patients about lifestyle and medicine use. Allergy status has been shown to be poorly recorded in medical records[161] and identification of this by students presents possible patient benefit. In a full trial, the recording of all student interventions is essential.

The patients in this study had been diagnosed with T2DM for at least two years and therefore the opportunity for intervention may have been minimal. Participating students demonstrated that they are also capable of identifying a range of care issues for other disease states suffered by intervention group patients. The most commonly identified issues were related to BNF sections for endocrine and cardiovascular. Diabetes is frequently referred to as a cardiovascular disease[147] and it is appropriate that this frequency of cardiovascular issues was identified. In addition, the students identified issues for a wide range of BNF sections, which, also shows an attempt, and possible competence, at applying a holistic approach to patient care.

The small number of issues rejected by the supervising pharmacists demonstrates that, although students still require supervision, they are capable of safe and effective work. Supervising pharmacists identified a very small number of issues which had not been identified by a student. Some of these appear to represent the normal day-to-day work of a PCT pharmacist, such as the requirement to change glucose testing strips. Such a change would be undertaken for financial reasons and it is unlikely that an undergraduate student would be aware of these issues. In addition, the need to monitor Dronedarone[162] would not have been known by a student as it was a recent Drug Safety Update from the MHRA and the medical practice were apparently not even aware of the new requirements. This issue presents an unexpected patient benefit from student-led medication reviews, as it was identified and implemented only because the researcher reviewed the medical record with the students.

Data demonstrate students capable of identifying pharmaceutical care issues during level 3 medication reviews which were not previously identified at level 2 medication reviews. Unfortunately it was found that students did not record all of the identified care issues and this prevents a full description of the activities undertaken within the medication reviews.

In any subsequent research this issue must be addressed. The most likely solutions would be either a simpler recording system, or more time made available at the end of the medication review for completion of records. Alternatively, the supervising pharmacist could record issues identified. With more consultation experience the students may find the issue of recording to be easier.

The benefit of undertaking student-led level 3 medication reviews cannot be fully assessed. However, results obtained demonstrate a number of patient-focused issues which could only have been identified whilst consulting with a patient. An example is a female patient stating that her most important issue was ankle oedema which prevented her from wearing dresses, due to embarrassment. The care issue was not recorded, or even known about by the medical practice. A student identified a patient with asthma prescribed propranolol and exhibiting respiratory problems. Data also displays a student possessing and using effective consultation skills by identifying that a patient was willing to join a smoking cessation programme.

Specialist nurses involved in the study also reported that pharmacy students had identified care issues, which had not been previously identified because patients had not mentioned these to doctors. Pilnick[150] (2011) identified that 'an asymmetry lies at the heart of medicine' and that it is unreasonable to expect doctors to change consultations to be totally patient-centred, as the asymmetry is why patients and doctors are there. In a scenario where patients recognise doctors as in control, they may be hesitant in informing doctors of some issues. Patients may, as suggested earlier, still like to tell somebody about some health or medication problems, and may tell a student as representative of a non-threatening or non-authoritative presence.

Students' preference for paper copies of the care plan, compared to electronic ones, was surprising. This does identify, however, that assumptions must not be made within a research study. In spite of the electronic care plan being trialled with one student, and also used by students during a preparative training workshop, no formal feedback was requested from the students. Had this been undertaken, the preference for a paper copy may have been identified earlier. Data in Chapter 3 showed one patient in a focus group recommending that a guide was required for students during a medication review. The care plan was initiated not only to act as a record at level 2 and level 3 medication reviews, but also to act as a guide for the students. It detailed those elements of a consultation which should be discussed and recorded (see Chapter 2 for development). The wide range of care issues identified by students, which include each intervention group (each

intervention group describes one section of the care plan) is partial evidence of care plan effectiveness as a guide to care planning. Students were instructed about NICE guidelines[82 144 163] during the undergraduate degree and reminded during the preparative training. These guidelines provided additional structure for identifying care issues.

When patients were asked additional questions at follow-up which related to pharmacy use, they did not present evidence of any significant effect on the number of times that patients spoke to a pharmacist about a range of issues. Reasons cannot be speculated with accuracy; however, it is possible that intervention patients had no need to seek further advice during that period as they had been provided with information at the medication review. Support for this view is provided because a large percentage of intervention patients (55.5%) are more likely to speak to a pharmacist for advice in the future. If true, this represents a useful indicator of benefit from, and confidence in, the student medication review.

The data obtained in this study enabled a sample size calculation to be undertaken for a future full trial. It is recommended that if a full trial is undertaken, that HbA1c is used as the primary outcome measure, with systolic blood pressure retained as a secondary outcome measure. The numbers of patients required to undertake a full trial with a full final year cohort of pharmacy students is possible. Five medical practices recruited 133 patients and with information collected in this study it is anticipated that this may be increased. The recruitment of more medical practices is expected to be possible, with the inclusion of city practices and other rural towns providing a suitable pool for this.

# **Chapter 6**

## **Review Phase Focus Groups and Semi Structured Interviews**



## **Chapter 6 Review phase focus groups and Semi Structured Interviews**

### **6.1 Background and context.**

The MRC guidance on implementing and evaluating complex interventions[48] recommends that appropriate 'users' should be involved at all stages in research, including evaluation, as this is likely to result in better and more relevant science with a greater chance of producing implementable data.

Kreuger[107] states that focus groups can be used at any stage of a study to assist in the exploration and generation of hypotheses or specific study issues. Huston and Hobson[83] state that the results generated by focus groups provide insight into past, present, or future actions, providing support further support for the review of a study.

Having completed the feasibility study and pilot, it is, therefore, necessary to determine the opinions of all stakeholders on the student-led medication review service, the education experience and the research process. To enable stakeholders to compare and exchange views, focus groups and semi structured interviews were chosen as the most appropriate method to obtain qualitative views on the service.

### **6.2 Aims.**

The aim of this chapter is to obtain opinions of stakeholders in the study to enhance the research process and future service delivery.

### **6.3 Objectives.**

The objectives of this element of the research were to explore stakeholder opinions on the:

- research process,
- supervised student led medication review service,
- preparation for the delivery of the service,
- educational value of the experience.

### **6.4 Results.**

#### **6.4.1 Recruitment.**

Questions for each focus group and semi structured interviews followed set topic guides (Appendix H) and consisted of open questions with subsequent questions to explore or clarify issues.

#### **6.4.1.1 Medical practices.**

Five specialist diabetes nurses and one GP, who had participated in the study, were recruited. Due to work commitments, one group meeting was undertaken with two nurses and the GP from one medical practice, whilst the other nurses were interviewed individually. In each case, the meetings were undertaken at their place of work.

#### **6.4.1.2 Primary care trust (PCT) pharmacists.**

Four PCT pharmacists were recruited. It proved impossible to achieve consensus for a meeting date due to holiday and work commitments. The pragmatic decision was, therefore, made to undertake a semi structured interview with one pharmacist and a focus group with the other three, to ensure that all views and opinions were captured.

The individual pharmacist met the researcher at his home, whilst the meeting for the three pharmacists was undertaken in a meeting room at a local hotel.

#### **6.4.1.3 Patients.**

Due to variable recruitment rates, patients from two medical practices undertook medication review with students much earlier than the other three medical practices. Therefore, two focus groups were undertaken; one with seven patients from the early recruiting practices and one with ten patients from the later recruiting practices. This reduced the time gap between the medication review and the focus group for the early patients. The aim was to ensure greater recall of events. In addition, this method enabled two focus groups which captured opinions from a greater number of patient participants.

Meetings were arranged in meeting rooms at two local hotels, with each being chosen as geographically easy for travel.

#### **6.4.1.4 Students.**

Nine final year pharmacy students, who had participated in the study, were recruited after their final exam. No students who had left the study volunteered to join the focus group. The student meeting took place in a meeting room at the UEA.

All focus groups and semi structured interviews were undertaken as detailed in Chapter 2.

## **6.5 Themes.**

The main themes identified were: general observations and overall opinions of the study, recruitment to the study; preparative training; undertaking level 2 medication reviews; level 3 medication review; patient questionnaire; future methods of undertaking this study.

Sub-themes were also identified and a description of each, based on the evidence obtained from the interviews is presented below.

### **6.5.1 Theme descriptions.**

#### **6.5.2 General observations and overall opinions of the study.**

Participants described their opinions of the value of the study. Sub- themes included good idea and cost effectiveness.

##### **6.5.2.1 Good idea.**

Consensus was displayed amongst participants of different groups that the study was a good idea.

The most frequent quote was the following:

*“I think it’s a good idea.”*

Recognition of the need for undergraduate pharmacy students to undertake communication skills training in the ‘outside’ world was displayed by patients:

*“I would have thought somewhere in the course there should be an element of communication for students, the students and the outside world...”*

Another patient stated that pharmacy students working on a one-to-one basis with patients is more beneficial for learning than standard teaching:

*“I think the more one-to-one work they get with potential patients is the best way of moving forward because you can read up and learn as much as you like, but it’s when you actually get in touch with people in real life situations that you start really learning.”*

There was consensus amongst patient participants in one focus group that this teaching can benefit patients:

*“Well I think it’s a brilliant service (general agreement) and if you can help them to help us it will be better.”*

Patient participants displayed a general enjoyment from participation in this programme:

*“I enjoyed it. I must confess I enjoyed it.”*

One patient said that patients would listen to a pharmacy student:

*“.. because of the environment you have a tendency to listen whereas in the doctor’s surgery you’re sitting there and all you really want to do is get out, .. so even though they tell you things . .don’t necessarily sink in, ...”*

A specialist nurse, whilst supporting the training of undergraduate pharmacy students with real patients, identified that a possible benefit was the promotion of inter-professional communication:

*“I think it’s brilliant, yeah. I think, as I’ve said before, the more disciplines that understand each other’s jobs, the better.”*

It was identified that there is poor awareness amongst patients of pharmacists’ knowledge:

*“I think a lot of patients maybe don’t know that pharmacists have this kind of knowledge and so it’s kind of a good process to raise awareness (laughter) that they can go to the pharmacist and talk about these things (general agreement)...”*

It was hoped by the students that participation in this study would stimulate future contact between patients and pharmacists in the future:

*“...not just picking up issues in that one session and maybe they’re opening up future conversations with the pharmacist.”*

A PCT pharmacist observed that patient contact may be of benefit by raising awareness.

*“Even raising awareness of what pharmacists can spot must be I mean that’s going to be building relationships for the future, ....”*

Students displayed satisfaction that their expectations of participation in the study had been met, which is apparently supported by other members of the group. The students also benefited by obtaining useful data to support their portfolio:

*“I think I got what I initially wanted out of it and I also got to put some stuff in my portfolio so that was always useful, but I was, I am really glad I did it (murmurs of agreement).”*

Comments from some PCT pharmacists showed that they enjoyed the experience themselves, partly due to the opportunity to interact with students:

*“...it’s a nice chance to meet with the students and to do, to discuss some ideas with them.”*

A PCT pharmacist stated that undergraduate pharmacy students do not normally obtain any consultation skills training on placements:

*“...on placements all they see is dispensing, they don’t see any of the consultation skills whatsoever.”*

Another PCT pharmacist provided support for the training programme:

*“If I’d been given that opportunity, twenty years ago I would have thought it would have been brilliant, absolutely brilliant.”*

Participating patients suggested that undergraduate pharmacy students should undertake training in communication skills in the ‘real world’:

*“I would have thought somewhere in the course there should be an element of communication for students, the students and the outside world...”*

Consensus was displayed amongst the patients within one focus group that the study was worthy of repeating:

*“I think you should repeat it, yeah.”*

The students recognised that the location would be important, possibly for a number of reasons:

*“If it could become a regular thing that there was a pharmacist at the GP surgery then it would work.”*

#### **6.5.2.2 Cost effectiveness.**

A PCT pharmacist observed that, whilst students obtained educational benefit, the logistics of the training made it too expensive and inefficient to pursue:

*“The students did learn things from it, but not enough to benefit all the man hours that were put in by the patient coming in and the two pharmacists who were there and the taxi fares to get them there.”*

Further explanation demonstrated that comments relating to time were not in relation to patients:

*“...I thought it was inefficient for the pharmacists and the students, but not for the patients.”*

Another PCT pharmacist identified that the training programme required a lot of organisation:

*“...it did take an awful lot of organising the placements so it was quite hard work I think for those who were having to book all the appointments. “*

### **6.5.2.3 Timing.**

Students stated a recurrent theme, which demonstrated firmly held beliefs, that the time between each of the elements of preparative training, role-play, level 3 medication review and then level 3 medication review were too long. They stated that this reduced the effectiveness of any preparation as they had forgotten elements of it:

*“...and because we were saying there was such a long gap between doing things, it was hard to try and think back to what we'd done previously and how to apply it to that situation.”*

### **6.5.3 Recruitment.**

Opinions were stated about individuals' reasons for joining the study, and these are presented according to the group to which the individual belonged, with each group representing one sub-theme.

#### **6.5.3.1 Students.**

Reasons for student enrolment included not only perceived personal benefit as expected, but also a desire to benefit the wider community of students and pharmacists:

This issue of benefiting other students is demonstrated by one student:

*“The reason I signed up to do this study was because I felt that it would be, I thought it was a really good idea to see if this would work for pharmacy students.”*

This student stated that one reason for joining the study was to demonstrate that pharmacists possess, and can utilise, useful skills and may also demonstrate a method of working with other healthcare professionals:

*"I think pharmacists are under-utilised and so it would be an opportunity to show what a pharmacist can do and show our skills and how we can be integrated into doing things like that..."*

A number of students quoted a desire to increase knowledge and/or skills by participation and the following quote shows that the experiential teaching methods were important:

*"...from the way I learn it's kind of through experiential type, if I'm doing something I learn it better than if I'm just reading it..."*

This was developed further to show that students had realised the benefits would be useful after qualifying:

*"...this would be useful kind of development of skills that will be useful like when I'm a pharmacist."*

The opportunity to undertake an experiential element of teaching or learning was a major theme of discussion about student recruitment and is exemplified by the following quote:

*"...dealing with patients on a one to one basis and we don't often get the opportunity to do that in practice as a pharmacist or a student, so I wanted to take that opportunity to be with the public and practice my consultation skills and communication skills."*

One student hoped that participation would provide practice and experience which would benefit confidence when undertaking duties after graduating:

*"...also to help make it less scary I suppose when you start work."*

The issue of specifically improving consultation skills was quoted as a reason for joining the study and one student hoped that this would benefit them when undertaking OSCEs:

*"I also wanted to do it just to help me like with my skills for during the year because well when we have the OSCE then it's kind of you need to know how to communicate..."*

Students identified a need for opportunities to participate outside the normal undergraduate curriculum and combining this with improving skills was a reason for volunteering:

*“I guess I just wanted to get involved in something that was sort of extra-curricular and it just seemed to be something sensible to improve my pharmaceutical skills.”*

Improving communication skills was repeated as a reason for volunteering:

*“I think any opportunity where we can use your communication skills is really important to take at the moment.”*

One student provided an unexpected reason of the kudos of participation in a research study for enjoying participation:

*“...yeah, like other people would ask like where you going and I'd say I'm going to my study (laughter) I liked that feeling.”*

#### **6.5.3.2 Patients.**

A specialist nurse who undertook patient recruitment at one medical practice observed that the timing of patient recruitment affected the response:

*“I know there were certainly some patients who would liked to have helped but because I think it was around Christmas or before Christmas felt that they couldn't at that time of year.”*

A specialist nurse related the recruitment of patients to meet medical students to this study and said that recruitment is difficult with the same patients volunteering each year:

*“...we struggle with the medical students finding people for them to talk to, so you'd have the same issues, wouldn't you?” “I'm sure the doctors seem to have the same list of people who are happy to come up here, but it's always them, always the same patients.”*

A specialist nurse demonstrated the opinion that posting information to patients was a far more effective method of recruiting than using a poster (at the medical practice):

*“I think by mailing patients was the most sort of sure fire way of getting the information to them. If you just have a look at a poster people will fleetingly look at it and then kind of disregard it and forget about it, whereas a bit paper addressed*



*to them, they're more likely to at least read it even if they then discard it afterwards."*

Consensus was displayed amongst patient participants that they were happy to volunteer for projects such as this.

One reason given was that they were happy to volunteer now that they are retired. No patients below retiring age participated in the focus groups:

*"...it makes a change, doesn't it, (laughter) when you live a hum drum life as a retired person anything is better than nothing, change of scene, change of face, chance to talk to somebody, whatever."*

Some patients expressed a desire to help, with statements suggesting that future recruitment may be possible:

*"...I personally like to volunteer for these things because now I've retired I think I can put something back in finally and I'd be quite happy to put my name on a list that you have, and not my GP had, provided you ask. (General agreement with the comment)."*

General consensus was demonstrated with respect to the recruitment documentation:

*"Friendly and considerate letter."*

When asked about the possibility of repeating the study, one patient said that recruitment should be by written invitation, as some patients do not visit the medical practice regularly.

*"I think writing is more reliable I mean I try only to go to the practice every six months..."*

Consensus was displayed by patients in one patient focus group that they thought that patients would volunteer:

*"Well I personally like to volunteer for these things."*

Differing opinions were displayed about including a wider range of disease states in order to deal with all the patients' problems:

*"I think the whole patient..."*

*"I think it should be restricted, I think it's too wide to be assessed."*

Discussion amongst patient participants identified that a number of them would be willing to volunteer again, with suggestions made of a database of patients' details:

*“You could ask for information which you put on database like what would you be prepared to do, you know come to UEA, come to the local hospital, etc.”*

One patient said that he would be prepared to volunteer in the future if he was asked to undertake medication review with more than one student, as that was more time efficient:

*“Having talked about time, if I was dealing with more than one student, I would then be prepared.”*

One patient said that an additional problem was the low likelihood of difficult patients volunteering:

*“You can’t really find volunteers who are the real worriers and health fanatics, can you?”*

#### **6.5.4 Preparative training.**

Participants described their opinions of the value of the preparative training provided for students within the study. Sub-themes included podcasts, workshops and role-play.

When asked their views about the preparative training, no specific comments were made by patients, however, based on their experience during the medication review, differing views were expressed, with some stating that the students displayed good preparation:

*“They ought to be good at that stage because you primed them well, got them ready.”*

Other patients stated that students displayed differing levels of preparation:

*“Variable, some were very well prepared, the very first ones I had but the second lot they were quite, they were fishing...”*

A specialist nurse expressed the view that underpinning knowledge is required to facilitate the learning of communication skills:

*“...you get your underpinning basic knowledge in the class room but it’s not until you deal with real people that you start gaining your skills, do you,..... but you have to have the theory to underpin what you’re then doing because if you have good theoretical knowledge you can then ease and tweak, can’t you, with the person...”*

#### **6.5.4.1 Podcasts.**

There was unanimity amongst participating students that the podcasts provided the least benefit in the context of this project.

One student's comments are displayed as representing the views of others, and demonstrate a lack of engagement with the pod-casts due partly to internet access as well as having received sufficient education relating to diabetes:

*"In terms of the pod-casts, I'll be honest, I don't think I found them that useful. I think I listened to one and half another one and that's partly because my internet at home is really bad, but I think, because it was on diabetes and we've done so much, I don't know if anyone else agrees, but over the last kind of three, four years, we've done so much on it, I think we probably had that basic knowledge already."*

No comments were received in relation to the pod-cast concerned with consultation skills and motivational interviewing:

#### **6.5.4.2 Workshops.**

Comments received in relation to workshops were only from students. No other participants had any contact with workshops.

A quote from one student demonstrates a number of issues raised by students that the workshop sessions could have been condensed, possibly due to the full timetable, with only an overview required for diabetes:

*"In terms of the workshops we had quite early on, I kind of felt that they could have been condensed quite a lot more, especially like XXXX was saying, we could have had just a quick overview of diabetes. I think it was because our time table was really, really packed in the first semester and I think they were important ..."*

One student also identified that more structure was required:

*".....a lot more structured."*

Comments demonstrated the view that the content of the workshops was acceptable, but that they were simply too long.

*“I think that the content was fine, what we were taught, if was just the presentations, or the way it was delivered, was perhaps too long or not done, not in an incorrect way, but it just made it quite hard to concentrate.”*

Comments received about individual workshops are displayed below.

No consensus was displayed by students about the workshop designed to teach students how to use the IT medical records. One student identified that the session was useful, but that the problem experienced was logistical, due to the training room entailing a thirty two mile round trip:

*“I think the first workshop where we learned about Systmone was useful. The trouble was it was off-site in Dereham so it made it seem like a much longer afternoon than it actually was.”*

Another student, however, had found the system to be complicated and that a longer time may be required:

*“...you can't really learn how to use a system within like an afternoon really, it's quite complicated, isn't it? “*

A possible solution to the problem with this session was proposed by one student who recommended the use of a checklist:

*“It might be more useful to kind of have a sheet which kind of explains the key things that you've got to do. And then do it as you go along the first time you go into the ...”*

The second workshop provided revision of care planning and practice in using the electronic care plan. Comments received demonstrated that some students thought that this session was of no value:

*“The second one, I distinctly remember just that, I felt like I didn't achieve anything. I think it was just like filling out the care plan on the computer or something like that. It was largely based on what we'd already done in the first workshop, wasn't it?”*

Students concurred that the workshop on consultation skills and motivational interviewing was useful. They recognised that not only was undertaking a medication review with a patient different to counselling, but also that they required background theory:

*“I think it was useful that one because it did show you how it was going to be different because obviously we knew how to do counselling and stuff but then it’s slightly different structure this one, so this was quite good this session because it showed you what you needed to ask before you had the practice session.”*

*“Yes, because you always need a bit of theory,…… because you don’t know where to start otherwise.”*

One student provides a useful insight into ways of improving the structure of this particular workshop:

*“It was long, we did have a break and have food in between, but in some respects I think you lose your concentration when that happens and it was hard to then, and because we were doing little miniature role-plays in between so it was stopping and starting and it was quite difficult, I found it quite difficult to follow.”*

#### **6.5.4.3 Role-play.**

Supervising PCT pharmacists displayed consensus in their support for the role-play session:

*“I thought they were exceptionally good and I thought the students learnt an awful lot.”*

Criticism was made by a PCT pharmacist that students had not received or remembered sufficient information and preparation in advance:

*“I had to explain to the student what they were having to do because the first couple of students just thought they were coming in for data collection, so I needed to explain to them what they were then going to go on and do with the actor. But I don’t know whether it was given to them and they haven’t actually registered it or whether they haven’t been given it, but they didn’t really appear to know it.”*

A PCT pharmacist recommended that the students should be given the opportunity to meet the actors prior to the practice medication review in order to reduce the stress of the situation:

*“...meeting them sort of informally just for five, ten minutes in the morning as they got there perhaps, not to discuss anything but just to see the faces and know that they’re kind of normal beings as such and reassure them that it’s not an exam it’s just a simple chat, but a development of their skills.”*

One PCT pharmacist said that the organisation of the role-play was good:

*“The efficiency of it, the way you’d constantly got it moving and there was a continuous stream.”*

The pharmacist stated that role-play would provide more benefit than medication review with real patients:

*“...whether it would be worth doing it with the real patients in the practices. I felt that they learnt an awful lot more working with the actors.”*

*Participating students displayed consensus that the role-play session with actors was useful preparation for undertaking a medication review with a real patient:*

One student expressed the view that role-play was the most important session as it mirrored the medication review, and that the workshops could have been dispensed with:

*“I felt that the session with the actors was the main session that prepared me because it was so realistic to what we were going to be doing, looking back in hindsight looking at when I was with my patient and then looking at the acting session before, it was a carbon copy, it was exactly what we were going to do so that was good. I don’t think, personally I don’t feel that the other sessions gave me anything more than what that session did...”*

However, another student observed that role-play sessions did not mirror real life where some patients do not exhibit care issues to be identified, whereas within role-play the ‘patients’ always exhibit a number of important issues:

*“I felt my patient sessions were kind of different from my actors one because the actors ones had issues whereas the patients ones they didn’t, I mean that’s true to real life, it’s not something that I was expecting maybe but yeah so.”*

One PCT pharmacist also discussed the differences between real patients and role-play actors, concluding that actors potentially provide more benefit for the students due to the full script:

*“Well I suppose in that they had a story, whereas a real patient very often didn’t have a story and there was nothing the student should be looking for really that was just a yeah okay, there’s nothing there, whereas at least with the actors there was usually a string in there for the student to hang on to. They did a really good*

*job. They were very believable. Yes, they pulled it out at the right time as well, as a real patient would."*

A PCT Pharmacist stated that the session was good practice for meeting patients, as it was still in a 'protected' environment:

*"I think it settled their nervousness as well, (unclear) their thoughts about oh my goodness I'm going to be talking to a real patient, but to get that before they leave university, before their sort of mollycoddling almost is gone, ..."*

A difficulty with the organisation of role-play sessions was identified by one student, with the recognition that actors cannot always mirror the characteristics of the patient within the script.

*"I mean it was a little bit difficult with the actors because mine was supposed to be really obese and she was a really skinny lady."*

However, the same student also reported that in spite of the problem the scenario provided realism which benefitted practice.

*"...but I forgot, I forgot she was an actor and I totally believed that she was the real patient and you do, you sort of learn to respond to their, and also to think on your feet as well a bit more when they ask you questions."*

One student said that that the role-play session was less stressful than communication skills training within the current curriculum when they felt judged by their peers:

*"It's weird, I found like on the day when we had the actors that I was less nervous than when we do it in dispensary because the actor, or patient, doesn't know all the technical terms or I don't feel I was judged by my knowledge by the patient and I know that I need to simplify things whereas in dispensary if I get things wrong everyone knows (laughter). I found that more like a relief in a way."*

The feedback provided to students after each medication review with an actor was supported as it provided guidance and reassurance:

*"...there was a feedback session bit and I remember that being useful for like pointers of how you could improve and things like that. It was also reassuring when they said oh yeah you did well because you think okay maybe I can do this."*

Students displayed consensus that feedback between the first and second actors provided student benefit, as this enabled the supervisors to give advice on how to improve:

*“And you got feedback in between the two patients as well so I found that really useful because I did the first one completely wrong and then xxxx said no this is what you need to do so then to then do the second one that was really useful.”*

Pharmacists agreed that feedback provided was of benefit, and it was requested by the participating students:

*“Every single student wanted feedback, individual feedback, so giving the feedback after the first session, after the first actor, invariably they were so much better on the second actor.”*

PCT pharmacists who had assisted with the role-play training displayed consensus that more time was required for feedback:

*“The only thing I would have said against it is that it was too efficient in that there should have been a bit more time for talking in between...so we need a bit longer than that for the feedback... if you could add an extra five minutes on to those times for feedback.”*

The actors, who regularly undertake sessions such as this for medical and nursing schools, provided feedback to the students, with one student commenting that this was beneficial:

*“.....I think the actors’ feedback was quite realistic because I mean they do it a lot more.”*

Feedback was also provided to groups of students by a GP after they had undertaken two medication reviews. A student said that the session with a real GP was good:

*“And I think it was really good after we’d seen the actors that we got to see the GP afterwards who wasn’t an actor, who was a GP, and so we got to kind of feedback what we would do in those situations and so that was good.”*

A PCT pharmacist said that the MRCF was an appropriate validated tool to assess students’ performance during the role-play medication review, but that it required explanation to the students:



*“The MRCF form, it probably is the right form because it’s an official form, it’s a recognised documented, got all the things on that you’re looking for, but it’s not self-explanatory, it’s just tick boxes so if you just give that MRCF form to the student, they have no idea what they’ve done wrong, it doesn’t give any explanations.”*

A PCT pharmacist, when asked if any changes could be made to the role-play session to reduce stress for students, said that not having academic staff present might help:

*“...if they haven’t got their particular professors in charge who they’re trying to impress, that might help but I wasn’t aware of that at the time, it’s only now that you ask the question, you know, possibly they’re nervous because their tutor are there, whereas if they were complete strangers there then they might be less nervous.”*

One PCT Pharmacist identified a possible reason and solution to student stress:

*“... the most stressful thing is just doing it for the first time with somebody else observing and not knowing how you’re going to do. I think once you’ve done it once or twice its better.”*

### **6.5.5 Level 2 medication review.**

Participants described their opinions of the level 2 medication review. Sub themes identified were the benefit of the sessions, organisational aspects of the level 2 medication reviews and students’ performance.

#### **6.5.5.1 Benefit of the sessions.**

Participating students demonstrated consensus that the level 2 medication reviews were useful, as they provided preparation and possible interventions for the level 3 medication review:

*“It was good to have like a background because then when you talked to them like it’s you’re not just like going in there blind, at least you’ve got some background of what the issues they might kind of pre-empt you what they might bring up and things.”*

### **6.5.5.2 Organisational aspects of the level 2 medication reviews.**

Participating students displayed no consensus about the duration of the session during which level 2 medication reviews were undertaken. The planned duration of each session was half a day:

*“I think that session was dragged out longer than it had to be...and it just seems realistically you could do that in like 20 minutes, have a look at someone’s records.”*

*“I kind of disagree with that we could just do it in 20 minutes. I think we took quite a long time to get through (agreement from another student) because we have four patients to get through and we really did take almost up the full amount of time to get through the whole of the records.”*

A student said that the method of two students accessing the medical records of four patients to create a care plan provided shared learning:

*“...I think doing it as a pair was really helpful as well because you weren’t faced like all on your own, you’d find you could sort of like you could discuss it with each other...”*

A student commented upon the difference between classroom and real life care planning:

*“... it was a bit different in compared to what you do in the classroom. These patients all had other conditions and some of them we’d never heard of and it’s trying to find out what they are and then deciding how that could affect their diabetes....”*

One student said that the format of the medical records and the care plan assisted the structuring of the level 3 medication review:

*“I think at least the notes that we saw wrote out was tailored so that we could look at it and then think you know this is the key things we need to ask them and then we had the clinical management plan as well so that sort of helped us to structure what we were going to say to them before, so I think that helped a lot.”*

### **6.5.5.3 Student performance in level 2 medication review.**

A specialist nurse commented on the difficulty of obtaining data from medical records and that, with experience, the students would find it easier:

*“I think there’s an awful lot of places to find information in records and I think it highlighted a little bit that we know our patients quite well, this group of patients in particular, so we know certain things about them and we know where to find that information about them and I think because they’re new to it and they’re new probably to the system and all that sort of thing, they didn’t perhaps know where to look for the information about people.”*

A PCT pharmacist’s comments demonstrate criticism of the participating students during level 2 medication reviews and provided examples, but suggested that with more practice they might improve:

*“They accessed the records and very often missed obvious things.”*

*“Ahh, such that the diabetic patient wasn’t on an ACE, they hadn’t noticed that a patient had just been into hospital and come out again on the records. Sort of really quite glaring things that would ring bells for me, but they didn’t even notice. A person who was on huge numbers of Ventolin inhalers, it wasn’t anything to do with the diabetes, but it was something that leapt out at me whereas they didn’t even notice it.”*

*“I’m sure it was just lack of experience. The more they did, the more experience they would get and the better at it they would get.”*

A PCT pharmacist identified that although the students possessed knowledge, they were reticent about using it.

*“Sometimes it was like pulling teeth, but they’d actually got a lot of ideas and it was just getting them to write it down.”*

The same pharmacist identified that questioning by the supervisor provided benefit:

*“...but once you started asking them questions then they came up with all sorts of things and sometimes things that I’d not spotted.”*

A possible reason for the reticence of students to identify issues was proposed by a pharmacist who suggested that committing issues to paper for forwarding to a doctor may be the reason:

*“...actually writing it down on this carbon paper where if you wrote the wrong thing, you couldn’t rub it out.”*

A PCT pharmacist said that the sessions required students to draw upon their acquired knowledge and put it into real life practice:

*“... it was a lot of learning, because I think they’re putting everything they’ve had taught to them into practice, real life situation.”*

### **6.5.6 Level 3 medication review.**

Discussions identified a number of issues relating to undertaking level 3 medication reviews with patients which are presented as sub-themes of location; organisational aspects; students’ identification of care issues, students’ performance; patient expectations or benefit; comparison of level 3 medication reviews and OSCEs; presentation of care issues after medication review (level 2 or 3); benefits for students and completion of the questionnaire immediately post- medication review.

Specialist nurses displayed general consensus regarding record keeping, that all of the medication reviews between pharmacy students and patients should be recorded in the medical notes:

*“...you should record in the patient notes. You’ve reviewed the patient, you’ve had access to the patient notes, I think yes you should record in the patient notes.*

#### **6.2.5.1 Location.**

Consensus was demonstrated amongst PCT pharmacists and patients that the GP practice is the best location for the medication review:

*“The patient will quite easily go to their own surgery, but they’re not going to be willing to go somewhere else.”*

A patient also said that the location would be better for the student:

*“I think it’s, for me anyway, on these types of thing, I think it’s better to get the student out of the academic institution.”*

#### **6.2.5.2 Organisational aspects.**

One student displayed the view that they did not feel that all academic staff supported them in the study:

*“... I didn’t feel all kind of maybe the staff in the department were kind of on board with it, because sometimes X (the researcher) would be like can you do this, can*

*you arrange this with your project tutor and then you'd arrange it and they'd go well this is more important, you've got to make that choice and it's kind of a bit like when you're trying to do a study because you find it interesting but then you've got your kind of project tutor you know well this is your project, why aren't you focusing just on this. So maybe if all the staff, if it could be something where all the staff agree that time can be made for it, it would be better."*

Students displayed consensus that the effect of support from research staff during the study was beneficial. One student said that the organisation and regular contact helped:

*"...I found that the organisation or just the constant emails and things like that helped me like keep it on my mind (agreement) and just the general involvement ... (agreement) helped a lot."*

Consensus was demonstrated amongst students that undertaking medication reviews with more than two patients would provide further learning, but in addition there was recognition that this provides an additional recruitment challenge:

*"I know it's difficult the get patients on board, the whole recruiting thing but it'd be really good to have more than just two patients or one patient just because I think it's something that is experience based learning and the more you do (murmurs of agreement) the more just sort of gets stored away."*

A possible reason for the benefit of meeting more than one patient is provided in a quote from another student:

*"...we've still got to approach each patient in the same way so keeping that consistency is something, that's why it's good to have a lot of different patients if possible."*

An organisational problem, with respect to finding and booking rooms for student-led medication reviews, was highlighted by specialist nurses when discussing making appointments for patients:

*"I know that we had issues with rooms so from our point of view you were, I think we had to delay it a bit didn't we, so we could've probably been a bit smoother for you..."*

Patients displayed a variety of opinions about the ideal duration of the student-led medication reviews; however, they agreed that some form of limit should be applied:

*“I think as long as long as you draw a line somewhere (general agreement).”*

One patient said that lack of a time limit for the medication review was a good thing:

*“I think another good think about it was that, at least in my case, it seemed to be a bit open ended, there wasn't a time limit...”*

One patient identified a practical issue when discussing the time allocation for student-led medication reviews, by questioning the students' ability to terminate the conversation:

*“Do you teach them how to terminate these interviews politely, when somebody doesn't want to?”*

One student said that supervision helped:

*“...I think (X the supervisor) helped because he ran through everything with me first because we were in the room where you can kind of bring it back and say that, I was nervous.”*

A PCT pharmacist recognised that problems had existed due to participants in the study being unable to complete the commitments made:

*“...there was a lot of people perhaps let you down, whether it was surgeries or things like that, so quite intensive work ...”*

### **6.2.5.3 Care issues identified.**

Students demonstrated consensus that they not only wanted to learn from the experience but to also provide benefit to the patients and that supervisor support helped them. One student's comments exemplify this:

*“I wanted to be able to answer like their questions and stuff but sometimes like they put quite like challenging questions and I found myself like X (supervisor), help me. I wanted to be able to help them and like I wanted to be able to find something that I could kind of help them because I didn't want them coming all this way and then like them just be like know everything and it's a waste of my time.”*

Students' desire to benefit patients is demonstrated by a student suffering disquiet due to their inability to identify pharmaceutical care issues, which resulted in the patient feeling that they had wasted their time by attending:

*“.... one of my patients she like she wasn't very pleased that there was nothing wrong (laughter)..... she thought that that .. she had issues, but like she didn't so I*

*like felt really bad for her, but so yeah I really wanted to, I expected myself to be able to answer their questions and you know respond to anything, their needs and whatever needed changing, but yeah I felt really disappointed when I couldn't for her."*

One student said that not every patient would have issues which require resolution at every review meeting, and this was a useful learning point:

*"I think that's another thing we can gain from the study, the fact that every patient we see we're not going to be able to make a massive difference like obviously we want to, but it's something that we have to learn that we can't constantly be solving every problem"*

One student said that the patients are self-selected (volunteers) and, therefore, may not represent the general patient population:

*"...maybe they were the ones that were more adherent because they're the ones that are more likely to come in and talk anyway."*

One student recognised, however, that education was the primary objective of this exercise for the students:

*"...definitely more swayed towards us like learning and picking stuff up..."*

A student said that the development of a professional relationship with a patient over a series of meetings to identify knowledge of the patient's background may enable improved medication reviews:

*"... it's very hard when you've got no relationship or prior relationship with the patient, .... and it's very hard to make suggestions then without knowing the rest of the family situation or building up that relationship as a doctor or a normal pharmacist may have with a patient, so although I could make suggestions whether they were actually any use or not it's hard to know."*

A student said that speaking to a patient during a medication review provided patient benefit which could not be gained from a level 2 medication review:

*"...even if you think from their records that they might not have any issues, is it still worth speaking to them because I had one of my patients ... his doses of metformin .....he was taking them before he'd had his food.... but when I actually spoke to him about it.... then I could say to him oh you know you're meant*

*to take it with your meals because that's how the drug works ...So it is useful to actually speak to people ..."*

#### **6.2.5.4 Student performance in level 3 medication review.**

A PCT pharmacist identified that feedback after the first medication review had improved performance by most students:

*"...and I think most of them, unless they were very good to start, actually improved on their second patient (unclear) from the feedback....you could see the difference in them once they'd had the feedback if they didn't maybe do so well the first time."*

A specialist nurse said that pharmacy students had identified previously unidentified care issues which they passed to the GP for action.

*"There were one or two things that were picked up that had been overlooked. ... you know it's good to have a third party looking at these things sometimes, things do get missed if you see the same patients every day."*

A specialist nurse gave a specific example of a previously unidentified issue:

*"One of mine was buying something abroad in Belgium, one of the patients, and they'd never said that to either J or S but said it to the pharmacy student. ....but they'd never told us that."*

A possible explanation was proposed by a specialist nurse:

*"...there were obviously things they wanted to ask and they obviously, for some reason, felt they could ask a pharmacy student about it. Maybe they thought the pharmacy student would know the answer..."*

A specialist nurse mentioned further issues identified by students during medication reviews:

*"And then medication wise,...I often look at results and think oh cholesterol is fine, sugar level a bit high, I must talk to them about their diabetic medications and then don't ... check that they might actually be on a cholesterol tablet, so quite a few things sort of flagged, although their cholesterol was up five they weren't actually on a statin ... that was quite nice to have that."*



A specialist nurse said that they had utilised care issues identified by participating students as a prompt during her own consultations with the patients at a later date, as exemplified by this quote:

*"...it was interesting you know, it was good... I flagged those in the notes so that when people came in I could discuss the issues raised."*

Views displayed by a specialist nurse show that, in her opinion, the benefits of a nurse or doctor providing feedback to the participating students are often the identification of practical issues:

*"...not lack of knowledge, it's just experience, I think, and it's probably why we were there to say well actually that wouldn't work in them because you know they're ninety and they're blind, that type of thing."*

One patient said that he was dissatisfied with a student's consultation skills, possibly due to command of English, however, the student did improve during the medication review.

*"...I thought mine would be better, to start with, ... but that was whether that was a language problem as well because I think, was she (country quoted), ....., I wasn't terribly impressed to start off with, it actually warmed up and I was quite happy at the end, ....."*

The following comments between two pharmacists, who had supervised and, therefore, witnessed medication review, demonstrates that students were able to engender honesty from patients during a medication review which resulted in the identification of previously unrecorded issues.

*"...I felt the students were empathetic with them so they wanted to tell them more and sort of probably be more honest than what they might be with the doctor as well..."*

One of the pharmacists proposed a possible reason:

*"And it's was a bit more personalised for them as well wasn't it, I mean your chronic disease management in most surgeries is tick, tick and you get asked to yes or no and you know people just say yes or no, whatever they think the answer should be. I felt that they were a bit more honest."*

More than one student demonstrated that ensuring efficient timing of the medication review is an issue:

*“There were a lot of...slightly older patients that do that do like to come in for a chat as well (agreement and laughter)...something I did find quite hard was just getting the information needed from them it's like one gentlemen I was like so tell me about your diet, he literally told me everything he ate and we were there for about 20 minutes (laughter) .... A skill that is quite important for us to learn is how to get the information that you need...”*

A PCT pharmacist said that students demonstrated good consultation skills which, however, still required improvement:

*“...It obviously needs a bit of honing and refining, but basically they were all pretty good.” “They had obviously practiced consultation skills quite a bit at university, you could see that they had got the basics of the consultation skills...”*

A PCT pharmacist displayed criticism of the knowledge of the students:

*“I would have expected them to have a better standard of knowledge, sort of being a fourth.(year).. Just about everything, really, they were at a pretty basic level of knowledge for everything.”*

One patient criticised a student's lack of knowledge:

*“... I'm a food technologist and I was a bit concerned that the students didn't know which ... various foods ... to recommend to their diabetic patients and I .. recommend this book (unclear) and they hadn't heard of it, that's a very good book to learn what's got sugar in and what hasn't...”*

When asked their opinion of the students' competence or confidence, another PCT pharmacist identified a variable level amongst the students:

*“It varied, a lot.”*

A specialist nurse said that some of her patients found the medication reviews interesting:

*“...patients did come back and say they found it interesting.”*

A specialist nurse who had met students to provide feedback following a student led medication review, said that they were knowledgeable:

*“...like when I spoke to the students afterwards they were very knowledgeable.”*

A doctor who had met students to discuss care issues following a student led medication review praised their communication skills:

*“...they were very....bright and interactive and quite up for it, I think.”*

A patient, in common with several others, said that the student they had met was prepared to admit gaps in her knowledge:

*“...and she had the sense just to say I don't know and turned round to the expert.”*

General consensus was displayed amongst patients that students were nervous; however, no patients reported that this negatively affected the medication review:

*“They obviously getting good out of it, they're just feeling uncomfortable while they're getting the goodness, like I am with my diet (laughter), but it's doing me good, but I'm not enjoying it.”*

One patient reflected the opinions of others that they expected the students to be nervous:

*“I think it's inevitable at their stage, isn't it?”*

Several patients praised the consultation skills of students with one patient actually providing a score for both knowledge and consultation skills:

*“But if I was to mark it out of ten, I would give my young lady eight out of ten for both and I take the two missing points from both things on inexperience because she is still learning.”*

Some negative comments, however, were made by patients about students' consultation skills. One patient was unhappy that a student had asked about alcohol intake:

*“I just thought it was a little bit insensitive but I suspect that that's the sort of thing you'd learn not to do fairly quickly in practice, but I mean it was just a youngster learning her trade.”*

#### **6.2.5.5 Patient expectations.**

Mixed opinions were displayed by participating patients about expectations from a medication review with a student pharmacist:

*“No, no expectations before.”*

*“I just thought they'd be competent.”*

A patient displayed possible negative expectations by stating that the provision of information about side effects of medicines was the role of the doctor and not a student pharmacist:

*“Isn’t that a job for the doctor, I mean they’re only students, you’re putting a lot on them, aren’t you?”*

Another patient, however, disagreed with this view:

*“Yeah, but it’s nice to know what the side effects are...”*

One patient said that lack of expectations was due to comparison with a qualified pharmacist:

*“Well not really because he’s qualified, isn’t he, and they’re not yet.”*

One patient displayed a low expectation of the students’ knowledge:

*“I have to say mine was I thought much better than I’d thought, I didn’t think they would know anything about it, but they did.”*

One patient was unsure why there was a need for patients to meet pharmacists for medication review:

*“Yeah, but if you’re okay with the tablets you’re taking, I am, I mean what’s need for the consultation with the pharmacist?”*

The current lack of contact with patients by some pharmacists and the competence of staff in the medical practice, led to questions relating to the benefit of a pharmacist involvement:

*“My concern is how often does a patient have contact with the pharmacist? ..... and this is what I said to my student, if I’ve got a problem I would go first of all to the diabetic nurse, who is absolutely wonderful as far as I’m concerned, and if she was concerned she would refer me to then to the doctor, but where would the pharmacist come in?”*

Patients displayed opinions regarding the competence of pharmacists which may have influenced their expectations of the students’ performance:

*“I found that most encouraging that I was actually referred to a pharmacist rather than the doctor (general agreement), because as much as I like my doctor, I don’t always think that she’s got all that knowledge.”*

However, comments displayed a wide range of opinions relating to individual pharmacist performance:

*“...by god he’s sorted it out, but he’s brilliant...”*

*“Well my experience with pharmacists only comes down to one who was an obnoxious little ...(laughter).”*

A specialist nurse stated that whilst, in her opinion, patients did not have expectations about the medication review with a pharmacy student, they would have enjoyed the opportunity to discuss their medical conditions:

*“I’m not sure they have a great deal of expectation other than just the joy of the ability to talk about their ailments for a little while (laughter), if you know what I mean, they just like talking about themselves.”*

Further opinions were expressed about this issue by another specialist nurse who stated that the older patients had no expectation of benefit but simply sought to help:

*“...yes, and the older ones would think well we’re just helping you out and you know I don’t think they’d come in thinking they’d potentially get any benefit at all, they’re there to help you know.”*

However, another specialist nurse stated that younger patients (i.e. in their 50s) would have had higher expectations of the consultation:

*“...we’ve got some who are in their sort of 50s I think would have much higher expectations of what they would get out of it.”*

One student said that they did not think the patients had major expectations of personal benefit:

*“I didn’t think they did really. I think they came in knowing they were going to talk about, ... primarily about diabetes, but mine actually ended up not really talking much about their diabetic medicine. I think they just thought they’d have a bit of a check on their medicines and they’re helping us more than anything.”*

There was consensus amongst students that patients required more information, in advance, about the medication review:

*“I don’t think all of them fully got why they were there, to be fair (general agreement to this), because I think they just turned up and like what are we doing today like yeah, so I think they need to be a little bit better informed....”*

A specialist nurse identified that there had been patient benefit from the student-led medication reviews due to a review of medication:

*“...when they’d had these meetings, certain medications had been queried and why was that, so yeah, so I think there were benefits to the patients.”*

A PCT pharmacist observed that whilst there had been benefits to students (educational), there had been no benefits to patients:

*“I can’t actually remember any benefits to the patient.”*

Patient benefit was identified by a specialist nurse who had spoken to patient recipients of student led medication reviews:

*“The patients found it useful talking about their medication, yeah, when they came back they’d say ooh this was pointed out and this was explained again, even though I’ve probably spoken to them about it a hundred times.”*

A patient described how they had benefitted from the intervention:

*“I mean the young chap who was interviewing me, he did actually say something quite useful because I seem to be taking far too many tablets and I tend to forget whether I have or not and he suggested doing ... splitting them up into separate containers, well ... what I do is, every night now, I put the morning ones out by the kettle and the evening ones somewhere else and I think that’s great.”*

A specialist nurse displayed the opinion that no patient benefit had been obtained, as all final actions were dependent on the GP:

*“... I’m not sure how useful it is for the patients to be honest, because ... they’re not really getting anything out of it, because the changes still have to be done by the GP ultimately.”*

One patient said that he had received no benefit, but that the exercise was all about providing benefit for students:

*“Well surely the question is was it of benefit for the students (agreement) because it’s no benefit to us, it’s for the students. If it’s useful for them...then it’s got to be right...”*

#### **6.2.5.6 Comparison of level 3 medication reviews and Objective Structured Clinical Evaluations (OSCEs).**

A student said that the marking and structure of an OSCE is very rigid and that the less rigid format of the medication review enabled a successful retrieval of information from the patient:

*“...we’re examined so hard in pharmacy practice to those damned marking schemes that like there is room to manoeuvre like you were saying to just flow with it and you don’t have to stick to that particular sequence of how you should say things and so we managed to get the information across and got the information from the patient. It might not have been in the same order as what pharmacy practice would like in pharmacy practice you know dispensary sessions, but nevertheless the end of it is that we got the information that we needed and they received the information that they needed, so in that respect I think we did, you know I’m sure we’re all very capable and we all did well.”*

Another student expanded this idea further by saying that within a medication review it was possible to explore issues rather than follow a marking scheme:

*“It’s quite nice not having a marking scheme I think because like you can just kind of like you know it’s just quite nice to just explore like different things with your patient rather than having to like follow a mark scheme and go through stuff so that was quite nice.”*

Students displayed recognition that OSCEs are often simply about obtaining information, rather than obtaining information in order to enable identification of suitable actions within a medication review:

*“I think quite often when we’ve done things in dispensary apart from maybe responding to symptoms, everything is about collecting information, it’s not about using the information to make a change so it was quite nice to maybe collect things and then thing oh actually you could do this and give a kind of possible something they could do...”*

However, it was stated that participation in this study which involved communication skills benefited students when they undertook OSCEs:

*“...we all really appreciated how much it helped us during OSCE...”*



### 6.2.5.7 Presentation of care issues after the medication reviews (Level 2 or Level 3).

A specialist nurse displayed the opinion that more time should be allocated for participating pharmacy students to present care issues identified during medication review to the medical practice and that this would enable oral feedback which is preferable:

*“Obviously, more time for feedback. I actually prefer the feedback when I’m speaking to the student at the time than having the sheets of paper to look at on my own later. It’s more useful.”*

Other quotes by specialist nurses observed that the process of a student making recommendations derived from a medication review to a nurse, demonstrated that the student did not always understand the importance (or significance) of care issues identified:

*“...they seemed to have been able to get the information but I think sometimes they didn’t know whether that information was important information, does that make sense?”*

One student said that the session which was planned to be undertaken with a doctor or nurse after medication reviews with the patients rarely happened:

*“...I don’t know that anybody got to feedback what they found to the real patients to a nurse or, I certainly didn’t, I didn’t see anybody after I’d seen my patients.”*

A specialist nurse said that the pharmacy students demonstrated confidence, competence and an awareness of their own limitations during the session when the student(s) discussed identified care issues with them:

*“Most of them were quite confident. ...But also did seem to know their limitations. There wasn’t anyone saying it’s all wrong, I’m going to do this, you know they were quite thoughtful in their process....”*

A specialist nurse said that shortage of time would probably prevent GP involvement in meetings with students to discuss care issues:

*“...you know you’re looking at a system where there is no give in the system for extra patient slots, taking out three or four patient slots to talk to the students is probably not going to be very likely.”*

The same nurse, however, said that discussing care issues identified with a GP, rather than a nurse, would be more effective as the GP would have greater generalist knowledge than the nurses did:

*“I think that the best thing that could have come out of it was that you maybe needed a GP rather than a specialist diabetes nurse because they (students) weren’t just looking at diabetes’ drugs, they were looking at patients with diabetes but have obviously got other co-morbidities and they were asking me questions that I simply didn’t know the answer to.”*

A specialist nurse said that the practicalities of providing sessions for students to present recommendations or care issues are difficult:

*“It would have been nice to have had a meeting with all of the students after every single session so yes but it’s always going to be tricky, because you know we’re all busy aren’t we, you’re busy, we’re busy and even if you book or allocate a time, that doesn’t mean that it will run to schedule, does it?”*

This same nurse, when asked about the likelihood of GPs being involved in process, gave the following reply:

*“Very low.”*

The only GP to be involved in the process said that, in her opinion, the availability of a doctor to provide feedback after medication review is more likely to be possible within a large medical practice:

*“It wasn’t a problem to me because it just meant that I had less patients booked into my surgery and I just did that in the middle, and I did find it quite interesting and it’s nice doing something different. I imagine, we’re a big practice so we can probably absorb that whereas if you’re a practice with four doctors and you took one of them out to do that on an afternoon when there’s only two doctors there, it just wouldn’t be practical.”*

#### **6.2.5.8 Student benefits.**

A student said that the training would be useful for them after graduation:

*“...it’s still kind of fresh in our minds for when we’re starting pre-reg and we’ll be doing it for real.”*

A student stated that the improved confidence possibly came from a personal confirmation of their own knowledge:

*“I think it scared us but we’ve probably got that little bit more confidence as well ready for next year, like it’s kind of proved to us that we do have gained all this knowledge ...”*

There was consensus among students that their consultation skills had improved during the study:

One student identified that the additional input received by them had provided a greater benefit in comparison to their colleagues who had not participated in the study:

*“And I think it probably did give us kind of that advantage over people who didn’t do the study because we’d just had that little bit more practice and that little bit more feedback from everyone.”*

Another benefit identified by one student was undertaking a medication review with a real patient as opposed to with actors:

*“...there’s only a certain level that you can go up to when you’re with an actor... .I was kind of like pushing myself... I just wanted to do for real because you don’t really know how it feels like to do it for real, then it was good to actually be with a patient and do it.”*

A student identified improved clinical skills as a benefit, not only with diabetes but also with other clinical conditions:

*“...I think when you’re looking at patient details and talking about them, it’s also clinical skills that you’re picking up, I think any opportunity to do that, because it wasn’t just diabetes they were on other medication as well, so you were kind of picking up more clinical knowledge as you went along as well. “*

One student said that practice in care planning in addition to consultation skills was useful:

*“...I pretty much wanted to do it to improve my patient skills and actually like everyone else says to kind of get into that real life situation, but also it gave us the chance to do care plan.”*

Statements by students demonstrate that they found the patient contact to be useful as well as enjoyable:

*“...it was so useful because we don’t get like patient contact (general agreement) so you know it really helped us.”*

A student said that it was useful to have the opportunity to experience a consultation with a real patient in spite of nervousness:

*“...we’ve never done anything with a real patient before, so we’ve always been told kind of they’ll talk on and on about something really irrelevant but you’ve never actually experienced that, you get there and it’s really useful to have done it but I was really nervous...”*

#### **6.2.5.9 Completion of the performance questionnaire immediately post medication review.**

There was consensus amongst students that they marked themselves more harshly than patients did:

*“It’s like (Y) said, you’re always more critical of your own performance (general agreement to this).”*

Students said that patients gave high scores because they wanted to be nice, partly because they had enjoyed themselves:

*“They were just giving us all fives (laughter and agreement). Patients scored you really high and that they just thought it was a really nice thing for us all to come and have a chat with them, they just really enjoyed and said oh we’ll give you five (laughter).”*

A student said that another possible reason for patients marking students’ performance in medication review highly was that they were concerned that the marks would be used against the students:

*“I’m not sure though when you when the patients mark like how well you did and stuff I feel like they thought ...that something was going to happen to...and they were like oh don’t worry, love, we’ll mark you good (laughter) and I was like I don’t mind like if you don’t but I felt like they thought that something would happen to me if they marked me bad, so I don’t think it was like a true reflection”*

Students said that because the patient was marking in the same room as the student, that this may affect the score they gave:

*“It’s also that element that we were sat there when they were doing it...”*

One student made the practical suggestion that the true score of the student's performance within the medication review was probably somewhere between the high patient score and the low student score:

*".....we were probably a bit harsh on ourselves and they were probably a bit too lenient."*

There was no consensus displayed amongst participating patients with some, such as this one, saying that they scored highly to encourage the students:

*"I think it must be relevant to trying to encourage the student as well"*

Some patients said that the scores were a true reflection of the student's performance:

*"I think from my point of view it was a fair reflection actually."*

### **6.5.7 Patient questionnaire.**

This was the baseline and follow-on questionnaire which was comprised of EQ5D, SIMS, MARS, BMQ and DTSQ.

Consensus was displayed that the wording of some questions was not ideal, which is exemplified by this patient:

*"I found a couple of questions wordy, that I struggled to answer..."*

Irritation with questions which apparently repeated issues caused annoyance for some patients when completing the questionnaire:

*"I think I found them why are you asking me that? Why are there so many options and I found a little bit irritating, no doubt each one was there for a specific purpose, but was it? And I think it felt that in some I can't remember, but they were you had all going down and down and down and I thought well I've answered that, maybe not in the way it was asked but it seemed to be the same issue."*

The frustration experienced by some patients about identifying the correct response when completing the questionnaire was demonstrated clearly in the response from one participating patient:

*"...when you get to the point of oh god what should I put down for this one..."*

Patients said that the time taken to complete the questionnaire was appropriate, which in some cases surprised them because it had been devised by academics.

*“I mean I did it well within the time, but I mean academics are notorious for being appalling form fillers.”*

#### **6.5.8 Future methods of undertaking this study.**

Opinions were stated by a number of participants about the best method of undertaking a study such as this in the future, if it was repeated.

A PCT pharmacist suggested a possible method of organising the level 3 medication review:

*“Would it be possible to do it so you booked an afternoon full of patients and then students do the data gathering in the morning and then see the patients in the afternoon so then they’ve just got one day out, so if it was a term, although it’s quite intense, that might be, I don’t know if it would be any easier for booking patients.”*

This prompted another suggestion:

*“Perhaps do it as part of diabetic clinic within the GP surgery.”*

A specialist nurse identified that pharmacy and medical students working together would be a practical situation:

*“...I think they (pharmacy and medical students) could work together quite nicely actually.”*

One nurse expanded this to demonstrate the potential benefit of this joint working/learning, including appreciation of each other’s roles, although there is little mention of educational outcomes:

*“Well there will be certain areas that they are learning at certain times that could tie in ... and I think it will probably interact quite nicely. And most of all, from the point of view of those are the next generation of doctors and the next generation of pharmacists who might work more closely together if they’ve more of an understanding of each other’s jobs.”*

One PCT pharmacist also suggested that a practical method of working would be to organise joint working of medical and pharmacy students:

*“...dual-working with medics and the pharmacy students...”*

That comment prompted another PCT pharmacist to state that the problem is that, unlike medical students, pharmacy students do not have the opportunity to observe qualified practitioners undertaking consultations:

*“... the other thing is with the medics they probably actually on placements see other doctors doing that whereas the pharmacy students on placements usually don't come into a consultation with a pharmacist.”*

One specialist nurse recommended a repeat of the study with more patients:

*“...it would be really interesting to do it with significantly more patients. Just from the students being able to see more and more and more and more, because again, that's the real world, isn't it?”*

Patients suggested that it may be better to not have a supervisor in the room, in a repeat of the study, but to have remote supervision via a video link:

*“...if there was a room set up with a hidden, or not very obvious, camera with just the student, us, as you say somebody in another room, let them get on with it basically.”*

One patient suggested a preparative meeting between the supervising pharmacist and patients to suggest possible ideas to use during the medication review:

*“I think it could possibly be an idea to have the meeting with you and volunteers (patients) and throw one or two ideas in that we might bring up with the student, a sort of preliminary you know be aware that you could ask these questions...”*

## **6.6 Discussion.**

Strong support was reported for the supervised student-led medication review service with patients, supervisors and students all enjoying the experience. Examples of potential patient benefit which derived from the service were provided, although the cost of supervising the service was questioned when considering tangible patient benefits which may accrue from the service.

Those students attending the focus group identified the educational experience as positive as it increased their consultation skills, confirmed their knowledge and ability to apply it, thereby increasing their confidence and prepared them for their future pre-registration training and practice.

Whilst the preparation of students for the delivery of medication reviews with actors was well received, elements of the student preparation process were identified for improvement. Supervisors and patients were largely positive regarding the student abilities within the medication reviews. This, however, may reflect low expectations by patients and supervisors rather than good performance by the students.

The research process was not identified as creating any significant difficulties but logistical issues such as the time period between training and service delivery, were identified for improvement in a future trial.

A good variety of opinions were obtained from a wide range of stakeholders, which displayed useful and interesting data. The student focus groups were independently moderated to ensure that the presence of the researcher, who was well known by the participants, did not affect responses given to questions.

Individual quotes could not be attributed to particular participants. This reduces some aspects of interpretation as it cannot be stated that one individual made connected statements or whether certain individuals dominated discussions. The sampling strategy was pragmatic, with participants of the study invited to join focus groups, so they were self-selected. This may have selected a particular type of participant, but is unavoidable.

It proved impossible to agree a mutual date for a focus group of the four pharmacists who had undertaken supervision within the study. This resulted in a semi structured interview of one pharmacist and a focus group for the remaining three. The majority of negative comments were from the pharmacist who was interviewed individually, and exchanging views with other pharmacists could have been useful and may have revealed more data, possibly explaining why views were held[50 103].

It also proved impossible to agree a date for the specialist nurses to meet, and consequently individual meetings were arranged for one-to-one interviews. These followed the same question guide as the planned focus group. At one medical practice, it proved possible to arrange a meeting with two of the participant nurses in addition to the only doctor involved in meeting students, which provided some useful additional insights.

No comments were received by students who had left the study, as none of those students volunteered to join the focus group. Their views may have added to the data received, particularly about why they left and whether the reason could have been rectified, for them or students in similar situations the future.



Questions asked in the focus groups and semi structured interviews reflect conduct of the study and, therefore, sought to identify issues of importance to the study. Homogeneity was demonstrated in groups[50], with the groups being naturally occurring[107] (i.e. individual groups of study participants) which is recognised as increasing the likelihood of obtaining useful data. Minority, divergent and difficult opinions[50] were included in the data presented, as this adds depth to the data.

Transcripts are available for viewing (Appendix H), although sufficient original data is presented in the thesis to satisfy the sceptical reader of the relationship between interpretation and evidence.

The focus groups and semi structured interviews generated large quantities of useful data which facilitated a better understanding of the development of both student training, within the context of undertaking real life medication reviews, and improving the study protocol for a possible RCT. This method is supported by a study in which Kassam[164] reported that the focus group process was a useful tool for developing a community pharmaceutical care syllabus. In particular, it enabled the development of student learning activities. Focus groups have been shown to be an effective and efficient method of collecting data which would otherwise be lost, and which enables an understanding of the quantitative data produced within the study[83 103 107 111]

There was agreement amongst the majority of participants that the idea of the study was good, and should be repeated. Strong support was provided for undergraduate pharmacy students learning communication skills through real world experience. Dewey[127] stated that “there is an intimate and necessary relationship between the processes of actual experience and education”. The process was enhanced by the patients who stated that they wanted to help the students to learn. Patients reported enjoying their medication review because the students had created the correct environment to listen to patients and provided greater time for discussion compared to that experience with their GPs. These findings concord with Little[64] who reported that consultation style, in particular patient-‘centredness’, resulted in greater patient satisfaction.

The General Medical Council (1993) recommended that communication skills should be taught throughout the education of medical students, although by 1998 progress was reported to be variable[165]. Whilst teaching communication skills throughout pharmacy undergraduate courses is currently undertaken, funding is not provided to enable a high intensity level of experiential training. This results in consultation skills being taught within the university, sometimes with the use of actors, but less commonly with patients.

Interestingly, it was not just the patients or students who enjoyed the experience, but also some pharmacists and nurses due to their interaction with students. Some pharmacists also reported that their knowledge had been improved by the experience. A study[166] (Italy 2005) using interviews with managers identified that when they took on the role of teacher, their own learning improved, partly through increased reflexivity and recognition of their own failings. Busari *et al.*[167] (Netherlands 2002) identified that residents (doctors) held the view that teaching students helped them to be better clinicians, possibly through stimulating their own critical thinking and reflection on knowledge. They also reported that enthusiasm and enjoying teaching were qualities of good teachers. Pharmacists reported that they enjoyed the process and also learned things themselves, and this may be useful in encouraging supervisor volunteering in any future study.

There was limited, but strongly made dissention, with the view proposed that the student-led medication review sessions, despite providing some benefit was expensive and possibly not cost effective in its present form. The reason suggested was that the time commitment for supervising pharmacists, in addition to travel costs and time of travel, were not justified by the perceived patient benefits. These views take no account of the fact that, as a pilot, this study would not be expected to determine this. Whilst immediate cost-effectiveness may not be observed, the comments about cost take no account of potential, long-term benefits and costs. The case has been made for the need to provide effective medication reviews by pharmacists. This is made in the light of the criticisms of pharmacists' consultation skills[67] and the course under evaluation is designed to address the consultation skills needs of pharmacists. If pharmacists receive effective consultation skills training whilst undergraduates, they should later be able to conduct more effective medication reviews for patients. The aim of these is to provide patient benefit, and according to one UK based study [33 34] they demonstrate cost-effectiveness in some scenarios. There is, therefore, a possible long-term benefit to consider, rather than simply focussing on the cost and/or value of any education at the point of implementation.

Students demonstrated a variety of positive reasons for enrolling in the study, including a desire to personally develop skills, which may benefit them in communication skills exams and which they could utilise in the future. The ability to take part in experiential learning, which is not currently available to them, was a strong driver to enrol. They also wanted to improve confidence prior to pre-registration training, and in some cases, to get involved with extra-curricular activities. Altruistic reasons were also quoted which included a desire

to help other students by helping to evaluate the course and also to highlight the skills of pharmacists.

Students who completed the trial displayed full consensus that they enjoyed the experience and would recommend it to other students. The data demonstrates that recruitment of pharmacy students for a full RCT would be possible and that informing potential recruits of the results of this study may encourage a greater level of recruitment. The large number of positive comments and experiences quoted, combined with timetabling problems suggest that a practical solution is to provide this training for all final year pharmacy students within the timetabled curriculum, rather than as volunteers. Student comments demonstrate the need for support, through regular communication, which may, therefore, be expected to increase retention of students in a study such as this.

A number of useful and practical issues relating to patient recruitment were identified, which could be incorporated into the protocol for an RCT. This included avoiding recruitment at or around Christmas as patients may be less likely to respond then. It was said, by nurses and patients, that a written request to patients is the most effective method of recruitment, with patients stating that the documentation used in this study was suitable and well presented. A change in the criteria for patient recruitment could possibly be made in order to improve the cost effectiveness of the student-led medication reviews. This study recruited patients based on a limited diagnosis criteria. Recruitment of patients with identified poor adherence to their prescribed medication, as identified by higher HbA1C levels, may prove to be more appropriate because students would have a greater potential for improving care.

Discussion by students about individual aspects of the preparative training proved very useful. There was no strong support for the podcasts which were seen to be either repeats of topics covered within the course or topics which should have been covered within the undergraduate course. It may, therefore, have been the content rather than the delivery method which was the problem.

A similar criticism was made of the care-planning workshops, although the key issue raised by students in relation to the workshops was timescale. General agreement was displayed that the sessions could have been condensed into a shorter time and should have been closer to the medication reviews. Disagreement was demonstrated about the training in the use of the IT medical records with some students supporting it and others not. Disagreement may arise from a difference in IT literacy, with some students able to quickly use an intuitive-style system. Prior assessment of IT skills may save time by

streaming students into groups with similar skills, thus resulting in differing levels of time input. There was a useful and practical suggestion for a paper-based checklist to be produced about the use of the IT medical records, for use when students arrive at a medical practice.

The role-play session was the most positively received preparative session, which is unsurprising as it has been reported as being a useful and popular technique to train students in consultation skills.[116 130]. The time efficiency[117] of the session was complemented; however, there were also calls for more time provided for feedback to students after medication reviews, as it was shown to be effective.

In chapter 4, it was demonstrated that students, in spite of receiving preparative paperwork and an introductory talk as they arrived at the role-play session, did not know what to expect of the session. This issue was raised during the focus groups and demonstrates, as reported elsewhere[117 130], that further work is required to ensure that this is fully understood by participating students. Actors' scripts were criticised for being too complete, which resulted in all actors having problems which required identification and resolution, in contrast to real life. In addition, actors' failure to perform consistently was perceived to be a problem; however, even with the stated concerns the role-play sessions were seen as vital preparation.

Strong support was displayed for feedback from actors, supervisors and the GP, due to the subsequent improvement in performance. Guidelines published in relation to role-play have also agreed that feedback is essential[130]. However, in addition to the individual feedback given, further group sessions were requested. The use of the MRCF[87] to assess student performance and, therefore, provide more structured feedback was supported; however, it was recognised that students require practice and training in its use to maximise the benefits of its feedback. This suggests that the regular use of such a tool in undergraduate work may benefit students. Joyner and Young[117] recommend the use of a structured form for feedback to ensure that various aspects of the consultation are considered without omissions and the use of the MRCF which has been validated and widely utilised for evaluation and teaching of students, could provide that.

Disagreement was displayed regarding the duration of the sessions when students accessed medical records of participating patients, but support was provided for students working in pairs. There was recognition that the medical records of real patients can be more complex than expected, with conditions observed in the records which were new to the students, therefore, providing additional training and learning opportunities. Students

valued the session due to the opportunity to create a care plan and the provision of structuring for the subsequent level 3 medication review.

It was reported that students' performance during the level 2 medication reviews demonstrated a lack of experience with respect to the use of medical records and creation of real life care plans. Pharmacist supervisors identified that this would improve with experience and that, as this is a training exercise, it is the aim. These activities required students to demonstrate application of knowledge in addition to possession and understanding of knowledge, which is a criticism of university students[74]. This experiential learning experience is designed to provide an opportunity to develop these skills. The modernising pharmacy careers discussion paper[74] encourages education initiatives to improve student ability to apply knowledge which they state is currently lacking.

Although the original plan was to deliver the student-led medication reviews at the university, this was changed when strong support was demonstrated amongst stakeholders for undertaking them at the patient's medical practice. An unexpected, and additional, benefit from this decision was recognised by students as the opportunity to train outside the academic environment. This is supported by published reports [124 168 169]. Another unexpected benefit, described by nurses, was patients providing previously unreported information to students which the nurses utilised later to benefit their patients. Unfortunately, due to a lack of GP availability to receive students' recommendations a large proportion were not implemented. It is, therefore, reassuring to find that nurses utilised the student-identified care issues.

Specialist nurses believed that shared record-keeping of all student-led medication reviews is essential as this not only displays good governance, but would also provide another mechanism for passing student recommendations to the medical practice if face-to-face meetings prove impossible.

Student meetings with doctors or nurses after student-led medication reviews were designed to enable students to present care issues identified to the doctor or designated specialist nurse after the medication reviews, whilst also receiving feedback on their performance. Failure to achieve the attendance of a doctor or nurse on all occasions resulted in a failure to implement care issues identified, whilst students missed a valuable training opportunity. The result was reduced opportunities for patient and student benefit. Participants described students displaying consultation skills which required improvement including nervousness; referred to in one instance as inevitable. Boyatzis[75] suggests a

possible solution to nervousness with reports that it is suggested anecdotally that students' confidence would have been improved if they were an established part of the health care team and received more training and education in medication review. Patients said they appreciated the provision of information, e.g. side effects, and general agreement was demonstrated that students should be providing this information.

Patient expectations of student performance prior to the student-led medication review varied widely. Previous experience with qualified pharmacists demonstrating both good and bad practice had influenced some opinions[170]. A belief existed that unqualified students could not be expected to perform at the level of a qualified pharmacist. The suggestion that expectations could be managed by providing patients with more information in advance about the medication review is potentially useful, but in a research context would require careful presentation in order to not bias patient views.

Students displayed surprise at some patient characteristics. This included the desire shown by some patients to discuss subjects at length, resulting in the student being unable to manage the discussion. One patient identified a possible solution being that students needed to be taught how to terminate a medication review.

Conflicting views were displayed regarding patient benefit from the medication review. Some participants stated a lack of benefit, other than students' education, whilst others reported patient benefit. Most student cohorts, including this one, display a range of abilities (see Chapter 4, section 4.2.2) and, in addition, it has been previously stated that there are patients who did not have issues which required intervention. Hata[169] reports patient benefit from student-led medication review through accepted recommendations made to doctors. However, in that study the training commenced earlier in the course whilst medication reviews were undertaken over nearly three months, which provided time for improvement. Hata reported that students stated a desire to provide patient benefit. This demonstrates a desire by students to ensure good patient care which is encouraging in the present climate, with care forming a key issue in the Francis report[171].

An interesting issue raised, which was not an aim of the study but demonstrates a useful outcome, was that participation in the study and meeting a student for a medication review raised awareness of pharmacists' roles by patients. This may be accompanied by improved professional relationships with healthcare staff. Increased awareness by patients and fellow professionals potentially increases opportunities to discuss patients' medication and provide direct patient benefit.

Students reported that they valued the fluid structure of medication reviews with real patients, as opposed to working with actors in OSCEs. A reason was stated as being the ability to explore issues as they arose in a medication review. Students also preferred the evaluation used with medication review (MRCF[87]) rather than the rigid marking schemes used for OSCEs as that made them focus on scores, rather than the overall consultation. Students stated that undertaking medication reviews had benefited their performance in OSCEs.

Specialist nurses indicated that, when meetings with students took place they were useful because they enabled them to present practical issues in addition to explaining the significance of any information retrieved by students from medical records. Focus group and semi structured interview participants identified that GP involvement is unlikely due to time constraints; although possibly, with prior planning, larger practices may be able to help. Jaffa[172] highlights the issue of involving clinicians early in research as “research and clinical perspectives are different and that accommodating both is not always easy”. He adds that clinicians should not simply be ‘providers of patients’. Medical practices were involved at an early stage, but only one medical practitioner (GP) was available for practical participation in the study as planned. It is evident that greater communication at the development stage is required with medical practices to understand the issues. This could potentially resolve the lack of medical involvement to receive recommendations. The only doctor involved in feedback reported that students displayed good communication skills, and that she received useful recommendations from students.

Participating students, as predicted, reported that they had benefited from the course to a greater degree than their peers who had not taken part. Reasons given demonstrate the need to include real life working into the undergraduate pharmacy curricula. These included skills such as the fact that patients communicate differently to pre-prepared actors, which cannot be demonstrated in an academic environment. Meeting real patients for medication reviews was also quoted as requiring students to push themselves whilst gaining in confidence, which further demonstrates that real life working exhibits additional benefits over solely academic teaching. Students reported that, in spite of the intensive teaching of these subjects at the university, they still learned more clinical skills during this study. They also reported that this did not just apply to diabetes. It is reasonable to speculate that the context and application of knowledge would have increased understanding and later recall of knowledge. The modernising pharmacy careers programme discussion paper[74] notes that pharmacists in their early years demonstrated gaps in knowledge, even in subjects which had been intensively taught. One possible

reason was the lack of knowledge of how to apply the knowledge in real life situations. Students reporting improved knowledge of subjects that they had been taught at the university provides further support for this teaching method.

Comments regarding post-medication review questionnaires by patients and students reveal an insight into scores provided by them. Whilst asking patients to complete the questionnaire immediately after the medication review provided immediate recall and a high response rate, the possible bias effect of the student in the room requires a change to the method in the future. The issue of students scoring themselves 'harshly', due to previous experience cannot be overcome, but still provides a valuable insight to their views, and is, therefore, worth retaining. The use of qualitative methods to identify the real meaning of the quantitative data are justified as demonstrated by Barbour[53]. Questionnaires provided quantitative data and explained how many patients held set opinions, which is very useful data, whilst focus groups explained how these opinions were arrived at, or what they meant[50 51].

Patients reported problems with completion of the baseline and follow-on questionnaire, but that the time taken to complete it was appropriate. This is evidence that researchers should not assume that validated tools in frequent use are always acceptable to patients, and evaluation of patient acceptability is required before a questionnaire is included in a final protocol.

Suggestions for changes to the logistics within the study were recommended by all groups of participants with respect to a repeat of the study. Timing of sessions and cost effectiveness, which were both criticised, also received practical suggestions. These included undertaking the level 2 and level 3 medication reviews on the same day; however, the protocol stated a clear reason for separating these two functions. Timing problems were reported to have adversely affected the benefit of preparation, with short timescales required between preparation and implemented sessions. The logistical and scheduling problems encountered were significant and require resolution to ensure any effective future study, but the study has identified possible reasons and, therefore, could enable solutions. Nurses recommended that medical and pharmacy students could work together when undertaking educational activities with patients, and that this would provide mutual benefit for them. This form of shared working has been demonstrated to benefit both patients and students[81]. The need for students to undertake medication reviews with more patients than the two provided within this trial was highlighted. It was also suggested that students may benefit from undertaking medication reviews with the



supervisor observing via a video link from another room, and also that patients and students should meet prior to the medication review. This would have the benefit of increasing the relationship between student and patient, as previously recommended by a student. In addition, it may reduce the student nervousness reported by patients, as observers can increase this[130].

The MRC guidance recommends a review of a study[48] and the use of the post-study (or review phase) focus groups and semi structured interviews in this case provided data which will enable improvement of the student preparation, the medication review and research process. Problems had been addressed and processes enhanced by the qualitative work undertaken before the service was implemented (development phase). However, the qualitative work in these post-study focus groups and semi structured interviews confirmed the appropriateness of the initial changes and identified further potential improvements with respect to student preparation, the medication review and research processes. If this study was undertaken as a full definitive trial, based on the data from this thesis, it would still be appropriate to undertake a qualitative review pre-and post-implementation to understand the elements which worked and which could be enhanced further.

# **Chapter 7**

## **Discussion and Conclusions**

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### **7.0 Discussion.**

The aim of this study was to feasibility test and pilot student-led medication review clinics in primary care for the purpose of designing a future trial. This study has provided evidence which is supportive of the teaching of medication review skills in the workplace (GP practice) to fourth year pharmacy students. In addition, it identified that not only can undergraduate pharmacy students potentially provide some patient benefits, but that the service is acceptable to patients and stakeholders. The pilot study proved successful, with recruitment demonstrated to be feasible, effective randomisation, limited withdrawals and potential benefit within some of the outcome measures. Data were provided which would enable the power of a future study to be calculated and for the research design to be optimised.

The preparation of students is an important element of the process which could be improved by more closely involving them in its design. Educationally, the students reported numerous benefits, thus supporting the concept.

The limited evidence for effectiveness and the cost of delivery suggest that the patient benefits may not be sufficient to justify funding the service through the NHS. The cost-effectiveness of the intervention requires elucidation but may be improved by better selection of patients, i.e. those with proven need of medication review. Whilst data from this study enables an estimate of cost-effectiveness to be undertaken, a full trial is required to accurately determine its costs and effects.

The concept for the study resulted from the government stated aims to increase the patient facing and clinical nature of pharmacy services [16 115 173-175]. Whilst hospital pharmacy has, over many years[176], evolved to incorporate many more clinical roles and a resultant separation from the dispensary, community pharmacy is still largely focussed around the supply of medicine. Increased automation and the simplification of medicines supply within community pharmacy has changed government expectations, with a current drive for community pharmacists to change their focus to medicines optimisation[175] and they must accept this challenge[177].

In recognition of the deficits within pharmacist undergraduate education and pre-registration training in the UK to adequately prepare pharmacists for clinical service provision, all newly appointed hospital pharmacists are required to undertake postgraduate training, in the form of a clinical diploma. Whilst community pharmacists are

starting to provide more patient facing services e.g. public health interventions and brief adherence interventions, the Royal Pharmaceutical Society of GB (RPSGB) has stated that this role will be further challenged unless it is developed to provide patient focused care. In order to maintain their status, community pharmacists will be expected to assume greater responsibility for chronic disease management[177]. To undertake such roles effectively, similar to hospital pharmacy, it is anticipated that they will require significant further training.

Further postgraduate education, similar to that seen in hospital, may be appropriate but more difficult to deliver due to the professional isolation and time constraints imposed on community pharmacists[177]. A longer term solution is, therefore, to revise undergraduate education and this is a recommendation within a recent national report which identifies the separation of undergraduate education and work-based learning as the most important weakness[74]. Work-based learning enables students to contextualise their theoretical learning, apply their knowledge in complex situations and to develop consultations skills which have been highlighted as a deficiency in the profession[67]

Pharmacy students providing medication review services which involve paper-based reviews and one-to-one consultations, form one potential approach to addressing these educational needs. Due to the complexity of organising and delivering such teaching and the need for close academic supervision, the cost is significant. This study was set up to test the educational concept, identify any potential benefits which could justify the increased costs and to inform the design of a future definitive study. This discussion will, therefore, consider each of these three components separately whilst, recognising the inherent overlap between them.

This study sought to investigate the education of undergraduate pharmacy students in the provision of medication review services, and this required complex clinical decision-making combined with patient consultation skills. The literature review in this study established that pharmacy students in other countries, such as the USA and Australia, can be effectively trained to undertake consultation skills by working with real patients whilst, in some cases, providing benefit to patients [75 76 81].

During the development of the study it was identified that published research, in relation to student-led medication reviews, frequently fails to establish the academic ability of recruited students. It was, therefore, decided to obtain this data for both those students volunteering to participate in the study (intervention) and those students not volunteering (control). No pre-determined view existed about the academic status of the students,

although it could be predicted that those exhibiting a greater academic status would volunteer. Data demonstrated that this was the case and, therefore, this reduces the generalisability of results. It is recommended therefore, that studies recruiting students for any activity involving intellectual input should establish the academic status of both intervention and control group students. Alternatively, the novel teaching approach should be incorporated into the timetable to ensure that all students participate.

This study intervention commenced with a preparative training programme, to further develop skills and knowledge of participating students prior to meeting patients for a student-led medication review. Knowles[178] believes that participants, similar to students in this study, can be considered to be adults and, therefore, andragogical principles may be applied. The first assumption underlying the andragogical model of learning is that adult learners want to take responsibility for their lives, with this including planning, implementing and evaluating their learning needs. It is recognised that whilst the training programme involved workshops and patient-directed activities, it was still essentially didactic in delivery. Taking full account of the andragogical model would have required the participating students to be involved in developing learning outcomes and the subsequent training programme. The result could have been an innovative and more effective preparation for meeting patients.

The training programme included experiential elements, such as meeting patients and, therefore, meets the recommendations of Dewey[127] and Kolb[128] for undertaking real life experiences to facilitate training. It is important to recognise, however, that they still emphasise the necessity of obtaining underpinning knowledge in addition to experience. This provides further evidence of the need for appropriate preparative training to provide the requisite knowledge. The students in this study largely chose not to access the knowledge-based teaching materials, which may reflect previous adequate preparation in the undergraduate course, or that students sought the information via other routes.

The preparative training programme received criticism from participating students during focus groups. Primarily, they criticised content which had already, or should have been, provided within the undergraduate curriculum. The modernising pharmacy careers report[74] notes that pharmacists in their early years of practice do not appear to retain knowledge imparted to them during their undergraduate training, and that real life experience is required to learn application of this knowledge. It is probable, therefore, that meeting patients was more effective at training the students than classroom sessions.

A key criticism of the preparative training for this study was that, due to logistical problems, there were frequent and extended periods of time between training and implementation of medication reviews. Problems were also exhibited with respect to the release of students, by academic supervisors, from activities associated with their final year project. These problems were recognised as reducing the effectiveness of training and, again, this supports the concept of timetabling the experience within the undergraduate curriculum for all students.

The development and planning of the role-play training session, which used professional actors as patients, was reported to be extremely effective. This session, undertaken in consultation rooms in the clinical trials unit to provide reality, received almost universal support amongst participants who completed the study. It has been reported Nestel (2006)[117] that students can recall more information from role-play than lectures. In reality, it is reasonable to propose that this is due to application of information provided in lectures, as proposed by the modernising pharmacy careers programme[74]. However, a small number of students found the session too difficult, indicating that more preparative training was required. Whilst a review of underpinning training in consultations skills may be required to better prepare students for patient contact, it may have been a lack of confidence in clinical knowledge, and the subsequent exposure of this deficiency which drove the decisions to withdraw. Unfortunately, it was not possible to ascertain the opinions of those students. Their views, if obtained, may have enabled additional improvements to be made to the preparative training programme. Including this role-play session and its preparation into the curriculum could potentially resolve the problems which were experienced.

Students in the review phase focus groups identified that more educational benefit would be obtained by them during role-play from a change in the scripts utilised by actors. They perceived that actors using full scripts did not always display the same characteristics as patients. This was because they always exhibited problems which required resolution and always knew the answer to questions. This is an important issue, not always recognised by role-play guidance[117]. In common with scripts prepared for OSCEs, those prepared for role-play by teaching staff could, therefore, provide better preparation for medication reviews with patients if gaps are ensured, similar to real life scenarios. Some students complained of being ill-informed about the aims and methods of the session, in spite of various written and verbal communications designed to inform them. This provides evidence that assumptions should never be made in a study, and the guidance should have been evaluated by at least one student.

Student and nurse participants suggested commencing real life training for pharmacy students in years one to three of the course. Smith *et al.*[179] (2012) reported a programme of real life training in which an iterative approach enabled pharmacy students to observe real life patient activities from year one and increase input throughout the course. Smith[179] reports benefits from this approach. Support is, therefore, demonstrated for the views of the focus group and semi structured interview participants, and if significant experiential elements are built into the pharmacy course in the future, this approach may, with further evidence, prove to be effective.

Feedback, which was provided following role-play, level 2 and level 3 medication reviews with patients displayed consistent support, due to enabling students to improve their consultation skills. In common with research into student education[117 130 164 180], students reported that feedback provided benefit, through increased confidence, whilst enabling improved subsequent performance. All of the pharmacists involved in student supervision and providing feedback were experienced practitioners, having worked with GP practices and undertaken medication reviews, and it is probable that this form of supervision requires this level of experience. The pharmacists are then able to provide in-depth advice built on the experience of clinical input. The fact that they generally enjoyed the experience of supervising students in both the level 2 and level 3 medication review, and would have wanted the opportunity to undertake this training themselves when they first started provides strong support for the course. An unexpected, but welcome, educational benefit was pharmacist supervisors reporting improvement of their knowledge during the process, partly through their perceived need to 'look things up' prior to supervisory sessions.

One pharmacist was not supportive of the educational programme, wanting more cost effective training. This may, however, reflect a lack of awareness of the true cost of this intervention and the different funding sources underpinning undergraduate education, i.e. they may have based this comment on the assumption of the full cost being borne by the NHS. This pharmacist may, in addition, have failed to consider the long-term benefits to patients and the NHS of educating pharmacy students in consultation skills. The modernising pharmacy careers programme[74] discusses the funding for pharmacy training and reminds us that considerable funding is provided for medical and dental training, via both educational and NHS sources, to deliver clinical training.

Medication related problems and care issues identified by participating students were judged as suitable by the experienced supervising pharmacists. Due to the unavailability

of GPs to meet students to receive recommendations arising from identification of care issues during student-led medication reviews, these were not implemented by the doctors. Therefore, the potential clinical benefit to patients, which includes the co-primary outcome measures, from intervention by students within this study is reduced. Interpretation of the clinical data is, therefore, further confounded.

It was reported by specialist nurses, who met students to receive recommendations following student-led medication reviews, that they utilised a number of care issues identified by students within their own practice. It could, therefore, be predicted, but not with confidence, that student intervention yielded some positive benefits for participating patients which were not captured within the outcome measures chosen. The issue of ensuring that recommendations made by participating students, if deemed to be suitable, were implemented by the patient's GP was a failure within this study and a future study would need to address this.

Students identified that they preferred undertaking medication reviews with real patients compared to undertaking OSCEs, as they learned more with the patient. One reason was stated to be the rigid marking scheme employed within OSCEs which, therefore, required students to act within constraints compared to medication reviews. Students preferred the MRCF[87], for evaluation, which is designed to ensure that consultations have the most appropriate elements but enables the structure to be fluid and somewhat dictated by the patient. Adoption of the MRCF within the undergraduate curriculum may, therefore, be appropriate and necessary if students are to be expected to provide real patient services later on within their degree.

Dewey[127] recognised that each student obtains a different experience from any experiential learning and this was seen by the students who outlined a variety of benefits resulting from providing the service. These included an awareness of the need to adapt consultations to different patients and how to deal with patients' questions, resulting in improved confidence. Kolb[128] states that experiential learning is the process whereby knowledge is created through the transformation of experience. Students stated that the experience enhanced their knowledge of not only how to undertake a consultation, but also clinical skills and roles of healthcare professionals in medical practices.

Schon[69] states that the rigorous professional knowledge held by professionals in order to resolve problems is based on technical rationality. He refers to an artificial scenario in which practitioners remain on the high ground solving manageable problems which are resolvable through the application of research-based theory and technique. He continues,



however, that these problems tend to be relatively unimportant, as in the “swampy low land” lies confusing problems which defy technical solution, and require communication and adaptive thinking. This is referred to as reflection in practice, as opposed to reflection on practice. It was gratifying to observe that students reported having to think on their feet and respond to new situations to effectively resolve patient care issues.

The strength of many patients’ statements, during focus groups, of their enjoyment of the experience of consulting a pharmacy student was surprising. In some cases, the reason was pragmatically stated as due to being able to do something interesting when retired, but data also demonstrates genuine enjoyment and benefit from the medication review. There were small numbers of dissenting voices and it was recognised that the students required further experience. However, this was their first opportunity to undertake activities such as this and the study data demonstrates students improving their consultation skills between the first and second medication reviews. An obvious interpretation would be that these skills would continue to improve during subsequent medication reviews. Results from only two data points, however, is insufficient to identify a trend and further work would be required to establish if this promising result improved with further experience.

Post medication review questionnaires demonstrated that patients found the medication review to be acceptable, and more significantly that they would recommend it to another patient. These results are similar to those reported in a previous study (Boyatzis and Batty[75]) in which fourth year pharmacy students met patients for medication reviews. Little *et al.*[64] assert that patient centredness is a vital element in patient satisfaction within a consultation. Patient acceptance of student-led medication review provides indirect, but important, evidence of student competence. Patients reported, during focus groups, that they valued the additional time available for student-led medication review versus those of GPs. It could, therefore, be argued that this is a major reason for their stated satisfaction. However, Ogden *et al.*[121] investigated the link between patient satisfaction with consultation and the time available. They reported that ‘a doctor who listens and tries to understand their patient may make the patient feel more satisfied with the consultation length and subsequently more motivated to follow any recommendations for change’. This, therefore, provides further support for an argument which states that patients’ stated satisfaction with the medication reviews was a result of students demonstrating good consultation skills which had been learned during this programme. In addition, some patients who had met a pharmacy student for a medication review agreed that they would be more likely to consult a pharmacist for information as a result of the

medication review. Further evidence is, therefore, provided for benefit in some cases beyond the immediate medication review.

Students reported educational benefit from meeting and interacting with other healthcare professionals during the visits to medical practices. One stated aim of future pharmacy undergraduate education within the modernising pharmacy careers programme[74] is to produce pharmacists, at registration, working in partnership with other healthcare professionals to deliver patient care through the use of medicines. Medicines optimisation requires more multi-disciplinary team working than has been seen previously in the UK, with healthcare professionals working closely together to improve patient care [175]. It is, therefore, essential to ensure effective collaborative working at the undergraduate level. This training programme has evidently provided some opportunity for undergraduate pharmacy students to commence the process of integration and partnership working.

Whilst undertaking medication reviews participant students identified large numbers of care issues, for the patients, which were agreed and approved by supervising pharmacists. Students, therefore, were able to demonstrate technical competence in identifying issues of importance for patient care, which meets with the requirements of the definition of pharmaceutical care [35]. Not only, therefore, was it demonstrated that participating students had learned from the programme, but that they were able to identify issues of clinical importance to patients.

If we are to produce confident clinical professionals (pharmacists) who are able to apply their knowledge in practice, as required by modernising pharmacy careers programme[74], evaluation of their clinical activity within the workplace is required. This will enable real assessment of the effects of such activity. Clinical outcome of patient participants in this study was evaluated using the co-primary outcome measures of HbA1c, blood pressure and total cholesterol.

No clinical benefit was demonstrated within the intervention group. Observation of the patient clinical data (both at baseline and post-intervention) demonstrates that patient groups, as demonstrated by mean, were within accepted ranges. With the wide standard deviation displayed, it is evident that some patients did require intervention to move outcome measures (HbA1c, BP and cholesterol) into range. However, the small numbers in this study, combined with the baseline results present a difficult target for students to improve.

Results obtained by patient questionnaires at baseline and six months post-intervention demonstrated a significant superiority by patients who had received a student-led medication review compared to control, with respect to change in quality of life. Whilst there were no changes in clinical outcomes, it might be predicted that providing patients with information to support their medication taking, and answering questions about disease and lifestyle, would reduce concerns and, therefore, improve quality of life.

The patients in the intervention arm demonstrated significant improvement in elements of the SIMS scale[91]. Horne *et al.*[91] (2001) state that higher levels of satisfaction with medicines information were associated with higher levels of reported adherence. The current study demonstrates that patients who had received a student-led medication review displayed lower concern about potential problems with their medicines than patients who had not received a medication review. The improvement in reported SIMS by participating patients did not result in an expected improvement in adherence [91]. However, the adherence tool utilised has not been fully validated and has been reported to show reduced confidence in results due to being a self-report scale[152-154]. Both groups of patients displayed a high use of medicine compliance aids (MCA) to assist with medicines taking. It is probable that this would have exerted a considerable effect on adherence prior to participation in the study, thus reducing any possible effect from the student-led medication review.

Patients within this study were required to have been diagnosed with T2DM for a minimum of two years. It is possible that patients within a timescale much closer to diagnosis would exhibit a greater need for information and education about medicines, lifestyle issues and their disease state. In such a scenario, students would have a significantly greater opportunity to improve patient outcomes. Therefore, it may be more effective to actively recruit more recently diagnosed patients, by amending the inclusion criteria, in a future study.

Undertaken within the guidance provided by the Medical Research Council (MRC)[48], significant changes to the original protocol have been identified as necessary for any repeat of the study. This study meets the criteria of a complex intervention through the number of interactions, the number and difficulty of behaviours required by those delivering the intervention, the number of stakeholder groups involved and the number and variability of outcomes. As the intervention is required to 'work in everyday practice' it is important to understand the whole range of effects, how they vary among recipients of the intervention, between sites, over time, etc. and the causes of those variations. This

study, through the implementation of a full and well developed protocol sought to follow those concepts.

Co-primary outcome measures were used within this study which is not usually accepted practice. However, the MRC guidance allows this approach within a pilot study, as a means of identifying the most appropriate outcome measure(s) for a full study. Data obtained showed that HbA1c is the primary outcome of choice for a future study, with a sample size calculation indicating the number of patients required in a full RCT.

The most significant positive finding from this study was that it was possible to recruit patients, suggesting that a full RCT would be feasible. However, whilst two medical practices recruited almost to target numbers and on time, with a third recruiting target numbers, but late: the remaining two practices recruited smaller numbers of patients and later than required. The ability of some practices to achieve the targets suggests that much closer communication is required with all practices to ensure that targets are met. The delay in recruiting exerted considerable pressures on planning and implementation of the intervention. Strong criticism was voiced by student participants that these delays reduced the effectiveness of training, due to the long time between learning skills and implementing them with patients.

In this study patient participants were those with T2DM for at least two years. The literature review identified that T2DM is responsible for extensive patient morbidity and cost to the NHS, whilst the prevalence is increasing dramatically. Over 15 million people in England have a long term condition with 75% saying that if they had support from a professional, or peer, they would feel more confident about taking care of their own health[115]. Between 2005/6 and 2011/12 the total number of items used to treat diabetes in England rose from 27.1million to 40.6million[181]. Patients with type 2 diabetes were chosen for inclusion in this study, as representative of a LTC with supporting guidelines which students could utilise. Review stage focus groups and semi structured interviews recognised that, whilst the participating patients had T2DM, students within the medication review evaluated care issues for all of the patients' existing conditions. Agreement was demonstrated that this was the correct approach. Therefore, recommendations were made that patients exhibiting other conditions should automatically be included. This would also result in easier recruitment due to a larger pool of patients. In a future iteration of this study it may be of value to use the patient criteria developed and used within the Australian Domiciliary Medication Management Review[41 182] (DMMR) as this is a service which is widely implemented throughout Australia with

approximately 20% of pharmacy graduates applying for accreditation. Use of the criteria would enable comparison to an established programme with a wealth of research to support this, with Prof Chen[183] being very active in this area. The Australian DMMR notes the risk factors contributing to medication-related adverse events, and which can help to target DMMR:

- currently taking five or more regular medicines,
- taking more than 12 doses of medicine per day,
- with significant changes to their medicine regimen in the last three months, including recent discharge from hospital,
- taking medicine with a narrow therapeutic index or required therapeutic monitoring,
- with symptoms suggestive of an adverse drug reaction,
- having difficulty managing their own medicines because of literacy or language difficulties or impaired sight.
- attending a number of different doctors, both general practitioners and specialists.

Future studies may benefit from patients meeting a student pharmacist more than once. Within this pilot study it was pragmatically appropriate to limit medication review by each student to two patients. Research published in the USA and Australia [75 76 81] demonstrated educational benefit from students meeting more than one patient, whilst additional patient benefit was demonstrated by more than one consultation meeting.

Recruitment of students demonstrated approximately 50% of the cohort which is the figure predicted by a survey the previous year. It is possible that with timely patient recruitment and a more innovative preparative training for students, that the dropout rate would be smaller. Patient recruitment should commence earlier to enable planning of medication review schedules. This would also provide information to enable the medication reviews to be scheduled into the undergraduate timetable.

It was stated earlier, that involvement of students in the development of the preparative training programme may have produced a better outcome. Obtaining their views retrospectively about the training, via a focus group, provided very useful information. Whilst earlier involvement of students is desirable, it is still valuable, as required by MRC guidance, to obtain their views after a study. The use of on-line surveys proved to be an effective tool and is one with which most students are experienced. However, the response rate from students of 40% is relatively low and better timing of the survey may have produced a greater response.

The key changes made following stakeholders' focus groups and semi structured interviews during the development stage of the study were to move the location of the student-led medication reviews from the university to the patient's own medical practice, and to provide transport to these locations for participating students. The patients also provided a very useful insight into their view of recruitment documentation. These included elements which were incorporated into documentation for this study, and which will be useful in the development of future studies. Examples include a dislike of the terms intervention and control, simply because patients do not always understand them. A preference was displayed for terms describing the groups such as 'the group receiving a consultation'. Another example was the recommendation to include an invitation paragraph to act as a short précis. Thirdly, strong dislike was displayed of the use of abbreviations, even if previously explained. This data enabled the recruitment documentation to be made more user friendly, although an earlier focus group would have enabled a full rewrite and, therefore, potentially a better outcome.

The late implementation of development phase focus groups and semi structured interviews was undoubtedly a key weakness of the study development process, as if implemented earlier they would have enabled better adherence to MRC guidance[48]. During the process of recruitment for the medical practice focus group it proved impossible to recruit a GP, which resulted in recruitment of specialist diabetes nurses. The protocol required the availability of a GP to enable students to present recommendations, following level 2 and level 3 medication reviews. The inability to recruit GPs for the focus groups should have been a signal that recruiting them to participate in the main study would also be problematic. Increased and improved communication should be attempted and with hindsight we should have utilised the medical supervisors within the project more effectively to facilitate this. The inability to provide a GP or nurse after each level 2 or 3 medication review session was a major failing, and highlights an issue requiring resolution before a full RCT. Student inability to present issues identified, along with recommendations resulted in a failure to implement recommendations. Specialist diabetes nurses involved in the study, however, stated that they used student-identified care issues in their clinical practice. In some cases, they did not utilise issues which referred to non-diabetes issues, due to their lack of knowledge in those areas and an understandable unwillingness to work outside their own competence. Failure to implement students' recommendations not only reduced the educational benefit for them, but may also have resulted in reduced, potential clinical benefit for patients from student recommendations.

A number of issues have been discussed which were not planned or undertaken in an ideal manner. The care plan designed for use within the study was in electronic format with drop-down boxes and was to be used for collection of patient data and formulation of care plans. However, with insufficient testing, full identification of student opinions was not obtained. It was assumed that students would prefer electronic records to paper records, but in practice, when given a free choice, they chose paper records on every occasion. The care plan was still effective, in paper form, in providing a guide to the students' care planning and for recording of care plans. This is evidence that assumptions should not be made in a research study, and that further testing of the care plan should have been undertaken.

When undertaking medication review with patients, students failed to record all care issues identified. This may have been predicted, as undertaking their first medication review with patients would have been stressful and they were working in an unknown environment. Even if not predicted, the researcher and supervising pharmacists should have observed this and undertaken the recording themselves. Failure to record this data reduced the ability to effectively describe the student activities. A recommendation by specialist nurses during review phase semi structured interviews was that supervising pharmacists should fully record the student-led medication review in the patient's medical record. Copies of this would resolve both governance and data collection requirements.

Another research design issue is the use of validated tools in the study. The main questionnaire and post- medication review questionnaire were both based on previously validated tools such as SIMS, MARS, BMQ, EQ5D, and DTSQ. Non-validated tools included care planning forms for presenting recommendations to GPs and intervention criteria to evaluate care issues identified by participating students. An attempt was made to identify validated tools which proved unsuccessful but a more prolonged search, if successful, may have presented more valid data. In the case of the post- medication review questionnaire, a published tool [75] was utilised, but following MRC guidance, the research protocol was evaluated with the use of focus groups and semi structured interviews. The patient stakeholders clearly identified that students displaying a lack of competence or confidence would not be acceptable within a medication review. Therefore, this issue was taken to the study steering group and questions asking about these two issues, worded in a manner acceptable to the patient and student members of the group, were added to the questionnaire. At this stage they also requested the addition of a question, for students, about required levels of knowledge. Evaluation of the protocol by the use of focus groups and the use of management and steering groups is recommended

by MRC[48]. Whilst this questionnaire was not fully validated, it was based on a validated tool with additional input following stakeholder and management input.

Review stage focus groups of stakeholders in the study provided invaluable information about the study and also ensured further compliance with MRC guidance[48]. Strong support was displayed that the study was enjoyed by participants. Practical issues identified included the time available for medication reviews, use of care plans by students, preparative training, logistics and students' performance. Recommendations from participants in each stakeholder group recommended methods of providing the intervention in the future.

## **7.1 Reflexivity.**

Reflexivity entails the researcher being aware of his/her effect on the process and outcomes of research based on the premise that knowledge cannot be separated from the knower[184]. Hamersley and Atkinson[185] observe that reflexivity acknowledges the effect on the researcher imposed by their previous social interactions which may have conferred values and interests on them. Tong *et al.*[84] state this simply as qualitative researchers being unable to completely avoid bias. The result may be the researcher unwittingly affecting data during collection or affecting data analysis. The effects, if observed, may also involve the researcher unwittingly imposing possible effects on responses provided by research participants.

Recognition of effects is not sufficient, as data must be presented to the reader of a qualitative paper to enable him/her to see that the researcher has dealt with this phenomenon effectively. Therefore, the data must enable the reader to evaluate for themselves the true effect of reflexivity. Mays and Pope[186] confirm this when reporting assessment criteria for qualitative research which includes reflexivity of the account. They define this as "the degree to which the effects of the research strategies on the findings are assessed or the amount of information about the research process that is provided to readers". They further state that reflexivity means sensitivity to the ways in which the researcher and research process have shaped the collected data and recommend reporting biases to enhance credibility of findings, with discussion also required about personal characteristics.

The COREQ criteria[84] further expand this by presenting a formal reporting checklist for in-depth interviews and focus groups, in which Domain 1 discusses the research team



and reflexivity. They recommend that researchers should recognise and clarify for their readers their identity, credentials, occupation, gender, experience and training to enable assessment of possible influence exerted by these factors. The COREQ criteria also recommend reporting the relationship and extent of interaction between the researcher and their participants. This is due, as stated earlier, to the potential effect exerted by relationships on participants' responses and the researcher's understanding of the phenomena. Accordingly, detail of relationships existing between the researcher and participants in focus groups or semi structured interviews is presented below to enable reader assessment of reflexivity within this study.

The researcher was new to qualitative research but was mentored by a Professor experienced in qualitative research for the first focus group. He gained experience through undertaking focus groups and semi structured interviews and subsequent reflective practice during the research, in addition to extensive reading.

Male, age 60+years, pharmacist with 30+ years clinical pharmacy and management experience in hospital pharmacy. In 2007 he commenced teaching at the UEA in addition to work with a PCT as a practice pharmacist and CPD mentor for PCT pharmacists. The researcher is committed to the development of clinical pharmacy in order to improve patient care and it is possible that this enthusiasm was unwittingly conveyed to participants. As this was the first qualitative research undertaken by the researcher bias cannot be ruled out, although the desire to fully learn this technique created an internal desire to ensure a lack of bias.

#### **Development phase semi structured interviews/focus groups:**

Students had recently completed their pharmacy degree and knew the researcher well due to his role in teaching, but having just left the university were not in a dependent role. However, the previous repeated contacts will have influenced interactions and may have influenced students' comments.

PCT Pharmacists were all colleagues with whom the researcher had worked and enjoyed a good working relationship.

Patients were unknown to the researcher before the meeting. As topics included the roles of pharmacists such as information provision by them, it is of relevance that the researcher is a pharmacist.

Only one specialist nurse was known to the researcher prior to the meeting. That nurse worked in a GP practice at which the researcher had worked as an advisor on a part-time basis, and they experienced short episodes of professional communication. The researcher had worked with large numbers of nurses in patient care for many years and was relaxed in communicating with them.

### **Review phase semi structured interviews/focus groups:**

A number of the students volunteered to participate in the study because they knew the researcher and his strong views on the future of clinical pharmacy. In addition we had worked closely together both during their undergraduate teaching and especially during the study. Due to the possible influence of this I requested two colleagues undertaking PhDs in the school of pharmacy at the UEA, who were unknown to the students, to facilitate the meeting. One was a female former secretary (mid 30's) and now research manager at the local hospital, with previous experience of facilitating focus groups. The other was a male psychology student (mid 20's). He had provided statistics teaching to pharmacy students, but not this cohort. The questions for the focus group were provided by the researcher. Participant students were informed that the meeting record would be typed and an anonymised version provided to the researcher, so that he could see their comments but not ascribe comments to individuals.

All four of the PCT pharmacists had attended the development phase pharmacist's focus group and had worked closely with the researcher during the stage of the intervention when students accessed patient records and met patients for medication reviews. It proved impossible to arrange a focus group for all four pharmacists due to commitments and the pharmacist providing negative comments on the research met the researcher for a one to one semi structured interview, whilst the other three attended a focus group.

The two patient focus groups represented patients from two different geographical locations. A number had met the researcher during student-led medication reviews, but for very short periods of time, during which introductions were made and then thanks for participation.

Specialist nurses were the same nurses represented at the development phase semi structured interviews. In addition a GP who met two students for feedback after student-led medication reviews participated in a meeting with two nurses from the same GP practice. Contact was very brief during that session.

Negative comments from some participants demonstrate that they were not inhibited from making these by the presence of the researcher. No further contact was planned between the researcher and participants.

## **7.2 Conclusions.**

This thesis identified that patients do not always benefit from their medicines as planned. Whilst medication review (MR) may provide assistance with this issue, resulting in patient benefit, no compelling evidence exists for the provision of this service by pharmacists within the UK. Suggested reasons for the failure to demonstrate this are poor study design, inappropriate intervention location and limited consultations skills demonstrated by pharmacists, with this last issue providing support for the proposal that UK pharmacy students should receive additional education to prepare them to undertake medication reviews. It has been demonstrated outside the UK, primarily in Australia, USA and Canada, that this can be effectively undertaken through pharmacy students undertaking medication reviews with real patients. Justification, therefore, exists that this should be evaluated within the UK.

The work in this thesis, undertaken as a feasibility and pilot study in accordance with MRC guidance, demonstrated that it is possible to effectively prepare final year pharmacy students to undertake medication reviews with patients with type 2 diabetes. Patient acceptability and some patient benefit were displayed in addition to educational benefit for students. Success was, therefore, demonstrated as a feasibility and pilot study not only through identification that the intervention is possible and acceptable to participants, but also through the demonstration of high rates for important issues such as recruitment, retention and completion of patient questionnaires. A number of negative findings were identified; however, these will prove to be effective in informing the amendment of the protocol for the implementation of a multi-site study. The key negative results related to the design and implementation of the preparative training for participating students and the engagement of GPs with the study.

Results obtained support the implementation of a multi-site study following retention of some elements of the current study and implementation of key changes to the current protocol identified during the study:

- Patient Information leaflets must be reviewed to ensure elimination of abbreviations and to replace any reference to control or intervention groups with a simple descriptor of the role of each group,
- within the patient questionnaire Medication Adherence Report Scale (MARS) should be replaced by Morisky 4[159],
- development phase focus groups or semi-structured interviews should be undertaken with stakeholders early to inform and enable further amendment and improvement of the current protocol,
- the intervention should form part of the curriculum for all final year pharmacy students at participating sites, including preparative training, level 2 and then level 3 medication reviews at GP Practices,
- a review of student education should be undertaken at each participating site to assess the need for each element of the preparative training. It is likely, however, that this will identify that additional training in the use the I.T. medical records and consultation skills training should be retained,
- each student should undertake a role-play session with actors to practice medication review prior to meeting real patients for a medication review,
- the medication related consultation framework (MRCF)[87] should be utilised both as a training tool within undergraduate teaching and for evaluation of consultations,
- recruitment of GPs should be undertaken by medical academics participating in the study to ensure at an early stage that a GP will be available to receive student recommendations and to provide feedback,
- patient recruitment criteria should be changed to enable recruitment of people with type 2 diabetes closer to diagnosis. This should be at any point after diagnosis agreed by the patient's GP to allow for exclusion of potential problems. Skyler[147] when reporting a position statement of the American Diabetes Association states that "glycaemic control early in the course of type 2 diabetes may have CVD benefit", and notes that intensive glycaemic control of relatively young patients with type 2 diabetes was associated (*in studies reviewed*) with a 57% reduction in major CVD outcomes. In addition it is reasonable to propose that patients nearer to diagnosis display a greater need for information about their medicines. These factors would provide pharmacy students with greater opportunities to provide benefit to patients,
- assessment of potential patient recruitment must be undertaken. Using the chosen criteria, assessment is required to evaluate if 20% (approximate recruitment rate identified within the study) of such patients represent sufficient

numbers. Within each school of pharmacy each final year student should meet two patients for medication review. Therefore to enable a similar sized control group four times the number of students in the year will be required as patient participants,

- if suitable numbers of patients with type 2 diabetes are not available for recruitment, then it is recommended that the Australian Domiciliary Medication Review[41] criteria (see page 245 in thesis resubmission) should be adopted,
- negotiation with participating GP practices is required to agree a read code for 'student-led medication review as part of a research study'. Supervising pharmacists should ensure that this code is attached to the medical record of all patients receiving a student-led medication review(MR) and that a précis of the MR is recorded there.

### **7.3 Recommendation for future work.**

A multi-site study is justified by the data presented within this study. However an internal pilot would be required to ensure that recruitment rates were the same at other sites. Patient benefit was only demonstrated with respect to a small number of aspects of care and a future study should seek to clearly provide this. A possible method of achieving this would be by changing the patient inclusion criteria to include those patients with a greater need of pharmaceutical care input. This may be achieved by including those patients with demonstrated or suspected adherence problems, or by including medical conditions other than diabetes and closer to diagnosis.

The results obtained suggest that focus groups should be used at an early stage in the development of a future study to facilitate optimal identification of the aims and development of the protocol for a full study.

Better communication with medical practitioners to ensure opportunities for students to present recommendations arising from medication reviews must be ensured, which might be best undertaken by the medical supervisors already working with the study. Students reported that even the minimal contact they obtained with other healthcare professionals in the medical practices provided benefit. A realistic contact at the undergraduate stage would benefit future integrated working.

This study identified the value of utilising both qualitative and quantitative research methods, and these should be incorporated into a future study. Early involvement of

stakeholders, and in particular patients, is advised. This should include evaluation of recruitment documentation and methods.

Further evaluation is required to establish the most effective, appropriate and if possible validated tools to incorporate into questionnaires, with the aims of the study and patient outcome measures driving the decision. Early evaluation of a questionnaire by patients would facilitate suitable changes.

The data from this study must be analysed to establish the cost-effectiveness: this is currently being undertaken and aims to calculate quality of life years (QALYs) for patients receiving a medication review from a student.

Further publications have been recorded since the literature review was undertaken for this study. A full systematic review of the available literature examining the role of pharmacists in undertaking medication review and training of pharmacy students with patients, with particular emphasis on undertaking medication review, is required. This will further facilitate the production of a protocol for a full study.

Preparative training models must be reviewed to establish the most effective and appropriate methods of preparing students for patient medication reviews. This must include evaluating if this training can be incorporated into the undergraduate curriculum.

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**Volume 2 Appendices**  
**Development and Feasibility Testing**  
**of a Supervised Pharmacy Student-**  
**Led Medication Review of Patients**  
**with Diabetes in Primary Care**

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Richard Paul Adams

**PhD**  
**2014**

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# **Appendix A: Application to RfPB**

Funding Approval



David Wright  
Professor in Pharmacy Practice  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
[d.i.wright@uea.ac.uk](mailto:d.i.wright@uea.ac.uk)  
01603 592042

Mr Rajive Sharma  
NIHR CCF  
Grange House  
15 Church Street  
Twickenham  
TW1 3NL

Dear Rajive

**NIHR Research for Patient Benefit (RfPB) Programme: PB-PG-0909-19198 – Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects**

Firstly, thank you for recommending that the project should be funded. We are delighted with this news. Our response to your comments and questions are outlined below:

- *The Committee considered the research team to be strong; however, the Committee agreed with Reviewer 1's comments that a statistician should be included as a co-applicant rather than in the wider research team. The Committee therefore requested the necessary adjustments to the team be made, while keeping within the overall funding limit of the programme.*

We are very happy to do this as we would have preferred to have included John Wood as an applicant from the outset. Although we chose not to include John as a co-applicant, due to the limitation of six co-applicants on the form, we had already costed him in appropriately. Consequently please find John's CV attached with this letter. We are unsure as to what further action is required on this as this had no effect on the funding request for this project.

Following our telephone discussion regarding the arbitrary limit to the number of applicants set by the form, I wonder if it would also be possible to include Richard Holland on the list as his input into the project design was also invaluable and he was not included for the same reasons as John Wood.

- *It was noted that the application lacked consideration of how far undergraduate education can affect long term practice and the Committee requested further detail.*



The time constraints of the project, which is a pilot, prevent evaluation of the impacts of this intervention on long term practice. We believe that if the results suggest a positive outcome and this is replicated in larger study, then use of pharmacy students may be one approach adopted by practice based commissioners to supporting patients with long term conditions. Such a model may change general practitioner and nurse opinions of the potential value of pharmacists and consequently result in greater multi-professional working. A definitive trial would run for a longer time period and consequently the effects on long term practice would be identified via qualitative methods.

- *The Committee suggested that the study could have been placed in a wider health professional context, for example by including practice nurses, and requested **further** information on this aspect.*

We agree that this was not adequately considered when describing the student intervention within the medical practice. The model of managing patients with type 2 diabetes in medical practices will be identified prior to students reviewing patients will be identified. Consequently the most appropriate practitioner for them to liaise with following their medication review will be identified and students will arrange meetings with them under the supervision of the primary care pharmacist. This may be the general practitioner or the practice nurse as suggested. We believe that the medical practice will ultimately decide on how the intervention should be managed and who will be involved in this process.

The letter of invite to medical practices for focus groups within phase 1 will ask the lead prescriber to identify the most appropriate person to send from the medical practice. Consequently the focus groups may include practice nurses, independent nurse or pharmacist prescribers or general practitioners, rather than just general practitioners as originally described.

- *In accordance with comments made by Reviewer 3, it was agreed that the dissemination plan requires expansion, for example, through dissemination to other pharmacy schools and the wider environment. The Committee invited the applicants to address this concern.*

With the recent dissolution of the UK pharmacy professional body, the Royal Pharmaceutical Society of Great Britain, the Academic Pharmacy Group conference which is the natural dissemination forum for this research has been lost. The conferences listed in the original application are consequently the most appropriate within the UK.

However, in addition to the proposed strategy we will send a bespoke report to the Heads of School and Heads of Pharmacy Practice at all Schools of Pharmacy which outlines how the service was set up, what we have learned from the process and the potential benefits which they can use to negotiate with local practice based commissioners. If deemed appropriate by the Heads of School of Pharmacy, CUHOPS, we will provide a presentation on the results at one of their national meetings. Additionally we will offer to present the findings to the Head of Education at the new General Pharmaceutical Committee and discuss how they would like to see this information disseminated. The costs of the additional printing and travel can be met within the current budget.

I hope that these responses are sufficient for your needs.

Yours sincerely

Start Certificate

Programme: Research for Patient Benefit

Our Reference (NIHR Number): PB-PG-0909-19198

On behalf of the Contractor, NHS Norfolk, I, Tracy Shalom certify that the research project entitled, "Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects" for which the lead researcher is Professor David Wright has commenced. With respect to this project I can confirm the following:

1. The project started on 1 February 2011 as confirmed by the lead researcher and has incurred expenditure as planned.

For the Contractor:

Name: DR TRACY SHALOM  
Signature: [Signature]  
Date: 7th March 2011  
Position: R & D MANAGER  
Host Trust Reference Number: 20101C02(63837)

This document should be authorised by the relevant person\* from the contracting institution and returned to the Central Commissioning Facility at the following address:

RIPB Programme  
NIHR CCF  
Grange House  
15 Church Street  
Twickenham  
TW1 3NL

\* Finance officer, chief executive or R&D manager

# Appendix B: Development

Protocol Version4

Pharmacy Student Medication Review RISP Final

Flowchart for Supervised Pharmacy Student-Led Medication Review in  
Primary Care

## Protocol and Flowchart

**Supervised Pharmacy Student-led  
Medication Review of Patients  
with Diabetes in Primary Care:  
A pilot study to ascertain the potential  
costs and effects**

## Annex 1

### Research Associate

Rick Adams Teacher Practitioner	School of Pharmacy UEA
------------------------------------	---------------------------

### Project Management Group

Professor David Wright Professor in Pharmacy Practice (Primary Investigator)	School of Pharmacy UEA
Dr Debi Bhattacharya Lecturer in Pharmacy Practice	School of Pharmacy UEA
John Wood Lecturer in Statistics	School of Pharmacy UEA
Dr Paul Grassby Senior Lecturer in Clinical Pharmacy	School of Pharmacy UEA
Dr Richard Holland Reader in Public Health Medicine	School of Medicine Health Policy and Practice UEA
Dr Tracey Sach Senior Lecturer in Health Economics	School of Medicine Health Policy and Practice UEA
Professor Nigel Norris Professor of Applied Education Research	School of Education & Lifelong Learning
Clare Symms Research Governance Manager	NHS Norfolk

### Project Steering Committee

Richard Adams & David Wright, plus Professor Amanda Howe Professor in Primary Care	School of Medicine Health Policy and Practice UEA
Gill Eddy Head of Prescribing and Medicines Management	NHS Norfolk
Patient representative TBA	Public & Patient involvement in Research TBC
David Rea (Patient representative)	Diabetes Patient Champion
Two Student representatives TBA	School of Pharmacy, UEA TBC

### **Summary**

This is a pilot study designed to estimate costs and effects in which fourth year pharmacy students will undertake medication reviews for patients with type 2 diabetes.

### **Background**

It has been estimated that only between 4% and 21% of patients achieved the optimum benefit from their medication (1). Studies in the US estimate that the consequences of prescription-related (iatrogenic) illness has been shown to be 100,000 deaths or \$1 billion per annum (2). The costs of unresolved medication related problems (MRPs) exceeds \$177.4 billion with over 200,000 deaths per year (3). In the elderly it has been estimated that 10-12% of all hospital admissions are the consequence of MRPs, and that they account for 18% of hospital deaths.(4) MRPs are common with evidence of 61% out of 2,985 patients (below 65) experiencing one or more (5). In addition it is estimated that over half of medication-related admissions in the elderly are preventable (6) It has been stated that although much of the academic literature on this subject comes from overseas it is now accepted that these findings can be transferred to the NHS (7, 8).

Medication review (MR) is defined as 'A structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of MRPs and reducing waste' (9). Four levels of MR have been described with level 0 being an opportunistic, ad hoc, unstructured review, level 1 with a list of patient's medicines only, level 2 with the patient's full notes and level 3 is with both the notes and the patient.

The key components of a Level 3 MR include:

- Improving patient understanding of treatment
- Answering patient questions and concerns
- Discussing practicalities of medicine usage
- Ensuring treatment efficacy
- Undertaking appropriate tests and measurements
- Identification of side effects and interactions
- Agreeing future plans

## Annex 1

Pharmacist-led medication reviews, which are increasingly common within primary care in the UK, have been shown to reduce unnecessary prescribing and to potentially improve patient adherence and reduced medication related costs (10,11) whilst being shown to be effective (12,13). Recent UK based research utilising pharmacists to provide level 1 medication reviews found a counterintuitive increase in hospitalisation (14) with one partial explanation being the didactic nature of the pharmacist communication (15,16). Effective communication skills are necessary to improve patient behaviours both in terms of lifestyle (17) and medication taking behaviour (18). Consequently, models of consultation behaviour have been developed (19,20) and are commonly utilised with healthcare professional education.

The recent government white paper for pharmacy identifies a need for significant and meaningful exposure to patients within the pharmacy undergraduate experience. Experience of pharmacy undergraduate training within secondary care is widespread amongst UK schools of pharmacy, whereas primary care education experience beyond the confines of the community pharmacy is limited.

Whilst UK pharmacy graduates develop expertise in the pharmacology and therapeutics of medicines, undergraduate curriculums currently lack significant patient contact and therefore the development of clinical and communication skills during training is limited (21). The government white paper for pharmacy (22) recommends greater clinical exposure for pharmacy students during their undergraduate years to address these needs. Medical students routinely work with patients during their undergraduate training (23) whilst undergraduate students within all UK schools of dentistry and optometry provide NHS remunerated services to patients under supervision of clinical tutors to improve both their clinical and communication skills (21,24,25). The use of pharmacy students in the UK to provide NHS services to patients with the dual aims of patient benefit and student education has not been tested. Involvement of pharmacy students in the provision of healthcare services in other countries has been reported (26,27) with very good prescriber acceptance of student recommendations (28). To gain acceptance of such an innovative model within the UK evidence to demonstrate the potential value of such a service to the NHS is required. Furthermore due to the limited experience of co-operative working between PCTs, general medical practices and schools of pharmacy, models for effective working require development.

2.5M of the UK population currently have type II diabetes with an estimated cost to the NHS of £9 billion/annum (29). Pharmacist led medication reviews in patients with diabetes have

## Annex 1

demonstrated significant reductions in blood pressure (30,31) and HbA1C (32), both of which are necessary to reduce long term morbidity (33,34). Due to the availability of clearly defined national treatment guidelines (18,34,35,36) and the increasing numbers of patients with type II diabetes due to the obesity epidemic (29) medication review for patients with diabetes is an NHS service which pharmacy students may be able to provide.

This pilot study is therefore designed to both estimate the costs and effects of pharmacy student-led medication review services to patients with type II diabetes to the NHS and to develop an effective model for working between schools of pharmacy and primary care trusts.

Lord Darzi in his 2008 report (42) suggests that delivering more personalised and effective care for patients by enhanced clinical roles for pharmacists should be explored through research. This proposed research is designed to make a small but significant contribution towards both developing pharmacists for enhanced clinical roles and providing evidence of pharmacists providing patient benefit.

### **Aims**

The primary aim of this pilot study therefore is to estimate the costs and effects of pharmacy student-led medication review and medicines related consultation.

The study will estimate the size of the intervention's effect on patient blood glucose control, blood pressure, health-related quality of life, medicine adherence and patient autonomy. It will allow the most efficient method of patient recruitment to be identified together with the likely 'drop out' rate, the best outcome measures (in terms of acceptability and convergent validity), and the feasibility of conducting a full cost effectiveness analysis. The results would then enable the design of a full RCT to establish definitively if training these students by undertaking medication reviews face to face with actual patients with a variety of conditions is of benefit.

Our secondary aim is therefore to develop and describe a novel primary care based pharmacy student training scheme and to describe the perceived effects of this training on inter-professional relationships, professional confidence and competence and on patient perceptions of the pharmacist.



## **Method**

### **Ethical approval**

A full ethics application will be made via IRAS and commencement of the research will await approval.

### **Phase 1 Development of intervention**

#### **1.1 Literature review**

Education and healthcare literature will be searched utilising commonly used search engines to identify descriptions and evaluations of student led medication review interventions.

Appropriate papers will be reviewed to identify appropriate models of practice and outcome measures which have not already been considered.

#### **1.2 Baseline questionnaire for data collection (annex 3.4)**

The questionnaire to be used for data collection throughout the study consists of the following validated scales:

- Health status measure EuroQol EQ-5D (37)
- The Diabetes Treatment Satisfaction Questionnaire (38)
- Patient reported medication adherence (39)
- Patient reported autonomy (40)
- Patient satisfaction with information about medicines (41)

Additionally, patient demographics will be ascertained.

#### **1.3 Focus groups**

Focus groups of 6-8 participants will be arranged with general practitioners (GPs) or Specialist Nurses, patients with type 2 diabetes (T2DM), final year pharmacy students at the School of Pharmacy, UEA and primary care trust (PCT) pharmacists. Each focus group will consist of at 6-8 participants from one stakeholder group, plus Rick Adams (RA) and Nigel Norris as facilitator. The venue for patients and students will be a room at the School of Pharmacy (SOP), whilst GP and (PCT) pharmacist focus groups will be held at a convenient location. A meal will be provided.

Participants for the focus groups from stakeholders will be recruited as follows:

- Letter of invite, consent form and stamped addressed envelope sent to all GPs or Nurses from the four recruited medical practices (annex 2.1) (see also section 2.1)

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- Letter of invite, consent form and stamped addressed envelope sent to all Norfolk Primary Care Trust pharmacists (annex 2.4)
- Letter of invite, consent form and stamped addressed envelope sent to patients recruited via Diabetes UK research group (annex 2.2)

All the above groups and individuals will have up to two weeks to decide if they will agree to provide consent. This will be provided by signing the forms sent to them.

Each focus group will receive a 5-10 minute presentation of the proposed study at the start of the session and will be expected to last for one hour whilst the following themes are considered (as appropriate for the stakeholder group):

- Perceived benefits
- Identified concerns
- Barriers to recruitment and participation
- Methods for optimising recruitment and participation
- Opinions on the patient questionnaire and covering letter
- Logistical issues

All focus groups will be recorded (audio) for simple content analysis undertaken by RA to identify common themes, issues and solutions which could be used to modify the final intervention. Written consent will be sought.

Main findings from the four focus groups will be presented to the management and steering committees, together with the data from the literature review to enable the intervention design to be optimised.

Ethical approval will be sought for any amendments to study documents or methodology including those arising from recommendations made by the focus groups.

## **Phase 2 Pilot intervention**

### **2.1 Recruitment**

Four local medical practices with a primary care pharmacist in-situ, to support the students, will be recruited by the lead PCT pharmacist for Norfolk. The PCT currently employs 10 primary care pharmacists on a sessional basis. No difficulties with recruiting four medical practices or with PCT pharmacist capacity are envisaged. The GP practices will receive support funding from Norfolk & Suffolk CLRN to cover the costs of participating in this study.

PCT pharmacists will be paid at their standard rate of pay for time spent on the project.

All final year pharmacy students will be invited by letter (annex 3.3) to participate in the study and consented in the usual manner. A survey of the final year pharmacy students in the cohort completing in summer 2010, which outlined the time commitment, identified that up to half of the year would volunteer with the stated time requirements (40 students). The students will not be paid for participation and will be expected to participate outside timetabled teaching, however, they will have the incentive of additional training. The timetable in the final year has significant gaps, to enable self-directed study, and it is anticipated that this process will take approximately six hours student preparation and eight hours for the intervention over two years, with the incentive being the additional clinical training and experience. Students will be randomly allocated to one of the four medical practices.

160 patients will be recruited (80 intervention and 80 control, in order to enable each student to undertake medication reviews on two patients).

### **2.2 Usual student preparation**

All final year pharmacy students invited to participate in the project will, irrespective of their decision to participate or not, as part of their usual undergraduate experience, have

- Training in the use of a 'pharmaceutical care planning' software package (to structure and record actions, decisions and plans during a medication review). This package has been extensively used in actual practice primarily in the USA
- Completed a basic lecture and practical course on communication skills
- Attended lectures and workshops on data protection and confidentiality
- Observed GP/patient consultations for at least two hours

### **Intervention student preparation**

Consenting students will additionally be asked to undertake:

- A medication review skills workshop utilising dummy patient records (two hours) in order to gain more practice with the IT package
- Two medicines related consultations with pre-prepared and scripted 'actor' patients (two hours) at the end of which feedback will be given by a supervising pharmacist. In addition the actor will be asked to complete a questionnaire (Appendix 1)
- A training session at the practice or PCT on the use of the practice information system (two hours)

Individualised feedback will be provided by Paul Grassby and Debi Bhattacharya to optimise consultation skills and minimise the likelihood of inappropriate student comments.

Students will apply for honorary PCT contracts and therefore vetting. They will be supervised by a PCT pharmacist and will sign patient confidentiality agreements.

### **2.3 Sample size**

The likely precision of the study for estimating the effect of the intervention on the continuous endpoints can be gauged from the expected value of the half-width of the 95% confidence interval around the difference in means between the intervention and control groups. For the primary outcome variable HbA1c, assuming 80 patients in each group and a standard deviation (between patients recruited from this population) of 1.5% (43) this is less than 0.5%. This implies that we can reasonably expect the estimate from the study of the effect of the intervention on this endpoint to be within 0.5% of its 'true' value. This figure, incidentally, is also equal to the expected 'least significant difference' between the groups. That is, should we observe a difference in means between the groups in excess of 0.5%, then this will be statistically significant (at the 5% level, 2-sided), conditional on an observed standard deviation of 1.5%.

For the co-primary of blood pressure, estimates of the standard deviation were taken from (44) Table 1 'Test' confidence intervals, giving estimates of (approx) 31 and 9 mmHg for systolic and diastolic BP respectively. Applying now the same calculation as was applied to HbA1c above, means we can reasonably expect the estimate from the study of the effect of the intervention on BP to be within 10 and 3 mmHg of its 'true' value for systolic and diastolic BP respectively (conditional on the value of the standard deviation, of course).

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It should be noted that the above calculations are likely to underestimate the true variation somewhat, as the study contains a component of variance due to differences between pharmacy students (in their consultation skills), and not just variations between patients (in the outcome variables). The calculations above take account only of the second component. However, there is no sensible basis at all (prior to doing the experiment) on which to base an estimate of the first component of variance, which is why no attempt has been made to do so. It is quite possible that it will not be large enough to make much difference and, after the study is completed, we will have an estimate of it.

It is also worth considering the 'populations' represented by the various studies. Lowey, et al was the most relevant study we could find for the estimate of standard deviation of BP, as the patients had type 2 diabetes. However, they were also selected for hypertension, which the patients in our study will not be. Therefore, it could be that the standard deviations we actually see are somewhat above the estimates given here, to the extent that our study will include patients with 'normal', as well as elevated, BP.

Co-primary outcome measures:

- HbA1c
- Cholesterol
- Blood pressure

Secondary outcome measures:

- Health status measure (EuroQol EQ-5D (37)
- Diabetes Treatment Satisfaction Questionnaire (38)
- Patient reported medication adherence (39)
- Patient reported autonomy (40)
- Patient satisfaction with information about medicines (41)

Patient inclusion criteria:

- Prescribed non-insulin medication for T2DM for at least two years
- Adult
- Willing to give consent
- Registered with one of the four participating medical practices

Patient exclusion criteria:

- Deemed unsuitable for inclusion in the trial for any reason by their GP
- Enrolled into other clinical trials

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- Suffering from terminal illness

The requirement for the patient to have received prescribed therapy to treat type 2 diabetes Mellitus for at least two years is to ensure that the patient is relatively stabilised on their therapy as it was deemed unreasonable to expect a student to identify issues during the acute phase. In addition a student medication review during this period may interfere with the GP/nurse lead stabilisation of therapy.

Initially 40 suitable patients from one medical practice will be identified by practice staff and randomly sampled from the practice records. A letter inviting participation, a patient information leaflet, a consent form and a sae will all be posted within the initial mailing (annex 3.2). Once the response rate from the invitation can be estimated the process will be repeated in all medical practices and the original medical practice with appropriate numbers of patients to ensure recruitment of 40 patients in each medical practice. Consent forms (including permission to access medical records) will be returned to RA. If the focus group identifies that other methods of recruitment, such as leaflets in diabetes clinics or diabetes support groups, ethical approval will be sought for any change in method.

Recruited patients will be randomised to either intervention or control via an automated randomisation system to ensure concealed allocation.

### **2.4 Baseline data**

All recruited participants (intervention and control) will be sent a copy of the baseline questionnaire, with a covering letter and stamped addressed envelope. Experience from other studies shows that the questionnaires should take 20 minutes to complete.

The most recent HbA1C and blood pressure results for each patient will be obtained from the patients' medical records by RA.

For a period of three months prior to baseline the following information will be obtained to estimate healthcare costs at baseline and also to check that groups are equal:

- Medication details and utilisation (as shown by issues of medication recorded on the patients' records at the GP practice)
- GP and nurse utilisation within the medical practice (as recorded in the patients' medical records at the GP practice)
- Hospital episode statistics

## Annex 1

### 2.5 Medication review

The students will, under the supervision of a PCT pharmacist or Rick Adams, work in pairs to undertake medication reviews for four intervention patients. Due to the limited number of computers available it was believed that this would be more efficient than individual students working in isolation and in addition will enable greater student exposure to the exercise, as well as peer support and critique. The review will take the form of a level 2 medication review (ie, utilising the full medical records but without the patient present) and will be undertaken in the GP practice at which the patient is registered utilising the medical records.

For each medication the student will compare prescribing and monitoring with NICE guidance (ref 18,34,35,36).

Additionally, students will use a pharmaceutical care plan (PCP) package, on a separate laptop, to standardise recording and to produce individualised PCPs. NB: the students will have been given training in the use of this package – see section 1.4.1. It is estimated that eight students can complete this process in a half day session with access to two practice computers and two laptops. Each medical practice will therefore be required to provide access for two half day sessions. The information on the laptops will be password protected and no information will be patient identifiable. The PCP package will record a unique patient identification number (PIN) only. The code sheet containing PINs and patient names will be held separately in locked cabinets in the office of David Wright. Rick Adams will collect the laptop (all of which will be used exclusively for the purpose of the study) from the PCT pharmacist managing the session and store in another locked cabinet in the pharmacy practice research room at UEA.

A PCT pharmacist or Rick Adams will moderate student questions for a one hour GP/specialist nurse practitioner feedback session prearranged for the students at the end of their visit to enable discussion of identified medication issues. Agreed therapy changes will be implemented, with GP consent, by the PCT pharmacist unless the GP prefers to undertake this themselves. (NB: feedback will be by a GP, however, if a specialist nurse practitioner runs a diabetes clinic there as a prescriber he/she could feedback.) If the practice wants they will be given a copy of the care plan.

Rick Adams will review all of the PCPs produced by the students to ensure that there are no errors and that all issues and actions identified by the students are appropriate. Any changes required to ensure optimum patient care will be discussed with individual students by Rick Adams to ensure that the students are aware and know and understand all the correct

## Annex 1

issues. After discussion between Rick Adams and the student, any changes recommended by the GP, nurse or Rick Adams will be incorporated into the PCP on the laptop.

It was deemed inappropriate for the student to undertake the medication review as part of the medicines related consultation as they could potentially identify medication issues which they are not in a position to rectify or question and this could create difficulties when providing information to the patient. A period of time would be left between the medication review and consultation to enable issues to be implemented and for student reflection.

### **2.6 Medicines related consultation (MRC)**

All intervention patients will be invited to attend a medicines related consultation (MRC) at the UEA NHS clinical trials unit and offered a range of dates and times, including some outside of normal working hours, to maximise participation.

From the four patients whose records were accessed by each pair of students RA will randomise (using the PIN) two patients to each student. Each student will provide a MRC with two patients taking the form of a level 3 medication review. The student will access the previously prepared PCP on the lap top and update accordingly. Students will be expected to discuss each medication separately, identify patient information needs and address them accordingly. The updated PCP will be retained for later analysis.

We will video record student performance in consultations using UEA equipment to facilitate feedback and self-reflection. The patient will provide verbal consent in addition to original written consent, although they will not be visible in any recording.

The students utilise this equipment on a regular basis during normal training in consultation skills at the University, so it should present no problem for them. Patients will be given the opportunity to provide verbal feedback on the MRC before leaving the clinical trials unit.

Patients will be asked to complete a short questionnaire on the student's consultation skills. In addition we will ask the students to complete the same questionnaire for comparison (Appendix1)

RA will be available at each session to answer identified problems. At the end of the session RA will evaluate any recommendations which result from the consultation and agree with the students which should be forwarded to the GP/specialist nurse practitioner in a format agreed during the initial focus groups.



## 2.7 Evaluation

Six months post intervention, for both intervention and control, the following data will be collected:

- Study questionnaire (updated from version in 1.3 but with ethical approval sought if required) will be posted to all participating patients.
- Any change in utilisation of community pharmacists
- HbA1c and blood pressure. We will request that the practices organise a blood test to measure HbA1c and cholesterol and also to check blood pressure. (NB: costs have been agreed from service costs.) If a test has been undertaken during the previous three months no test will be requested
- Medication details and utilisation (from medical records)
- GP and nurse utilisation within the medical practice (from medical records)
- Hospital episode statistics (HES)

Comparison of all outcome measures between groups will be undertaken on an intention-to-treat basis using Chi squared tests for categorical outcomes and unpaired T tests (Mann-Whitney U tests where data are not normally distributed) for continuous variables. Analysis of covariance will be used for continuous variables where baseline data are available.

Comparisons between medication usage and cost will be made utilising the collated data to estimate the effect size of the intervention.

Response rate and medicines related consultation uptake rate will also provide useful information for future studies.

All recorded consultations will be reviewed by RA utilising the medicines related consultation framework (20) to identify areas required for improvement in the training and preparation of the students and to provide individualised feedback on their performance. The MRCF is a tool widely used by universities, including the UEA, to evaluate the MRC process.

## 2.8 Economic evaluation

An early economic evaluation will be undertaken to inform full RCT design and to estimate the likely cost effectiveness of student-led medication review for patients with T2DM compared to usual care from NHS perspective. Cost analysis will capture intervention costs and its consequences on NHS resource use via data from medical records, questionnaires

## Annex 1

and HES. Published unit costs for the most recent common price year will be applied to estimate intergroup cost variance.

Main economic outcome measure will be EuroQol EQ-5D (37). The difference between baseline and six month utility per patient will be used to estimate mean difference in QALYs over the trial period.

Incremental cost effectiveness ratio combining costs and benefits will be calculated if the student-led medication reviews are not dominated or dominant. Decision uncertainty will be estimated using cost effectiveness acceptability curves and over-sensitivity analysis.

### **Phase 3 Post-intervention follow-up**

Repeat focus groups, utilising where possible the same participants. Recruitment will be identical to the previous focus groups with invitation letter, consent form and sae being posted to the individuals (GPs, patients, students, pharmacists) (annex 4.1, 4.2, 4.3, 4.4).

Questions will be developed from information arising in Phase 2 but the following are suggested:

- Scheme benefits, problems and reproducibility
- Changes if the research is repeated
- The appropriateness of randomising at GP level rather than medical practice

Sessions will be managed identically to Phase 1 except that tapes will be transcribed for more detailed content analysis to identify issues for possible follow-on studies or publication.



## Annex 1

### **Method of dissemination of findings**

The dissemination strategy will be determined and agreed by the members of the project management and steering committees as the results present.

However, in addition to the proposed strategy we will send a bespoke report to the Heads of School and Heads of Pharmacy Practice at all Schools of Pharmacy which outlines how the service was set up, what we have learned from the process and the potential benefits which they can use to negotiate with local practice-based commissioners. If deemed appropriate by the Heads of School of Pharmacy, CUHOPS, we will provide a presentation on the results at one of their national meetings. Additionally we will offer to present the findings to the Head of Education at the new General Pharmaceutical Committee and discuss how they would like to see this information disseminated.

Locally we are planning to present to NHS Norfolk - exact group as decided by the Medical Director and the Head of Prescribing and Medicines Management. Report to be sent to those officers plus the Chief Executive. With the changes currently planned to the role of PCTs the exact method of dissemination will require further discussion with the organisation.

National dissemination within the healthcare and academic community will be achieved via publication in relevant professional journals (eg, Family Practice, International Journal of Pharmacy Practice, Pharmacy World and Science, British Medical Journal, British Journal of General Practice, Pharmacy Education) and relevant conference presentations (eg, SAPC conference, British Pharmaceutical Conference, United Kingdom Clinical Pharmacy Association Conference, Health Services Research Conference for Pharmacy Practice). With the recent dissolution of the UK pharmacy professional body, the Royal Pharmaceutical Society of Great Britain, the Academic Pharmacy Group conference which is the natural dissemination forum for this research has been lost. The conferences listed above are consequently currently the most appropriate within the UK.

In the case of patient groups, we will take advice from the patient representative on the steering group who will be active with diabetes groups at a local level. The most likely route is that results of this study will be disseminated through diabetes groups, their newsletters and national conferences.

## Annex 1

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Annex 1

Appendix 1

Questionnaire for Patients

Now that you have met the student for a consultation we would like to ask if you would complete a short questionnaire. You do not have to complete the questionnaire, and it will not affect your care if you do not do so. But it would help us to see how useful the consultation was and if you decided to do so it would take about 2 minutes. Please tick ONE box one EACH line

Statement	Please tick the box which most represents how much you agree with the statement about the student consultation <b>5 = most 1 = least</b>				
The student was well organised.	1	2	3	4	5
The student had a very professional attitude.	1	2	3	4	5
The student communicated well	1	2	3	4	5
The student showed good confidence	1	2	3	4	5
I was comfortable with the level of knowledge the student had to carry out this review	1	2	3	4	5
The student was an appropriate person to review my medicines.	1	2	3	4	5
I learnt something useful about my medicines	1	2	3	4	5

**Please turn over**



Annex 1

The review of my medicines was interesting	1	2	3	4	5
The review of my medicines was important for my health	1	2	3	4	5
I would recommend this medication review to other people	1	2	3	4	5

Any other comments

.....

.....

.....

Thank you Rick Adams UEA

# SUMMARY PRACTICE INFORMATION SHEET

Pharmacy student led medication review in patients with type II diabetes

NIHR CRN Portfolio Study No 63837  
MREC number: 10/H0306/77

**Chief Investigator:**

Prof David Wright  
d.j.wright@uea.ac.uk

**Trial Manager / Study Contact:**

Mr Rick Adams  
Teacher/Practitioner  
School of Pharmacy  
UEA  
01603 593144  
[Richard.adams@uea.ac.uk](mailto:Richard.adams@uea.ac.uk)

## The Study

**Summary / Aim:**

To establish if 4<sup>th</sup> year Pharmacy Students can provide benefit to patients with type 2 diabetes during medication reviews whilst also providing an opportunity for the students to improve their consultation skills.

**Type of Study:**

Randomised Controlled Trial

**Number of Patients Required:** Four practices – SystmOne – large diabetes registers

160 in total (40 patients per practice)- comprising 80 controls and 80 intervention arm patients

**Inclusion Criteria:**

Patient prescribed non-insulin medication for the treatment of type 2 diabetes for at least 2 years  
Patient willing to provide consent  
Patients registered with one of the 4 Medical Practices

**Exclusion Criteria:**

Patient deemed unsuitable for inclusion in the trial for any reason by their GP  
Suffering from terminal illness

**Sponsor:**

NHS Norfolk

**Funder:**

NIHR (Research for Patient Benefit)

**Duration of study within a practice:** 16 months.(from start of recruiting to final data gathering)

**Planned recruitment start date:** May 2011    **Planned recruitment closure date:** December 2011

**Recruiting in NHS Norfolk only**

**Study requires input from:**

GPs  
Specialist Diabetic Nurses if in Practice

Rick Adams study final RISP version 1 HL/CS/RA checked

Practice Manager  
Database Manager

## Study Activities (Details of process)

Study overview: 3 phases:

1<sup>st</sup> phase: Small groups GPs, patients, pharmacists and students will be invited to join separate focus groups to inform the fine tuning of the project. The focus groups will occur at the beginning and at the end of the project.

2<sup>nd</sup> phase:

A. Recruitment of patients. Patients to complete baseline questionnaire

B. Eligible patients to consent to a pharmacy student examining their medical record, reviewing their medications and making recommendations to the GP.

C. Consented patients invited to UEA clinical Trials Unit to attend face to face medication reviews. Any further recommendations will be forwarded to the GP.

D. Patients to complete follow up questionnaire

3<sup>rd</sup> phase: Repeat of Focus groups to review the study and inform the design of future research

Please note that the study team are planning to access consented patient records to monitor the diabetes control of the patients before and after the reviews – this is likely to take place on PCT premises but will require the practices to open up access ( RA02) to the research teams members- all will hold Smartcards.

### Research Team Activities

Meet with the practice and ensure that the practice have all of the information that they need to ensure the practice is happy to proceed with the study

Provide guidance on the database search if needed.

Provide all of the materials for the mail merge including postage and reply paid postage. Manage the patient responses.

Co-ordination of focus groups (will not happen within the practice)

Tutoring and mentoring of pharmacy students to undertake medication reviews.

Data collection and analysis

Feedback to patients GP with recommendations following the review

Arrange for phase 2C activities at UEA- patient travel expenses will be paid.

### Network Activities

Meet with research team

Development of study summary sheet for practices.

Identification of appropriate practices on Systmone with large enough diabetes registers to meet the likely practice recruitment targets

Engage with practices to take part in the study.

Ensure that practices are paid the service support costs for the work that they undertake

#### **Practice Activities team**

Agree to meet with a representative of the study team to talk through the study to ensure that the practice is in a position to host the project.

Arrange for RA02 form completion to allow the pharmacy students and Rick Adams access to the consented patient records

Carry out database search including manual search by 31/5/2011.

GP to check patient list from database search by 14/6/2011.

One Practice to carry out administration including initial mail outs by 31/6/2011. The aim of the initial mail out is to estimate response rate. This will enable the calculation of appropriate number of patients to mail for all Practices

To undertake a repeat mail out to non responders (4 weeks later)

Main mail out to be undertaken commencing 5/9/2011 and completed by 16/9/2011

To undertake a repeat mail out to non responders (4 weeks later)

N.B. Stamped addressed envelopes will state UEA address

Provide a room for approximately 4 hours on 2 occasions to enable training in the IT system only in the unlikely event that the PCT is unable to provide

Provide access to 2 PCs for 4 hours on 2 occasions to enable students to access medical records and compile care plans. A total of 10 students per Practice will require this and will work in pairs.

Provide a 1 hr feedback session on 2 occasions by a GP or Specialist Diabetic Nurse

To undertake a blood pressure reading, HbA1c test and cholesterol test where a test has not been done and recorded in the patients' medical notes in the 3 months since the patient met the student for the medication review at the UEA

#### **Resources provided by the study team**

Stamps & envelopes (or payment for these)

Printed letter to be signed

Patient Information sheet and Consent form

#### ***Patient Involvement***

Patients will be invited to take part in the study by letter from the practice

Permission to access medical records

Completion of baseline questionnaire (both control and intervention arms)

Permission for 4<sup>th</sup> year pharmacy students to access medical records (supervised)

Attend a face to face medication review with a student at the UEA (supervised)

Completion of end of study questionnaire

Provide a blood sample for HbA1c and lipid profile as well as have blood pressure measured if these have not been recorded in the last 3 months

The patient will need to visit University of East Anglia once during the duration of the study. Each visit would last approximately 1 hour. Travel expenses will be reimbursed by the study team

### **Reimbursement & Support**

<b>Costs for practices - per practice costs</b>		<b>VAT</b>
Set up & dissemination	£272.88	£54.58
Focus Group GP attendance - per GP per meeting	£154.36	0
Recruitment of pts for intervention - initial search & mailshot	£265.30	£53.06
Recruitment of pts for intervention - reminder mailshot	£99.75	£19.95
Intervention costs - to include receipt of consent forms, room costs and facilitation of notes access at start & end of study	£453.15	£90.63
Evaluation of level 2 & 3 medication reviews	£282.99	0
HbA1c, cholesterol and Blood Pressure <b>per patient - if needed</b>	£13.78	0

#### **How is this claimed?**

**This will be paid via the usual service support cost payment mechanism via NHS Norfolk**

#### **Approvals**

Research Governance approval has been granted from NHS Norfolk PCT  
Cambridgeshire 3 Research Ethics Committee ref 10/Ho306/77

#### **Patient Confidentiality**

All patient information collected during the course of the research will be kept strictly confidential.

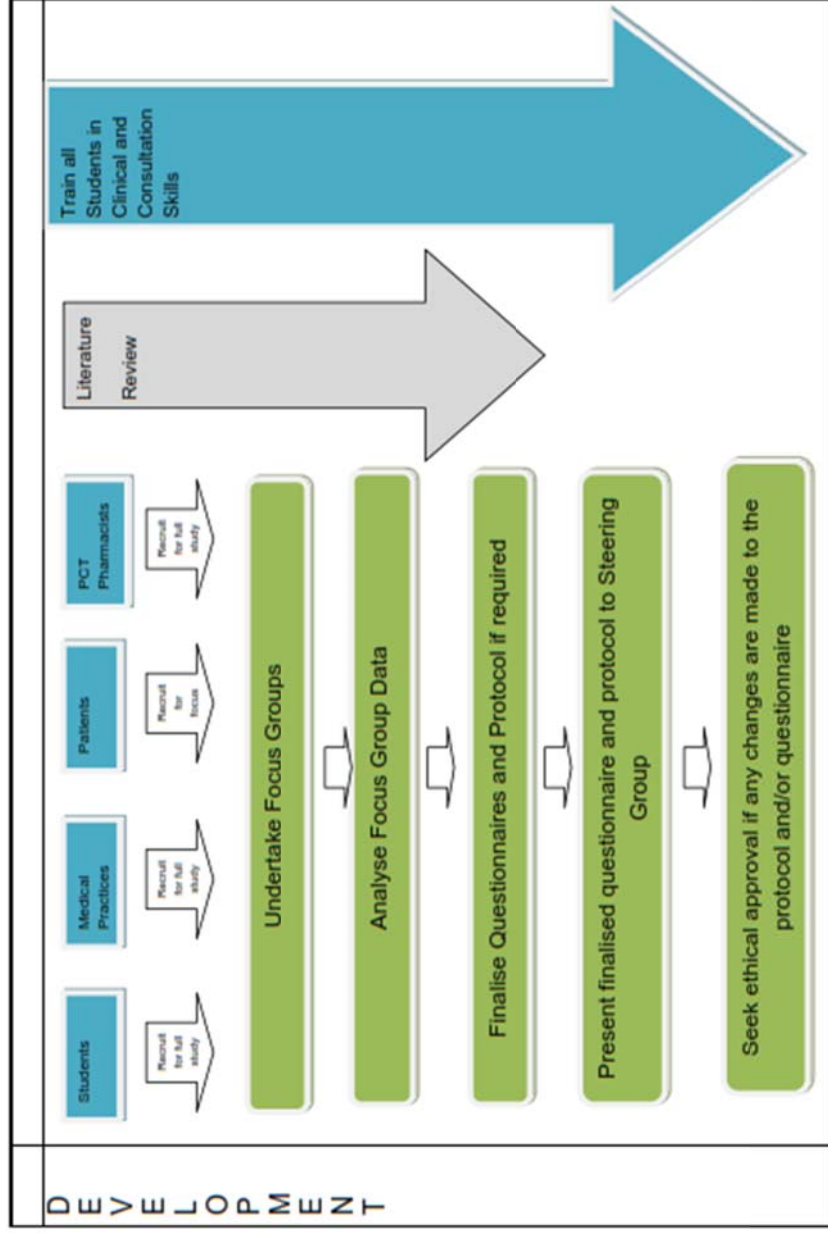
On the occasion that the students access the patients' medical records they will also compile care plan utilising an IT care plan package. This will be stored on laptops dedicated for this research project. Each patient's care plan will be identified only by a PIN. Rick Adams will remove both the laptop and the code breaker for the PINs and lock them separately in a secure cupboards used only for this trial to which only Prof David Wright and Rick Adams have access.

The information will be made available to the student during the medication review at the UEA and then the information will be locked away again.

All information will be stored and used according to guidelines on data protection and confidentiality as outlined in the Data Protection Act 1998.

Your details will be passed to the National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) to inform funding flows.

Flowchart for Supervised pharmacy student led medication review in primary care



I N T E R V E N T I O N

Recruit patients –initial recruitment to determine

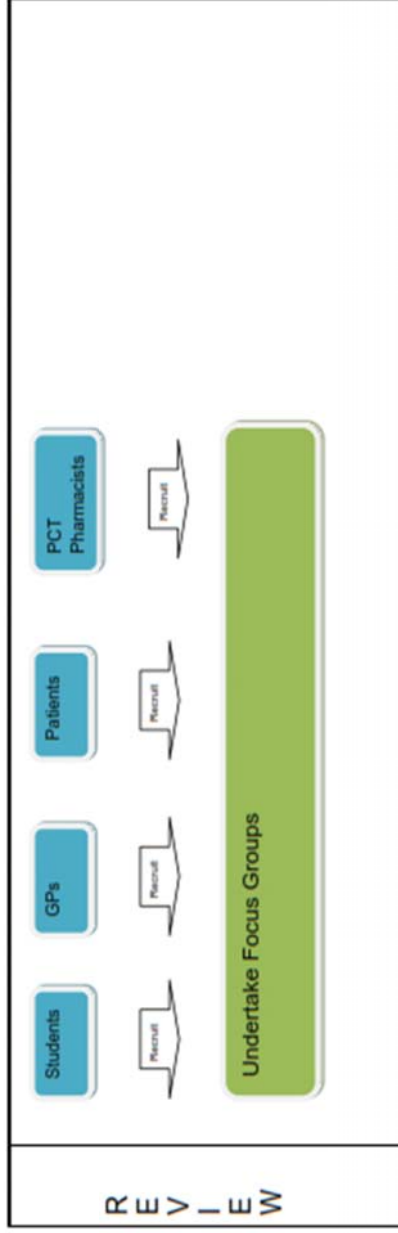
Main patient recruitment and posting of baseline questionnaires

Medication reviews by students at GP Practices

Consultation with patients by students

Follow up questionnaires

Training of participating students in Database, IT Care Package and with 'Dummy' Patients





# Appendix C: Development Stage

## Focus Groups

Medical Practices

Students

Pharmacists

Patients

## Focus Group Introduction – GP Practice Staff

### **Introduction**

Thank you for sharing your time with us and for attending today in order to help us make sure that the design of the research is the best possible.

We need to ask for your views and opinions in order to make sure that we do not miss anything or that we do not try and undertake activities which would be a problem for you or other participants. Our feeling is that it is important that as researchers we do not assume that we have got automatically it right, and your views will be used to help us decide if we need to make changes. If we do need to make changes we will go back to the research ethics committee (which approves research)

The Focus Group will last for 1 hour in total including this introduction. I will ask a series of 5 or 6 questions and may follow these up to check that I have understood correctly. There is no right or wrong answer, so do not worry about getting it right. Your views are what we want.

I will audio record the session so that I can go back and check what was said as it is very difficult to run the session and remember everything. Nobody will be identifiable from anything that we may later publish in relation to the research. I know that you have all signed consent forms but is everyone still willing to be recorded?

I will try to make sure that everyone has their chance to speak but please respect the views of other participants and if you want to speak but have not had a chance please just let me know.

Once again thank you for attending and now I will give a very brief overview of the study.

## Questions

1. Having read the information about the project do you want me to clarify anything?

Follow up might include

This is not an MUR – I will explain the difference

Do you have views about pharmacy students accessing patient notes?

Is it a good idea or not?

Do you think there are any benefits for patients?

Do you think there are any concerns for patients?

Is there anything good?

Could you explain that (or give me more information) please?

Can you give me an example?

Why do you think that?

2. What are your thoughts about the student preparation training?

Follow up might include

Will it prepare them for the intervention?

Is the content of the correct level?

Is there anything missing

Any other thoughts?

Is there anything that needs missing out?

3. What are your thoughts about the practicality of undertaking these sessions in GP Practices?

- a. First session to obtain data from medical records

- b. Second session when the student meets the patient

Follow up might include

Please explain that further

Is the GP Practice the right place or should the student meet the patient at the UEA or elsewhere

What changes would you recommend?

What problems do you envisage?

Are there any likely benefits for the Practice or your patients

4. If the study of 4<sup>th</sup> year pharmacy students undertaking consultations (specifically medication reviews) with patients shows benefit do you have any views on its' roll out

Follow up might include:

Are they appropriate people to do this?

Are your views affected by current MURs?

Do you have any particular thoughts about how the session should be run?

Do you think that this is something which should be done?

4<sup>th</sup> October 2011 Meeting

RA: So okay, I've given you the background, first question is a simple one, is there anything I should clarify about the project, anything that doesn't make sense or that you're not sure about?

N: How long is it going to go on for?

RA: We've started the first bit of the training, so the students have, well half of the students have had system 1 training and the first students will see patients November, 23<sup>rd</sup> and the last patient will be seen January, 23<sup>rd</sup>. As far as this individual practice is concerned it will be four, may be five, sessions. This is not an MUR, have you had much experience with MURs coming?

N: No.

RA: (Unclear).

N: What's an MUR?

RA: Medication use review.

N: No.

RA: Okay, that's interesting that. Because okay this is at a higher level. Do you think it's a good idea or a bad idea that we this?

N: I think it's a good idea. I think there will be a crossover where patients will, they don't always say what has been said in our consultations, so I think there may be a bit of, the students are going to really figure out which ones are kind of pulling the line a bit and kind of saying things that perhaps haven't been said in our consultations, because we find that between ourselves they'll do that. So they'll come and see me one time and then they may go and see Jenny another time, but what I've said won't necessarily go to Jenny or what Jenny's said won't necessarily come to me so they will not always be absolutely correct in what they are saying about previous discussions about medication, or it's just they'll misunderstand what you've said, or misinterpret it, or take their own view on what, they will take what they want out of the consultation and they will feedback whatever they choose, so I think people need to have an awareness of...

RA: And do you have a strategy generally for dealing with that?

N: Always look at what the last person wrote.

N: Yeah, it's looking back and also we know the patients and we know what's normally been going on and we're lucky because we can feedback to each other regularly and we are literally opposite each other, so any problems like that then we'll go oh I'll just have a word and we'll get them for you, I didn't actually say it like that did I?

N: Not today.

N: Yeah.

RA: So do you think there's an issue in terms of the student, well I think there's two issues possibly. The student consultation, so the student actually getting the right message – do you think they might get the wrong message?

N: Yeah, I'm worried about the wrong message and also some of the plans, some of the medication plans that we have are ongoing, dependent on how well controlled they are, so it can be ongoing and it can be that we are actually trying to achieve an end result but slowly because people won't often, you know you can't, people don't like the idea of taking medication so sometimes we have to really gently, gently with them and so we may be just trying to be very careful with that person because of the message they've given us in clinic, so sometimes we might

be very careful with the plan that we've got in progress to get an end result that we just have to be very careful with how we are going ahead with a plan.

N: Obviously it's, unlike students, it's not all black and white because we're dealing with patients with different expectations of what they expect from us and different expectations as to what can be achieved and what they want to do and quite often...

N: ...and past history as well...

N: ...and past history...

N: ...experiences...

N: ...and you won't always stick to a plan very rigidly because something, you know you might say oh well if this doesn't suit we'll start this one next line, but if you find your patient, being an individual, is not going to suit that particular one then you try a different drug, so it's okay having the students coming in to say well you should go in there, step one, step two, step three, step four and then they suddenly find we've gone a different way and there's a different thinking behind it as to why we've gone that way, unless we've actually documented every single thing, because we normally know why we've done something, we can read between the lines, but you know if you've got students coming in that don't know these patients and aren't used to these treatment plans then they just may find they're in deep, deep water as to wondering why. And the other thing I'm worried about, in fact they say oh well you shouldn't be on that, you should be on this and that is another worry because they'll just come back to us and say oh well they said I shouldn't be on that...

N: ...and that's the other side that I'm worried about is them saying they said to us, and then come back us and say they said, and you do have to be very careful to be very clear and to be not actually putting us in a position where actually we've been trying to build something for a little while for it to be knocked back down again, you think (unclear) you've just tried to get them on to some medication because they're out of control and then it...

RA: So are there any particular messages we need to give the student?

N: Read the notes.

N: Yeah, definitely, read the notes.

RA: So the key message is read the notes?

N: And get a feel for the patient before, if you know you might find that it says there will be a lot of intolerances or something on the screen and you just know to be careful with what you're saying and how you're saying it because it sometimes they just don't like the idea of medication.

N: I think it would be useful to know what's written in their script, to know the kind of questions that they're going to be asking the patients.

RA: Okay.

N: Would that help you?

N: Yeah.

RA: I can share copies of the care plan with you, if you like?

N: I mean is, a real basic idea of, one of the things I'm thinking of is, I had a lady that last week I changed her insulin ever so slightly, I changed her lunchtime one and it was because she was getting hypos at night so I've written everything up in her notes, put her down as a telephone call with Jenny this afternoon and when Jenny phoned her

she said, I didn't start that lunchtime one because I didn't know what dose was to do and I didn't know what to do with the other two doses of insulin that I'd had even though I had gone through that really clearly with her...

N: ...and you'd written it all down in the notes...

N: ...and I'd written it up, I'd gone through that clearly with her last week, she hadn't got back in touch with me, she'd waited for Jenny to phone today and then said well I wasn't clear. Well I know that I went through it and I know that I was very clear, but Jenny didn't get that story today from her and it's that kind of thing that they need to be aware of really to just be very careful. And sometimes it's that, you have to not sometimes, people get a really kind of positive feedback from that, if you start going God that's really bad, isn't that bad that you didn't know that, oh God, they should've thought about that when they, it's not feeding that kind of, because normally it's not what has happened...

RA: So you've got concerned about may be, am I interpreting this right, that you've got concerns about the student making a patient lose confidence in yourselves?

N: Either lose confidence or feed something that...

N: ...confuse them even more...

N: ...yeah, I just think some of them can get off a bit on a bit of controversy and, do you know what I mean?

N: ...hmmm...

N: ...and it's just not feeding that.

RA: And you said read the notes...

N: We put everything in the diabetic notes... everything.

RA: ...is there anything else that we could do, in your opinion, to may be mitigate this?

N: I don't know really...

N: I don't know, I think (unclear – talking over each other).

N: I think the script may be a good idea... I think that's a really good idea to get a copy of that so we know what kind of things will be...

N: ...and it's also going to be different personalities of your students as well, you see, I've had experience with student before when they...

RA: And what sort of student (unclear)...

N: ...well, student nurses to start with, I had one experience where we had a chap who had been dealing with a really bad leg ulcer for years, and in fact he was due for an amputation, and so we tried every dressing under the sun to get this healed and he'd been up to the clinics and what not, and this student came in and she was helping me with this dressing and she just looked and she said I can heal this for you, they're using all the wrong dressings. Well, she shouldn't have said that, she hadn't read the notes, she hadn't seen the list of dressings he'd had previously, as a student she had no right to do that over an experienced nurse and she wasn't in the good books, she found out when that patient had gone (unclear).

RA: Okay, so am I reading this right, you would like us to give them, when you say script...

N: Not... an idea of what they're going to be asking and saying and how they're going to be I suppose running their consultation really, well their ideas on what they're going to be...

N: I guess what I'm trying to say is that so that after the sessions with the patients, then if they've got a script they can kind of glean how the consultation would have gone as opposed to it just being kind of a free consultation if you like, if there are set questions and they know...

RA: ...and certainly it is structured according to a care plan, certain information to gain and then interpret into actions... do you think that sort of thing would help? Do we need additional information?

N: I guess from your point of view if you knew what kind of questions were being asked at the outset and then the patient comes back to see Sam or Jenny, they will then know, because will they be actually then putting their information on to the system? Well, they will be I guess, or are they just navigating around to get information?

RA: They've got read only access.

N: They've got read only.

RA: Would you like, in fact, that's led on possibly to another question, would you like anything put onto system 1 and if so by whom? And at present we haven't planned putting anything on system 1.

N: I suppose if they're writing it, it could be scanned on anyway, couldn't it onto the patient's notes if they're writing a care plan...

N: ... yeah...

N: ... then it wouldn't be in the main journal, would it, that way?

N: ...no, and I think you could then miss vital information.

RA: They are in fact feeding back issues to, well would it be yourselves?

N: Did they want, would it be interesting, would it be of use to them or us or anybody if they spoke to us before they saw the patients to kind of to just go over anything like is this done for a reason or did you choose this pathway because or is that...

N: That's a design of the study is to see whether or not this intervention with the pharmacists leads to a different pathway.

N: Okay.

RA: Well, there is a, there are a number of safety valves, so to speak. There is a pharmacist supervising whilst they are accessing information and whilst they are seeing the patient, but they access the patients' records and discuss issues with doctor and nurse at the end and if the doctor or nurse wishes they can either accept or reject and if they accept then it's up to them if they action it and then after a gap they see those patients, so there is a gap in between accessing the record and seeing the patient. If anyone has concerns then they can feedback and certainly we would welcome that.

N: So I guess the question is still what happens to the consultation that happens between the student and the patient in terms of system 1, where does that information then go?

RA: Well currently it isn't planned to go on but do you think it should?

N: It's always nice to know what somebody else has said, you know because one we're responsible for a treatment plan of any kind...

N: ...because it still would be (unclear)...

N: ...and some ask that they'll be taking, won't it...



N: ... and somebody's advised them something differently and we don't know anything about it, it's a bit like getting patients discharged from the hospital without a letter, we're working in the dark and wondering what's going on.

N: It could be put in some sort of discussion, couldn't it? Discussion between patient and...

N: ...hmm, I think it would need to be clear on system 1 that it is part of the student-led pharmacy review.

RA: Now, one thought that comes to mind is that, as I said on every occasion there's a pharmacist supervising, and all the pharmacists will have smart cards and access to system 1, would you want the pharmacist to input something, may be even head it consultation with student as part of research project?

N: What we could do, because it's only a temporary thing, isn't it, it's not going to go on for very long, is on our template we could put a heading there saying...

N: ... because it's short term, yeah...

N: ... yeah, for what study it is and then they've just got to tick the box and then they can write...

N: ... yeah, so we could get Dave on our diabetic template, if we get Dave to just put a consultation box specifically for the study, then it would have its own read code, wouldn't it? And it would come up as its own separate thing...

N: ... yeah, and you just tick the box and then you can actually write in it...

N: ... write the consultation up, yeah.

RA: Would you want the student to input it under supervision or the pharmacist to input it, according to what they have seen?

N: There's going to be a pharmacist with them every time, I don't know... I suppose if the pharmacist is taking over all responsibility, then they should be the ones to put it in...

N: Unless whatever they put in is supervised, it just depends...

RA: I mean certainly currently the plan is the students only have read only access for lots of reasons.

N: I guess you probably need to check with Kevin first...

N: ... yeah, that would be, yeah...

N: ... what he would be happy with.

N: I'm sure you would need some sort of documentation, wouldn't you, just so that we know what's been said?

N: It's patient safety at the end of the day.

N: And they'll feedback to us and it'll be interesting to know what the students said so that we can either back up what the student has said or you know say actually well we're going to carry on with our previous plan, this is it, so it would be interesting just to have a knowledge of what they're saying.

RA: Okay, now, this has raised another thought in my mind, something that we haven't thought of before. Would you, as healthcare professionals responsible for the care of these patients, wish to at any stage to be able to give feedback? They will have face to face feedback with an individual, but would you want, when you later see the patients to have the possibility for feedback or would it be of no value?

N: Feedback from who? From the patient or the student?

N: From the student and their experience?

RA: No, from myself, if there are any particular issues.

N: I'm not quite sure what you mean.

RA: So if, for instance, a student sees patient A and that's one of your patients and they then say a fortnight later come and see yourself and you find that there are issues, either good or bad, would you want to feed those back or not?

N: I think it would be important to feedback, you'd want to know, wouldn't you?

RA: It's something we hadn't thought of, to be honest. Do you think that would take much of your time? Would it be a practical thing to do?

N: I think if somebody had a particularly good or bad feedback I think it would be nice to feed it back, and so I would take the time.

N: So when you say feedback, you mean feedback to the student?

RA: To us, well I mean we can then feed that to the student.

N: Oh definitely, I wasn't quite sure where the feedback was going to.

N: Definitely.

RA: We'd obviously have to maintain confidentiality so we'll have to think about the practicalities of it. Okay, so without putting words in your mouth, you're saying that you think feedback at any point, if you see issues, you would like the capability to do that?

N: Yeah.

N: Well I think of both, if they're being seen, what was it, four to five times in two months...

RA: No, they're literally being seen, the student's actually only seeing the patient once.

N: So where did the four to five sessions come in?

RA: It's the number of sessions in the practice over all the students.

N: Oh, I see, sorry.

RA: Being a pilot study, it's very small numbers.

N: Yeah, I think that feedback after that session is vital.

N: Yeah.

RA: Okay.

N: You'll have to excuse me because I've got a patient due at 2 o'clock.

RA: Thanks for your input.

N: Thanks for coming, Julie.

RA: Okay, so we've discussed some of the concerns, do you have any other concerns? I'll go on to more specific things later.

(No response to this.)

RA: Do you think that there is anything that we should say (unclear) or benefits, or...?

N: I think it's a really good idea. I think trying to get the students to get more involved with the...

RA: Can I ask why?

N: Because I think it's really important for patients to feel able to talk to people and go through concerns with people and if people aren't able to consult well it leads to a dead end really, so I think it's important to...

RA: Can I go on the pieces of paper with the blue on, the student training, do you have any thoughts about that? About the information in it, the content, or is anything missing?

N: Would the pharmacy student be discussing guidelines as such and is that something that patients would absorb?

RA: When you say discussing guidelines?

N: It says (read from sheet in front of her) including relevant guidelines.

RA: Right, what they're getting is background clinical information. They've already had teaching in the subject of diabetes, but they're having additional information, which includes obviously things like NICE guidelines, etc, but I'm not sure that they would specifically say to the patient I'm going to discuss NICE guidelines.

N: I'm thinking about the sort of complexities of some of the patients and the age population and etc if that information, especially at the outset, would kind of drain them before we've got to the meaty, see what I'm saying?

RA: Can I check that I'm absolutely sure on this, that are you saying if the student has a discussion with the patient about guidelines that that would distract?

N: I'm just saying it might, I don't, Sam, if given your population of patients that you see do you think that would be a problem?

N: I don't know, it really depends on the patient.

RA: I mean to some extent I would hope the student would use this information in the background to guide their actions, would that be better? Or not?

N: Yeah, so it's tailored for that individual person, once they've read up on their history and their current regime.

RA: And in fact something that is a recurring theme is tailoring and in fact not only tailoring but looking at the patient's information, is that right?

N: Yeah.

RA: So you obviously hold those views quite strongly.

N: Absolutely, yeah.

RA: Which I don't agree with, sorry don't disagree with. So is there anything that you think is missing in the training?

N: Compliance.

RA: Okay.

N: Reasons for compliance in terms of their understanding that if they are given a regime to take at x and y points during the day, why it's important to do that. And I don't know if it's useful for patients to know in very, very simple terms how the body works in terms of the drugs that they're taking, in terms of compliance and linking that in.

RA: Do you think there would be a benefit then?

N: I do, because I sometimes draw little diagrams of boxes and little arrows to explain in my line of work how the study works, what's going to happen and when they're going to take certain drugs and come back, etc, etc but it's very, very kind of simple use of drawings and I find that that information, along with any kind of wordy document kind of helps with the process of understanding in terms of, because obviously if you've only studied compliance as a major issue, as is taking drugs, etc, so I just wonder if that may be useful.

RA: So make sure we emphasise compliance. Make sure we emphasise giving simple information about mode of action of drugs? Yeah.

N: Hmm.

RA: Okay. Any other comments about that before I, or should I move on?

No response to that.

RA: I want to ask about the practicalities of the sessions in the GP practice, so there's two. The first one is where students will come to the practice and access medical records on patients. So do you think there are any practical issues there? Are there easy or hard, or good or bad?

N: No, I think once it's been you know times and dates have been organised then I can't see a reason why there'd be any practical issues.

RA: The second session is where the patient meets the student, again any other comments about the practicalities or problems or benefits?

N: No.

N: No.

RA: So that's fairly easy then. Do you think that there is likely to be any benefit for the patient?

N: Yeah.

RA: Can I ask what you think the benefits might be?

N: I knew you were going to say that!

N: There's no such thing as a free lunch!

N: Absolutely not! I think it will be nice but for the patients I think it will benefit them in hopefully confidence in their medication, you know don't really like them taking medication and hopefully it will give them some confidence in you know they're taking care of their health and the medication they receive here.

N: I think if two separate groups of healthcare professionals if you like are saying the same thing, hopefully, then, like as Sam says, patients are going to feel much more, I'm sure they feel confident anyway, but if two separate groups of people are saying yes the regime that you're taking is exactly that's right for you in line with NICE guidelines etc, etc, then...

N: ... absolutely, and, and you know if something new was picked out, somebody thought something different that would appear to be something that people hadn't thought about and it was going to benefit the patient with their care, then brilliant.

RA: Can I just check something that we were discussing earlier before we started, do you think the GP practice is the right place for the patient to be seen rather than the UEA?

N: Yeah.

N: Often that's a really good decision, a changing decision, because it's a place that they know, it's a place that they feel comfortable.

RA: I was going to say, so it's comfort and...

N: It's symbolic to them in terms of their healthcare, isn't it? It's the same place.

N: I think it will give them confidence in speaking to somebody as well you know that we've accepted these students in, it kind of makes it more reliable and you know I don't think people would necessarily openly speak about their health outside of, I think it's somewhere that they know, they've confidence and they'll talk about their health probably more easily than they would.

N: Do you think a bit of a less them and us type of feeling in their minds?

N: Yeah.

RA: I mean one of the initial reasons for changing it was logistics, travel, but something that is coming through is (unclear) about being the right place, not just getting there.

N: Probably geographically for them, the patients are within an x mile radius to get to the UEA, it probably isn't from here, but it mustn't be difficult but it's just probably not that easy either, and it's a strange place for them.

RA: Okay, so we're getting through the questions quite well. If, assuming that this project shows benefit, do you have any views about its roll-out? So do you think it should be rolled out as a future scheme or do you think there'll be problems?

N: I think pilot studies do just that, they tell you exactly where you can improve on things and if something is going to work or not based on sort of early kind of responses from patients and the students, but I think you know it's such a good idea that you know to roll it out to other Norfolk practices, and perhaps beyond, is something to definitely think about, but I think there probably may be a couple of teething problems, just based around the kind of what we were talking about earlier in terms of how're we going to communicate what the students glean and communicate that back to the practice, how we're going to do that and how is that going to work and what's the best way around that.

RA: Okay. Do you think students are appropriate people to actually do proper medication reviews with real patients?

N: If it was something that, if the student gave an opinion that we might agree with, I think that we'd be able to sort that out anyway, I think we could soon sort any glitches out with the patient if there was a problem, but I don't see why, I mean it's not going to be an official medication review as that's where it will come to an end, we would still carry on doing our medication reviews, as would the GPs do their one so it's a good learning curve for the student, isn't it?

RA: And if, extrapolating so much further forward, assuming everything is fine and we've sorted out all the problems, do you think it would be appropriate on a regular basis for final year pharmacy students to come out from the UEA to places such as this to undertake medication reviews with patients?

N: Unsupervised? That's a question.

RA: Well, no, I mean, when you say unsupervised are you saying that you think it should or shouldn't be?

N: I think if you're thinking that, if I get right what you're thinking, you're saying do you think that if we were to roll this out in the future that the final year pharmacy students would do the consultations, I'm not sure if that's appropriate because I think until anybody that's going through any kind of medical training is qualified, thinking about it, if I was a patient and I had a final year student making decisions on my care, etc, I possibly wouldn't have the same confidence, rightly or wrongly.

RA: No, it's your opinions that I'm after. Would you have a different opinion if they were supervised?

N: Yes, rightly or wrongly, yeah, but that's my personal view.

N: I look at as in until you've got that bit of paper to say you're done and dusted, it's them having, would they want that on their shoulders before they're actually qualified, the responsibility of doing medication review and...

N: Every patient wants to have confidence in the person that is a practitioner at whatever, whether it's a nurse, doctor, pharmacist, everybody wants to have confidence in that practitioners and one would like to understand that that practitioner is you know got the certificates and sat exams and passed them.

RA: And in fact it raises a question in my mind that (unclear) a medical or a nursing student out here and are they supervised?

N: Yeah.

RA: So that's possibly answered the question.

N: Yeah they do supervised time...

N: They wouldn't make any decisions...

N: No they wouldn't make any, no, I mean the medical students come out and we would get patients to come in with specific problems for that specific group, so say for instance, in a couple of weeks I'm doing a vaccination morning and I will have students coming in and out and they just will be observing me consulting and vaccinating so it's all dependent on their level, but they, in general they aren't actually making any decisions, it's kind of basic learning that they're doing really, isn't it, on consultation and blood pressures even, chest examinations, they'll come out and learn those here. They don't actually have a clinic.

RA: And following on from that comment then, do you think it's appropriate that, and this is something that we haven't particularly planned, but would it be appropriate for pharmacy students at earlier stages to come out and do, undertake duties or observe things at a lower level. My interpretation there is that you're saying that nurses or medical students come out and gradually build what they're doing. Do you think there's any, no, do you think pharmacy students should do that or nor? Or would they just get in the way?

N: They wouldn't get in the way, would they? Because it's just a...

N: ... Yeah, from an observation point of view I think it's something that'd be really useful.

N: The UEA are trying to sort of build up with the nursing students where they will actually, they're hoping that they will get placements within general practice and that those placements as they go through their training will become more independent so at the end of their course they could perhaps do certain clinics where they see certain patients, say a hypertensive check or something, and they'd be able to do sort of a basic review on them by the end of their training, so they're trying to figure out how they could bring student nurses into general practices

N: I think it would be good to glean what their current trends are if you like in terms of diet, lifestyle, etc. Yes, this will already have been captured by you when you do your diabetics reviews...

N: ... I think it's important that anybody who is in contact with people with type 2 diabetes, I think they do need, you know, need to go through it, it's so important I mean we know that it's the mainstay of the care really, they need to be looking after their health and I think any opportunity to promote that needs to be taken, doesn't it?

N: Hmmm.

RA: So you'd like them to do that?

N: Yeah, because I think as healthcare professionals in whatever capacity, you kind of, that kind of comes under everyone's umbrella, whether or not it's, because you can't really get away with it, or get away from it, sorry I didn't mean that, you can't really get away from it because it forms such a big part of everyone's healthcare, no matter what disease area.

RA: It's something they all practice in all we do, but I'm not sure it's the same depth that you do or not.

N: I'm just wondering if that would help with the kind of you know the compliance as well as all the other topics you've got listed here.

RA: So you're looking at a question in the training schedule there, do you think we should give another short module in terms of information to the student about diet and lifestyle?

N: I think it is, as Sam says, a really good opportunity to promote a really important aspect of their life.

N: They do need it, you do need to go over it again and again, on every consultation with our patients we go over it every single time, what's your diet like, have you increased your exercise, are you still exercising, well done, you know it's like positive reinforcement where you can, which we definitely try not to be negative about things but it's that kind of reinforcing every single time and we do try and get, we try not to encourage them to think that their medication is there in place of diet and lifestyle measures so I think it's important that they know that you know yes they talk about medication here but actually these other aspects are still as important and so it would be nice that they knew that this person is thinking that lifestyle is as important but we're now going to talk about medication as well, so that that is constantly at the forefront really because it's so important that they don't think the medication is going to sort them out.

RA: Okay, you've raised an important point there, so that's great. Is there anything else that you want to raise that I haven't asked, because that was a good one?

N: I can't think of anything.

RA: Okay. End of tape.

Meeting held 11 October 2011

RA: So the first question is, having read some of the information and having had the explanation about the project, is there anything you require clarified?

N: Not at this point, no.

RA: Something that has come up at other locations is the difference between this and MURs, do you get many MURs from local pharmacies, Medicines Use Reviews?

N: No.

RA: You don't? Interesting.

N: I don't think so.

RA: Because in fact the issue in other places has been that the...

N: What's the difference?

RA: Well people have worried about it but in fact they are of a lower level than, so if you're not getting them, then it's not a problem.

N: Not as far as I know.

RA: Do you think it's a good or bad idea that we're doing this?

N: I think it's an excellent idea.

RA: Can I ask why?

N: I just think it's one of those, utilising the skills that somebody has got, I mean I know you're teaching these to become, so I do, I think it's a, I also think that pharmacists probably come at things from a different angle to doctors and nurses that patients are used to getting so I think that, yeah, I think it's a very good idea. Utilising the skills that you're trained to use really.

RA: We spoke earlier about patient benefit, so I told you if I thought there would be but can I ask if you think there's any benefit?

N: I think there is potential for it definitely because I think perhaps they will, I mean certainly just from pharmacists I've talked about who talk to patients about other things in their life to do with their medicines, the food that they eat and those sorts of things, and also the interaction of all the tablets so I do think there's going to be potentially massive benefit to the patient. One of the pharmacists who comes here periodically wanders round her local supermarket saying to people I don't think you should have that because you're on a statin you know to things that are in their trolley and stuff so yeah I do.

RA: So will this may be get in the way of the work of specialist nurses such as yourself and doctors or not?

N: I think that that's a concern because I think everyone's worried about their job and somebody else taking over their job, but I think it's complementary to what we do and I think it is, it's another place for people to visit as well, isn't it? We're trying to make healthcare etc accessible to people so going down to their dispensary and talking to their local pharmacist about the drugs that he dispenses or she dispenses to them all the time, no I think it's complementary and it's all for the patient benefit to be honest.



RA: Okay. One concern that was expressed at another practice was that the students, when they're out here, might say something which contradicts something the doctor or nurse has been doing and/or saying, do you think that is a risk and if so is there any way that we could mitigate that?

N: Are they going to be, is somebody going to be supervising them when they are actually doing it or would it be taped or how will that...?

RA: Both in fact. They will be supervised by a fully qualified pharmacist...

N: At the time?

RA: Yes. So that will either be myself or a PCT pharmacist.

N: Right, because I think that essentially if there's somebody there who's qualified then if they say something wrong that's going to be picked up at the time and presumably corrected if it's an issue, real issue wrong, but otherwise I think we all contradict each other, sadly, all the time because there is still a lot of opinion in medicine, isn't there? Even if there is you know you try this and you try this, there's still an awful lot of opinion so I do think that patients are possibly fairly used to a bit of contradictory advice, but there could be different advice that's not wrong, so as long as it's picked up at the time, if it's wrong and the patient doesn't go away with wrong advice, then people do contradict... I mean one of our GPs told somebody to start smoking again because they were so stressed at quitting smoking, I mean how can that be right when you've got somebody else, you know, so, you know I think so long as they're not being given wrong information.

RA: Okay, and should they, in your opinion, go back through records and see what other people have said and to try and avoid contradicting or ...?

N: I do think that that's always helpful because I think if you go back through records you might find why somebody's, for example, some big fat diabetic's not on Metformin, because if you go back through the records there may be very clear documentation as to why they're not on Metformin as opposed to saying you should be because it's the first line for x, y and z, so yeah I think going back and having a look through what other people have said is a good idea. Because again if you overtly contradict somebody they immediately they might not have some confidence in what you're then going to go ahead and say.

RA: Okay, yeah, makes sense. We talked about the training...

N: Yes.

RA: ... the duration is that as I said they had a number of podcasts over the summer, they had a half day training session on system 1, a half day care planning, half day consultation skills and they'll all have a practice session with actors taking the place of patients and then they'll proceed to the practice. Have you any thoughts about the training?

N: I've got no idea.

RA: Okay.

N: I think it sounds like a rounded training but I think you've just got to go and do one and see whether it was...

RA: And do you have any thoughts about whether it would prepare them or do you think that is sounds like it's long enough or any gaps or...?

N: I mean I think it sounds like it would prepare them but as I say I don't think that until you've actually done a consultation with a patient you're really going to know whether it did or didn't, it's a difficult one, isn't it? And I think I'm sure individuals will be different as well as to...

RA: And as a specialist nurse who undertakes consultations with patients, are there any particular skills that you think that you know you have to use that we should make sure that they have?

N: I think a lot of the time when we're talking to people, there's a lot of negotiation with you know I might sit here and think well I want you to have this, this, this and this but we're not going to get there today and you may have other, and patients have their own ideas already what other people have told them, what their neighbour's told them, all that sort of thing, so I do think that eliciting somebody's health beliefs themselves, finding out what the patient thinks and believes is a good place to start. And I do think there is definitely some negotiation, I mean this is the benefits of being in primary care, isn't it? Because it's a bit of a process that you would like them on these things, but you're going to gradually get there as opposed to necessarily do that on day one.

RA: And that is an interesting comment, so really you're saying a negotiation is not a thing just for today, it's a long process?

N: Absolutely, and I think sometimes working here and living and working in a similar place, you have this conversation with somebody who's got x disease and y disease and you want to this that or the other and then you go out and you see them on their bike chatting to their neighbour down at Roys or something and it just suddenly makes you think actually do you know that's a real person and I think sometimes you, probably especially when you're a student and when you're training, you can just forget all the other things that they do and you know, do you know what I mean? You can get very focused on what's the matter with them and what you want them to do as opposed and also you see a lot of people don't want the side effects to all their tablets, do they? Because they can't get on their bike or whatever so I think remembering that they're a whole person as opposed to just a...

RA: Okay, that's an interesting one and the side effects thing I find interesting.

N: Well I just think particularly for people like, I mean perhaps not so much diabetes, but certainly for things like hypertension if you discover somebody has hypertension and over a period of time you diagnose them with essential hypertension usually they've got no symptoms of that disease and you suddenly start giving them tablets that they could have, you know so you've got this completely riled person that you're trying, and then you're making them have a blood test and la la la and you know it's, a lot of people aren't that keen

RA: Do you have any particular techniques that you use to sell that?

N: Erm, again talking about their understanding of the risks of disease, so again if you go back to diabetes and things like Metformin and the side effects with Metformin, if you're talking to them about their diabetes and what the potential implications are if we do nothing and that we're trying to keep you well and really, really telling people about what the side effect might be, because people tend I think if they get them they think well this is all right she told me that, that is fine, I know that. It's more about if something happens that they are unprepared for that they might be more alarmed. So being truthful and honest about things they might because, I just think that they're more prepared and they are less likely to say oh god that's awful and stop taking it. They can read the literature at the end of the day anyway, can't they? So you might as well tell them.

RA: And the comment about beliefs...

N: People have unusual beliefs, weird beliefs because they can be told something like you that their sister tells them but a doctor tells them something different but they still believe their sister or their friend, and that's people unfortunately, or Hilary Jones might tell them and they'll believe him off the telly.

RA: So we have to make sure that...

N: You kind of want to know where they're coming from, don't you?

RA: They ask basically about beliefs and they use that really as part of the negotiation process?

N: Yes, and their understanding of things, I think so.

RA: And side effects are important?

N: I think they're very important because if I think if you forewarn people then they know and they are not worried and they're not anxious and you if you say to somebody you may well, say Metformin, you may well have you know windy, bloaty, you might be a bit loose but it'll hopefully settle down by the end of the first packet may be, or something, you know, then they might think well that's what I'll do, I'll carry on because that's what she said.

RA: It's an interesting one. So we're hoping to bring the students out to practices. I'm interested in what you think about the practicalities, are there any problems or things that we need to do or you know will it just run smoothly. So there are two sessions, so the first one is where we bring the student, or sorry a group of students to a practice and they access the patients' records, do you see any practical issues there?

N: No, it shouldn't be, I mean there are some days that are a little more difficult but because of the health education room that we've got with the computer access up there, it shouldn't be a problem at all. If you physically want a room, you know an individual room, then that's you have to think about that on the day that you're coming, but...

RA: And do you have any concerns about students accessing the records of real patients?

N: No.

RA: Good. Okay. And then of course the second session. We would aim to bring the students to the practice. Originally we were going to invite the patients to the UEA. Which way would you go, UEA or here?

N: Here, definitely, for our practice population, the UEA is a day trip.

RA: And is it simply logistics, you know, travel?

N: Yes, I think so, yeah. I think it's probably easier just to invite them to their practice. I think if they're seeing that we're involved in this, people feel much more comfortable about something, but I think mostly it is the fact that they just wouldn't be particularly keen to travel, because why would they?

RA: Yeah, true. And the other thing you mentioned there is something that I've had mentioned in other places so do you think there will be a confidence issue imparted by being in the practice?

N: Yes, I do, yeah. We have a variety of private clinics here and although we advertise them in that they have, there's a private thing where they put their literature and that sort of thing, I'm sure there is an implied belief that we support them because they are physically in our building. I mean clearly we wouldn't have somebody who we disapproved of in the building...

RA: ... hopefully not...

N: ... but yeah, I'm sure that there will be a feeling that actually it's all right because it's here, I'm sure there will be. Whether that's good or bad, I don't know.

RA: We've also had comments about whether the student or patient or both may feel that it's a more real situation. Do you think is?

N: Being here rather than at...? Yeah, probably.

RA: We should therefore forget any ideas of having the clinics at the UEA in future?

N: I think on the whole it probably depends which practices you're looking at because there are, as you go further into Norwich, a lot of practices where patients will be just used to, I think it's more about there again what the patient perceives as their benefit or the benefit and I think perhaps if they don't perceive a massive benefit for them I'm not sure that it's just why would they travel all that way? I mean they might, but that's just my thoughts really. So I wouldn't say rule it out particularly but I just can't see our group of patients going all that way.

RA: You talked about whether there might or might not be benefits for patients, do you think there'll be any benefits or otherwise for the practice?

N: I mean there could well be because they could identify something glaringly obvious that's been missed, but it's a possibility isn't it? And also if somebody, if a patient's got somebody focussing in on them, showing an interest in them and spending some time with them, I think potentially that's always a benefit to assist them complying, or whatever you'd like use, with not only their medicines but the other things that you're asking people to do as part of their disease management.

RA: Okay. If we assume that the project shows benefit, do you have any views on future rollout of the same project?

N: I think that's perhaps more difficult area to think about really because we obviously do chronic disease management reviews and as part of that we do a medication review but people come in for a session and we look at everything, you know and I think, I don't know that it's, we've gone more to that to look at everything. So if somebody's got diabetes and asthma and high blood pressure we look at everything because why bring them back into separate things, so I think in a way if you're just looking at medicines, it's potentially a bit fragmented. But I think at certainly, it's difficult to know where I'd put it because I think it's a benefit, I really do think it's a good thing, but it's difficult as to where I'd put it. Do you say to somebody well once every so often when you go and pick up your medicines spend some time with the pharmacist and look at those specifically. I don't know, but it is about where it would slot in slickly with patient care.

RA: So can I just ask, you're saying when they go and see the pharmacist, do you see that may be there would be a place for having a clinic such as this in a community pharmacy?

N: Yes, yeah I do, because I think that possibly, with our dispensing practice, with a dispensary round there, because we don't have a pharmacist in there, so we don't have anybody particularly qualified in that area to address comments or to look at things in that way because they are dispensers ultimately, aren't we? So I think, I kind of think it would sit well where people are having their medicines dished out from, may be.

RA: Do you think the students are suitable people to undertake a medication review?

N: Ermm, as part of their ongoing training, for them, so yes, I think for them it's a lot of benefit for them. Whether they're the ideal person if this became a regular thing, whether they would be the ideal persons to be doing medication reviews on patients or not, I don't know and I think that would be probably for some individual students yeah they'd be great and for other individual students they wouldn't be. I don't know, I think if it was going to be a definite, if that was going to be what was going to happen I would want a qualified pharmacist if this was me having my medication review I would want a qualified pharmacist doing that. But then you could argue, couldn't you, that as nurses we're doing things that doctors used to previously do and patients sit there and say do you know what I'd rather have a doctor do that. I don't know, I think pharmacy students will have a lot to give because they'll be enthusiastic and will probably know everything and I think there's a lot for them to gain but whether that would sit as part of their role, I don't know.

RA: And if they did do it in the future, because obviously they're not qualified, having, if there was at some point in the process a qualified pharmacist able to intervene and prevent an error, would that change your view?

N: Yes, possibly. Again so long as everybody has access to the same computer system. See I think we do need, everybody needs to have access to the same computer system so that they can go back through time and find out why people haven't perhaps done the things that you would traditionally have expected them to do as far as their medicine's concerned because if you sit in front of somebody, I mean a classic example, the other day I was at Fakenham surgery, very large diabetic who was on gliclazide and piglitzone and not a hint of Metformin with an Hba1c of 10 or whatever, but unless you've got that background of information up until that point you could make all these sweeping statements about what you should and shouldn't do, so you need access to everything, don't you? If you're going to do it for an individual.

RA: Yes. So, wherever they do it they would need access to the records...

N: ... I think so...

RA: ... and that nicely brings me on to a comment raised by another practice. When the students have undertaken their session here, should we get the qualified pharmacist to put any kind of comment on the patient's record? Or any kind of record of that meeting?

N: I think that's a fair enough thing to do. I think that's quite a good thing to do.

RA: So you think, is it okay to do or should we do it?

N: Don't know, I think if there's something particular to highlight then I think you probably should do it, I think professionally you should do it. I don't know that you should do it just as a record of having done it, you know, you can because there's a box to tick for that, but I think if you've identified something that is a genuine thing, then I think you should do it because we've got to address that, haven't we?

RA: That's all my questions, the only other thing, is there anything else you wish to add or any questions you think I should have asked?

N: I would want to know when the students are doing their feedback, because they've looked at the notes and now they've seen the patients and they're going to feedback, will it be a two way feedback thing, so for example, are they going to be feeding back saying look at the notes I think this, this and this, so will it be then well that's not happening because of this, this and this?

RA: How do you think they should do it?

N: I think there is a, I mean some of it, may well be, I hope not, but it may well be that they say well the patient should be doing this, this and this and we go oh my goodness, you're totally right, but it may be that actually it would be if you looked at the notes we could say to them well the reason we're not doing this is you look at this, and the reason we're not doing this if you look at this, because that's a learning exercise then, isn't it?

RA: Hm, hm, so in fact you're saying it should be a dialogue?

N: I think it should be, yes, because I say it may be cringey for us that we haven't done some things but actually it may be an opportunity to point out something else that was within the patient notes somewhere.

RA: So in effect it becomes a true learning exercise because... they get either positive or negative feedback on what they've said?

N: Yes.

RA: That's a good comment. Is there anything else that you think I should've asked?

N: Not that springs to mind, no.

RA: Okay, I'll turn off.

N: Good, thanks very much. End of tape.

Meeting on 24 October 2011

RA: Okay, recording's going. So my first question is having had the papers and I've done a précis of what we're doing, is there anything you want me to clarify?

N: No, no, it seems quite clear.

RA: Okay. Something was picked up elsewhere is that there may be some cross-over in ideas between MURs and what we're doing here. Are you happy about the distinction there?

N: MUR?

RA: Do you get MURs from your local pharmacies? Medicines use reviews?

N: Oh, right, yes, sorry I didn't understand the abbreviation. Well we get the yellow bulletin so I don't, I'm not too concerned if there's any, there may be conflicting things on there but they're guidelines, aren't they?

RA: Okay, and do you get reviews between community pharmacies and patients coming through?

N: Occasionally but my patients, the patients that have spoken to me about that are not so keen on community pharmacy reviews.

RA: Okay, do you know why?

N: Yes, they don't quite understand why they're getting involved, that seems to be, you know why did the pharmacist want to talk to me because my doctor's put me on this and they can't, there seems to be a bit of gap between...

RA: And is it the person and their abilities or simply that someone else other than the doctor is...

N: Yes, just the fact that someone else other than the doctor is getting involved. And they'll think the doctor has prescribed it and they need to stay on it, whether they've been on something that should be for six months for three years is still, that's the sort of thing I think they should be picking up on in community. It doesn't seem to be the most popular area.

RA: Yeah. The obvious follow on question there then is if students or qualified pharmacists undertake full medication reviews, do you think this attitude would be continued?

N: I think there is a difficulty there because to meet QOFF points we have to see our patients every year and whether the patient's then going to want to see somebody else in a different area, I'm not sure. I think because it doesn't seem to be offered to everybody, speaking from my own experience, I've been on medication for ten years, I've never had a pharmacist ask me if I want a medication review, I think if it was more, I think it would eventually become engrained but at the moment I don't think it's been, I don't think people really realise what's going on or don't see it as a routine that they should be going through necessarily.

RA: So therefore do you think it's a good idea or a bad idea that we're undertaking this study?

N: I think it's a good idea because, just because it's not a routine in most people's lives doesn't mean it shouldn't be, don't get me wrong, you know I think the more places a patient can go to for help that they respect and trust the better, really, so if you can't get an appointment at your GPs and you need to ask something, why shouldn't you have somewhere else that you can go to and feel secure in the information that you're given.

RA: Okay, so do you think there'll be any benefits for patients from this?

N: I think of course there will be, there will be because like I just said you they're going to have somewhere else that they can go to, you don't always want to go to the doctor for certain things, I just don't think it's happening routinely enough for people to think of it as something that they should be doing or should be being offered.

RA: So, okay, maybe I'll come back to that point at the end.

N: Yeah, yeah.

RA: Do you think there are any concerns that you have for the patients if students see patients in this way?

N: No, not if they're overseen and you know, what's the word I'm looking for, supervised, no, not at all.

RA: Okay. Do you think there's, you've said various good and bad things, is there anything particularly good about it, what would you say is the best?

N: I think it is an area of you know, pharmacy does seem to be an area where there's not a lot of patient contact historically, apart from looking at a form at the end of a bed maybe and just reviewing what the doctors have prescribed. Of course it will improve the patient's communication skills with the patients and the students you know so future generations of pharmacists will be able to interact better with the patients.

RA: Okay. I quickly ran through the student training, any thoughts about that?

N: No, it seems fairly comprehensive and good.

RA: Do you think there's anything particularly missing from it that we should have added?

N: Not at this point, obviously you know once we start actually doing the study and working with the students things might pop up, but it's an unknown area, isn't it?

RA: And are there any particular things, or is there an essential that we must teach them above all else before they see patients?

N: I want to go back to my training now and think what I had to do. No, I mean to be honest with you I think just being polite to the patients, calling them Mr and Mrs until they're instructed otherwise and just generally listening to the patient as well and letting them make some decision in their own treatment.

RA: So in other words really the essential of communication?

N: Yes, yeah.

RA: Okay, what about the practicality of undertaking the sessions at GP practices, so the first one where the students come along and access the patient records, so what we'll bring is four students each time to access two computers?

N: The way that our practice is set up it shouldn't be a problem as long as they're on days that you've agreed with the senior receptionist that there is a room available, we've got a training room with four computers in it, as long as that room's empty there shouldn't be any problems accommodating the students.

RA: Okay, and again, will that cause problems if this was rolled out, would it cause problems in relation to your, you presumably get medical students, is there likely to be a clash in terms of simply room availability or numbers?

N: Potentially, yes, yes. If you're saying, it would have to all be organised because we are very tight on space here, very tight and I think that so long as you've given us a list of dates and we can work out what's going on then potentially it shouldn't be a problem, but there could be a problem, because we do have students two days a week at the moment.

RA: Okay, now the next session would be when the student meets the patient for the medication review consultation. Do you have any thoughts about that?

N: Did you tell me before, it's a while ago at the meeting that we last had, did you tell me before that they would be seeing a patient on their own or would they be seeing them with...



RA: There will be a pharmacist present, but hopefully not taking part, in the background to ensure safety or to intervene if there is a problem.

N: No I think they'll be absolutely fine. Most patients here are quite good in donating their time to help with the students, they quite like it.

RA: Okay, so that's two things there, I'll just take one thing. You obviously want the pharmacist to be there as a supervisor or whatever?

N: Hmm.

RA: What role should they take and how much could a student do without supervision?

N: I think again it's just the fact that we've never done this before so if the, I think it's just important that there's a third party, whether it's two students working together, we often do that with the medical students, that two students will go and interview a patient together on their own without a nurse or a doctor, we don't send them in with another qualified person, but just the fact that you know it's just things that you might miss or things that need prompting or maybe things that just need to ask before the patient walks out the door that might be thought of better by somebody else.

RA: So it's really just the third party and...

N: It's a safety catch.

RA: ... and it's also the unknown.

N: Yeah, yeah.

RA: And you alluded to the fact there that your patients would probably be likely to volunteer?

N: Yeah, my, I can speak for my diabetic patients because I see them all so frequently, no they are very helpful, most of them.

RA: Okay, and I mean, we need to recruit 32 patients for this practice, do you think that's a viable option?

N: Absolutely, yeah.

RA: Right, that's good.

N: It's less than ten per cent of my diabetic workload, so...

RA: This would be type 2s only...

N: Yes.

RA: And that's still...?

N: Yeah, it's about ten per cent.

RA: Right. What is your catchment for the practice?

N: Seven and a half thousand.

RA: So there's quite a high diabetes around...

N: We do a lot of screening, yeah.

RA: Okay, and do these patients come in for other studies?

N: Some of them are on the diabetic study at the hospital and some of them are on one that's been going for quite some time, which I can't, the initials escape me...

RA: Not the EPIC?

N: Yeah, EPIC, yes so we do have a lot of studies with regards to the diabetics at the moment.

RA: Is the GP practice the right place for the student to see the patient?

N: Yes I think so because the patients are comfortable here.

RA: Okay, and initially we had assumed that we would use the clinical trials unit at the UEA and after speaking to various other groups we then asked for the practice, so you say the patients are more comfortable, any more reasons or...?

N: Travel, especially from north Norfolk to get to the UEA would be quite difficult and most of the patients that you're talking about will be an older generation of patients and some of them don't like to drive in the city which would mean that they've got to get at least two buses or a train and a bus, so for them to come here you're going to get a higher rate of volunteer than if you asked them to go to the Norfolk and Norwich, even if you paid their expenses.

RA: Now you're a fairly rural area, what's the furthest your patients would have to come here?

N: I would say Colby in one direction, east Ruston in the other, so maybe seven or eight miles.

RA: Okay, and would they have any problems getting here? Is there anything that we would need to do to help or do you think they would be happy?

N: Some of them, most of them that drive would be happy to come here because like say a lot of them don't want to drive in the city but they're happy to drive the routes that they're used to driving. Obviously there are some people who don't drive at all and would either have to rely on relatives or get public transport.

RA: So in that case would there be a need for us to help with travel?

N: If they were coming in and seeing your students as part of a review with myself I can't see any reason why they would need to have any extra assistance. If they were coming in separately and it was going to cost them £16 for a taxi then may be, but if they were coming in and it was part of what I do then I think that would be okay.

RA: And would you call the study part of what you do?

N: It could be incorporated with a, what day was it that you were coming to see us?

RA: There's a variety of dates to be honest.

N: I can't see any reason why we couldn't combine it with a clinic. I could do a diabetic clinic and they could can you now go and see the student while I you know as a sort of an add on to their clinic appointment.

RA: That's an interesting point, it's not one that's come up elsewhere, so something I was going to ask about was if this study was to prove beneficial or positive, if we rolled out were there any particular issues, so presumably that would be one practical issue in terms of trying to co-ordinate...

N: Yeah, you know the QAFF every year we have to go through the drums thing, the dispensing review of medication, we try and get a lot of those done, for example, when we do our flu jab day. So the patients come in and see the nurse, have their flu jab and then the pharmacist would grab the patient and go and do their dispensing reviews, so that's just for example to save the patients coming back again if you can you know I run a

clinic once a week and could perhaps change the dates if it suited you, but there would be no reason why we couldn't see ten patients in a day and the students see them as a five minute, ten minute add on at the end of their appointment.

RA: That's an interesting practical point. So and again assuming the research is positive and we roll out, in the future do you think that pharmacy students would be appropriate people to undertake medication reviews?

N: Absolutely, I do, but it's like I said it's not something that has been culturally part of the furniture and that's why, you know, when you're talking about an older group of people they are very used to dealing with nurses and more used to dealing with doctors even when it comes to medication reviews so it's just a cultural, you know, shift to include, and also even with nurses and doctors we don't work that closely with pharmacists generally so it would be, it needs to be more of a team.

RA: So is that really down to us communicating, I use the word advertising loosely, but making people aware of it?

N: Yes, I think it could be partly, I just think about hospitals, for example you've got your nurses and your doctors working on the ward, the pharmacist might pop up once every now and then, or if you go to a chemist shop you've got the people on the front desk and you can see the chemist's head bobbing around behind the signs at the back, you know, they do tend to, it does tend to be a separate group which...

RA: So it is, I think the word you used there was cultural shift and I think that's may be...

N: Well there's no reason why it shouldn't happen, it just never has.

RA: Okay. Do you have any particular thoughts about how the consultations should be run? And particularly in two aspects, one would be during the study and one would be assuming that this continues in the future.

N: Well again it's an unknown, isn't it? So it's very difficult to say, but obviously the patients will have, no the students will have had access to the patient records and will know the patient history, no there's no, I don't quite know what it is you're trying to...

RA: Well I did, it's just really, we're just making sure that we haven't missed any thoughts, I mean for instance you talked about med students working in pairs and that's something I hadn't thought of before. Does that work?

N: It does, yes. It does work because again like I said what one doesn't think of the other one does so often if they're asking a patient about their medical condition, they'll pool their ideas, they work literally side by side, you know so there'd be two of them sat facing the patient, a very informal situation, no desk, no nothing.

RA: And do they work in tandem or does one take the lead and the other one just checks the other?

N: They work in tandem.

RA: Okay, that's an interesting thought. I've more or less covered my questions, is there anything that I haven't covered or any questions that you think I should have asked?

N: No, I can't wait to do it though, I think it will be good and I think that's why taking part in the research will start giving people that shift to feeling that you know pharmacists are part of the medical team rather than a separate entity because you know the patients will get to know them in this environment then they'll understand what it is that they do other than just being dispensers and counting pills, what is what a lot of, yes exactly which is what a lot of people think is the role.

RA: Okay, in that case thank you. End of tape.

## Focus Group Introduction - Student

### **Introduction**

Thank you for sharing your time with us and for attending today in order to help us make sure that the design of the research is the best possible.

We need to ask for your views and opinions in order to make sure that we do not miss anything or that we do not try and undertake activities which would be a problem for you or other participants. Our feeling is that it is important that as researchers we do not assume that we have got automatically it right, and your views will be used to help us decide if we need to make changes. If we do need to make changes we will go back to the research ethics committee (which approves research)

The Focus Group will last for 1 hour in total including this introduction. I will ask a series of 5 or 6 questions and may follow these up to check that I have understood correctly. There is no right or wrong answer, so do not worry about getting it right. Your views are what we want.

I will audio record the session so that I can go back and check what was said as it is very difficult to run the session and remember everything. Nobody will be identifiable from anything that we may later publish in relation to the research. I know that you have all signed consent forms but is everyone still willing to be recorded?

I will try to make sure that everyone has their chance to speak but please respect the views of other participants and if you want to speak but have not had a chance please just let me know.

Once again thank you for attending and now I will give a very brief overview of the study.

## Questions

1. Having read the summary of the project what are your thoughts about the time input required by students?

Follow up might include

What are your concerns?

Is there anything good?

Could you explain that (or give me more information) please?

Can you give me an example?

Why do you think that?

2. Do you have any thoughts about the invitation letter and information leaflet?

Follow up might include:

Is the presentation alright?

Is there any content missing?

What might make students likely to participate?

What is likely to make students less likely to participate

3. What are your thoughts about the preparative training?

Follow up might include:

What do you think about the time input?

Is the scheduling OK?

Would you need this training to undertake a medication review with a patient?

Are there any aspects that you would change?

4. Do you have any concerns about the session at the GP Practice?

Follow up might include:

Could you explain that?

Would you have any concerns?

What are the good aspects?

What is your opinion of the feedback session?

5. Do you have any concerns about the medication review session with the patient?

Follow up might include:

Could you explain that?

Would you have any concerns?

What are the good aspects?

What is your opinion of feedback?

If time allows

6. What are your thoughts about including training similar to this as part of the MPharM course?

Follow up might include

Could you explain further

If this was includede what might have to be left out?

Student Focus Group 02/06/2011

RA: We are recording. I will probably ask you if you could speak up please, because obviously we've got a mic in the middle of a largish room. So having told you about the study, do you have any thoughts really about the time required that the students will have to input?

S: Well the first thing I looked at was the prequel to reading in staff directed about all the guidelines and regimes and things like that. How are you going to check that the students have knowledge because I know obviously there are some students who are more motivated than others and some students won't do any reading around the subject so how and that needs to be guaranteed that they actually know all this stuff before they start?

RA: Ok right, any other thoughts on the time input, because we are asking the students to do a fair bit, but...

S: It doesn't seem an unreasonable amount of time though considering it's over the whole of the first semester...

S: And for what they're going to get out of it I think it's fine, because I know especially with us we only have we only have one medication review in a hospital and it was like it was very heavily prepared by somebody, it wasn't in a natural kind of scenario, so I think that would be a really good idea for they're going to get two views...

S: Yeah, with two patients or professional actors...

RA: And you were saying something similar?

S: Yes, I think it's only like those amounts of sessions and I think that for what we would benefit from it I think that it's fine, I'd be happy to come to the sessions? They're not too long and they're going to teach us a lot about it.

S: And it's quite varied sessions as well that means you got a lot, the reading is obviously self-directed so you do that when you want, but with the IT practices if it's only half a day then you're doing care planning so it's not like you're doing the same thing every session anyway so there's lots of differences as well.

RA: Ok, do you have any concerns about the time input?

S: I wouldn't have any.

S: No, I don't have any concerns about the time input I just don't know for the directed reading whether there ought to be something when they first come back at the beginning of that semester just maybe half an hour, an hour to go over that material that they've done as a directed reading so that everyone is up to date with that before they then go on and do further work because they have covered the end of chronology module the year before so they have already covered it but just as a recap.

RA: Ok. Can I now become more indepth on the training in a few minutes, so and following on the thing of timing, some of the sessions will have to be on by their simple nature outside the university so the IT training we're hoping for Norwich, might have to be in Dereham and of course the working with GP practices has to be where the GP practices are. Is it ok or is it a problem to (unclear)?

S: As long as the GP practices aren't too unreasonable to get to in terms of transport and distance, I think it will be fine, because I know we've had placements in GP practices that people have complained about due to the lack of transport.

RA: And what would you call unreasonable?

S: Over an hour.

S: I mean, some of the ones this year were in King's Lynn and to get to the placement on time, I know one of my friends did one and she had to catch a bus at 10 to seven from Norwich to get to a placement for half past nine just because of the lack of public transport, so I think it depends. If the students have cars or if transport could be provided, like pools cars or something like that students who can drive but don't have a car something like that because I know that I work as a student ambassador and you can drive for them, they have a group insurance policy, they just have to check your licence and put you on it. Something like that because it takes less than an hour (unclear) depending on how fast you speed and so it will probably be a bit easier then, maybe, a bit easier with the transport.

S: I think group transport is good because all the earlier placements we did when you got group transport you were a little bit less worried about it as well because you're all going, you're all going at the same time, you'll all talk to the same person whilst we had GPs where three or four of us would go to the place, but they wouldn't put any transport on for all of us so you'd go each separately, you'd then arrive all separately and then you'd stand there and someone would go to you oh is so and so coming and you're like I don't know if they're coming or and it's quite an awkward introduction plus if you're just there, you arrive there and you start off it's quite a nice way, it's a comforting way to start something which is unfamiliar if that makes sense.

S: Also you don't have to worry about public transport and it turning up or not turning up, if it's already been provided.

RA: Ok, there will be some occasions when I think we can supply transport and other occasions where it will have to be public, we're endeavouring to get practices within easy reach but I can't, for the future I couldn't guarantee it. For this one we will probably be Aylsham, Costessey, Wymondham and Dereham.

S: That's not all that far, I mean Aylsham is what? Half an hour?

S: Anywhere in the Norwich or just the Norwich outskirts isn't unfeasible, it's when you start going to outer Norfolk...

S: And it's sometimes as well if you're relying on public transport it's not always that regular or turning up.

S: Yes, it's just a bit more indepth into where are you going, how all the students get there, do they have a car? Can we get a few of them to get together? So that's almost the thing which seems to lack about placements is you're going here, here and here, that's it. No thought of that person has a car, that person doesn't have a car, are they friends? Are they going to talk to each other? No. Well that person has to get up at ridiculous-o'clock to get there for nine, while that person gets up at eight and travels down.

RA: So my interpretation here is that you've actually got more concerns about the logistics of getting there than actually the time that you are spending on the sessions?

S: Because it's not unfeasible that we've had placements where you spend longer getting to the placement than you do actually during the placement, where you start to hit a point where you think is it really worth it?

RA: And is that everybody's feeling?

Ss: Yes.

S: In the first few years of Uni, at the beginning of every year for the placements, they used to make you fill out a survey saying whether you had access to a car to drive to the placements and then they assigned your placements based on your location, things like that and it worked at lot better for everyone. So if you lived out in the middle of nowhere then they gave you a practice out in the middle of nowhere, if you had a car to get to them and the people in the Norwich with no cars they gave placements in those places.



S: They still do that to a certain extent, because I do know they emailed, because I remember Amanda (unclear) said that she had a car and she was happy to travel further, but I think a lot of people (unclear) if I say I have a car they're going to make me drive because it means she got Beccles which is like an hour to drive into Suffolk so I think people think if I have a car and I say I've got a car they're going to make me trek forever, so that's also kind of a (unclear), so you've got to get students to sign up to the fact and not mind if they've got to go quite a way, but I don't think Aylsham is prohibitive, it's about half an hour to drive.

RA: I think it's about the furthest, but that's this year, well obviously we're not looking just at this year.

S: If there is somewhere far away, if they can take on a couple of students at the practice rather than just say one, if they could have a few there together then everyone could go together the transport could be either organised by the university or you could say right you three are all going to the same place at the same time, try and organise it together that you all turn up together, and just that little bit more operation can make it a bit easier.

RA: We're aiming that you wouldn't have any less than four in the practice at any one time.

S: I think that's probably right.

General agreement to this point.

RA: Ok, any other thoughts about timing? Ok. My next question is, thinking about the other papers, the invitation and the information you have given, I don't know if you want just two minutes to have a look at it or can you just give me two minutes to just have a quick read through it, might be advantageous to us all.

RA: Ok, my second question is, have you got any thoughts about, this obviously is an invitation to students to say would you like to join the project.

S: It seems quite straight forward and says what's going to happen, seems fine.

S: It's optional as well so I mean you tell them it's optional as well.

S: If you have more than 40 students wanting to do it, how are you going to select just 40 students?

RA: In fact we are in that position but we are having to do by a first come.

S: And if you don't get enough students will you limit the amount of patients or will you give more patients to each student?

RA: The aim would be a planned number per student.

S: The other thing I was looking at is that you do it in your third year and fourth year, what about students who fail third year, or re-sit third year for whatever reason, and don't go onto fourth year directly after their third year?

RA: They would be ineligible.

S: Ok.

RA: So do you feel there is any content that is missing, is there anything that you would like to have known that we haven't told you?

S: Have they done any medication history training or anything before they agree to take part in this?

S: We do it in third year.

S: Yeah I know...

S: They do it in the second year now as well.

S: Because they've changed it, because if you already know what constitutes the medication history taking I think you'd probably be more open to doing it.

RA: Can you expand on that?

S: Well when we started we did all our medication and communication skills and counselling in third year and it was quite a lot to take on board in one go because all the forms are different and you have to learn all the different styles quite quickly on top of each other, so if they're learning that in their second year I think that's a good idea because you've already seen in practice how it works and then you can say I've done this in second year and I've seen how it works, but if I do this study it's going to give me extra knowledge and skills and I'll get to do repeat it more, which obviously generally it makes you better at something the more you do it. Obviously give them more confidence to go in and do it, if they already know sort of what they're doing already because they've already experienced medication history taking at some point, instead of saying a bit like with us at the beginning of third year if you'd have said this we might have said well we're having medication history taking anyway this year so why do we need to do extra study?

RA: Do other people think that's an issue?

S: Yeah, like if you've done it in your second year and you know how awkward it is trying to get one of your friends to play a student or some member of staff playing the student, it doesn't really work so it'd encourage you to go and try it with other people may like caveats as to real data is going to make it feel more practice related and possibly encourage people.

S: And I think if you don't tell them that they're actors as well maybe that they're going to go in thinking it's real patients because I think the problem with our medication history taking is when we turned up to do it we knew that the person had been prepped ready for us to take that medication history and it just wasn't very natural.

RA: So focussing on the paperwork then, I've asked is there any other content that you'd want? You've mentioned the history taking...

S: The fact that you might have to get transport.

RA: Yeah, ok.

S: Yeah, that's not a bad point, to attract (unclear)...

S: Sorry to bring up about transport again.

RA: No, it's obviously an issue.

S: It's in how much time you have to spend, isn't it? In addition will be travel time (unclear)...

RA: Would you want it made clearer?

S: Maybe say a maximum amount, it will take a maximum of time.

S: Yeah, where is it, sorry?

S: How much time will I need to spend? It just says that (unclear).

S: Yeah, but I feel like maybe it should say that oh I guess if we don't know how travel is going to be arranged, but if they would have to sort out their own transport (unclear).

RA: That's a very valid point (unclear).

S: Or the fact that you're going to be sending four people at a time along to a surgery, you're not going to be going it alone.

S: (Unclear) to me when you mentioned that this was something which was quite like a really interesting, quite big idea, I don't know if the document itself necessarily springs it as this is a really good opportunity as much as it possibly could do.

RA: So ok so following that idea, what do you think we could add or should do to these documents to make it more likely for students to participate?

S: Maybe some comments from fourth years saying about how they would have liked to have done it, because I personally would have really liked to have done this.

General agreement on this point.

S: (Unclear) the benefits is the contact with GPs and nurses, patient records, consultations, building confidence, but also it's the potential for employment in that you're quite unique having done this opportunity and gone out learnt all these things, you're one up against a colleague who hasn't done it. This is hands on training but also in a supervised situation where you can ask more questions and you'll be really well trained up for it, it's even better than a summer placement where you just go along and follow the guidelines and you're being trained into this process and it's a bit more real life experience so even though you've got the contacts and things...

RA: Is there anything else that we could do to encourage people to participate or is there anything in here that you think would actually make you not want to participate?

S: I don't know if it's just the way it's worded because of ethics and stuff, it's just saying at the beginning that we can't guarantee you will benefit from participation, stick that at the end maybe...

S: You can't guarantee something like that, you can't, but I wouldn't want to see that as the first thing that I read.

RA: I think one has to say that for ethics because we cannot guarantee because we must be above and beyond honest about it.

S: Just put it at the end!

S: You need to apply for an honorary contract with NHS Norfolk, although we will assist you with the paper work, it makes it sound like it's a really difficult process to do. To apply for the honorary contract and if people already have employment elsewhere they might think well can I do that and it might be, so maybe a little bit more explanation about that.

S: Maybe a time limit like this will only take you 20 minutes to fill in or something because then you know it's a simple process.

RA: Were you similar with that?

S: Yeah, that to me started to look a bit daunting and I was a little frightened about a contract, I thought contracts are scary and...

S: I know it stresses that you're not obliged to fulfil this or anything like that, but it's like you're under a contract with the NHS it's like...

RA: It's important to you, then it's important.

S: I think making it may be a bit more concise because I can also imagine a lot of people by the point they've read that just being a bit like hmm, do I really want to do it, plus if you've really took the main bits about what they need to know and then say we will help you and it will take this sort of length of time to do it and if it does have any implications if you do any other work or anything like that...

S: Key points maybe?

RA: Is there anything that you think should be left out?

S: Could you bullet point it? Because then it would look a little less daunting. I know it's something very simple, but if it was just like...

S: You will do this, this, this...

RA: And is that the main section on the intervention or the whole thing?

S: The you will then undertake a session at the GP's practice (unclear)...

(Unclear – over-talking.)

S: (Unclear) you will do computer practice, you will do PCP, you will go back, you will get feedback.

RA: Is that the general view then?

General agreement to this point.

S: The problem is it already has some bullet points, but I don't know...

S: I think sometimes it's because if you look at a load of writing, I don't know about anybody else, it just freaks me out before I've even read it.

S: Yeah, everything else on that page is really broken up in smaller then there's just a big chunk at the bottom.

S: That probably made the words contract and things like that (unclear) think of first.

(Unclear – over-talking.)

S: It could almost be in a table like this because if you like this is a lot easier to see what we're doing, whereas this is just text.

RA: (Unclear) training, so put it into blocks?

S: Yeah.

RA: That's a good idea.

S: I was thinking maybe if you've got different groups reading it maybe, you could rearrange the order it goes in, like for us if you want students you really want to be telling them this is really important, this is really (unclear) opportunity for you, so maybe put at the beginning (unclear) say, what would this study give you

the opportunity of doing? Well I'll be able to do loads of medication reviews and I'll be doing it in a real life setting, something like that so it's right bang in front of your face, it's the first thing you read.

S: So it captures your interest straight away and then you go on to read all contract stuff and it's not so horrible.

S: Yeah, by the end of the first page you've already made up your mind, like yeah I like the sound of this.

RA: So you think, am I right in thinking that you're saying that we should put the benefit, sorry the potential benefit to the student at the very beginning?

General agreement to this point.

S: Because to be honest, the course is quite heavy in time constraints, so if you want to do something that's going to help you and give you extra stuff and going to take you time, you want to know it right up front, well I do anyway, the benefit that's going to be there.

RA: Ok, are there any other issues on this paperwork?

S: Yeah I've got one other thing. The other thing is, it's in the same section, it says data will be recorded by you onto a laptop and if you're carrying that laptop around between GP surgeries and back to the Uni and things like that with patient information on, there's nothing in here, it talks about maintaining your confidentiality and how you can't be identified from it, but I can't see anything that says how we're going to maintain the patient confidentiality and like Data protection from that...

RA: In fact the computers will all be pin controls and which I'll only have the pin and be locked in Dave's office, but obviously an issue...

S: That will probably come up in the patient focus group, but it's just if, especially if there's like public transport and stuff involved, it could ease your mind a little bit...

S: If you don't quite manage to do something right, you're not going to...

RA: It's nice to know you've got those concerns.

S: I just didn't know whether there should be, even if it's just a couple of lines in here, just to say like pin protected or something, because I know that's part of our ethics code that we have to sign at the beginning of the year, don't we, that we maintain patient confidentiality.

RA: Are there any other issues on the paperwork?

S: It's more from mentioning the laptops, if you put your information straight into a laptop, what happens then if the information gets lost? Is it going to be backed up somewhere else, just because you know you don't want to go to the next session and suddenly realise that it's gone?

RA: As I understand it will be safe but I will double check it, it's a valid point. Ok so if I move onto another issue then, is that all right? So the training; I very briefly went through the training package, do you have any thoughts about it?

S: I like it.

S: I think there's some really good points in it but it's actually quite close together, but there's a maximum of two weeks between using the IT system and the medical practice and doing the care plan package and things like that so you don't have time to forget things.

S: I think it made it very obvious what you need gain from each session so reading it you knew what was going to happen but also if you were participating in it you could still use this document to almost say these are my learning outcomes so maybe almost changing what was included is actually being in the learning outcomes for this session and then again that also gives you a bit more of an idea of this is what I'll achieve from being there rather than just was included I'll achieve this by doing this and this is the aim I meant to get to from it and that could also be a bit more of a selling point of this is everything I'll get from doing it.

RA: That's an interesting one.

S: With the pre-course reading and stuff about random guidelines and including stuff like saying caring about evidence-based medicine and things like that and all the skills that involves and the fact that if you choose to do a module in the fourth year on it could help you towards that and things like that maybe and how it fits in with other things as well.

RA: (Unclear.)

S: For the IT systems not all medical practices have the same IT system, there's different ones so will the training account for that?

RA: We've actually, as far as this project goes, we're only going for GPs who have got System One, which is the system which is most widespread in this part of the country, but I take your point.

S: Another big thing they've said that we're using or you will be trained on the most widely used GP system...

S: I'd say what the training system was.

S: Yeah, as many selling points as you possibly can.

S: Because that's quite a big one because it's a bit like the hospital, they all have different ones that you use than say the community, and once you've learned how to use one, if it's a big one, you feel quite happy because you know you could probably go anywhere then and use it, ok it's a selling point on your employment perspective that I can use a very widely used system for computers, you can employ me, you don't have to train me on this and therefore I'm fantastic.

RA: Any comments?

S: I think it looks fine.

RA: Ok what about the scheduling of it? I've heard one or two comments about the frequency of sessions, they are roughly fortnightly intervals, is that too close, too far apart?

S: Are they all on a Monday by the looks of it? Could it be the case that you're missing so many lectures on a Monday because of the same day?

RA: I've gone for Mondays because they said in that term that's when it's potentially free. It's when people are working on their projects.

S: Ah, so this is for the fourth year?

RA: This is fourth year, I'm recruiting people who are third year but all the input will be in the fourth year.

S: I was thinking third year Mondays.

S: They're really hectic.

S: (Unclear) is that you start on the 3<sup>rd</sup> and 10<sup>th</sup> October then I suppose you've got the summer basic reading but that's the whole of summer for two hours that's quite a long length of time even by our standards and then on the 3<sup>rd</sup> and 10<sup>th</sup> you've got something, then 17<sup>th</sup> and then 31<sup>st</sup> October you've got something and then it's the 14<sup>th</sup> November, could it may be be eased out a little bit further that people have a bit of time in between because say you started to have a busy couple of weeks then you might start to be a bit like oh no but I've got to go and do this or I need to read this beforehand.

S: Or it might be the complete opposite, because I was going to say in that if they're still going to do assigned projects like they did to us this year, we didn't get our project until week three so we didn't actually start anything until week four so the only thing is you could squish it in the first four weeks, if it were possible, because then you could do it before you have to do your project but that was to be totally dependent on whether they change the project thing, which hopefully they will...

S: Special topics didn't start up till quite a while into it, but if you could find out when the special topics start, when's the main project going start and if it isn't till later on you could maybe actually get most of this in to the start of September, if people aren't doing much anyway.

S: The first three weeks of term is term work, semester one were actually quite light before all our, and then it was like woow in the middle.

RA: The 3<sup>rd</sup> of October is the second Monday in term.

S: I think it would be better if it was just weekly because it would be in your mind, wouldn't it, and you would try to have it done in that amount of weeks, rather than dragging it over like (unclear).

RA: (Unclear) mixed feelings here, some more quickly, some slower, I would say?

S: It depends how they do the timetable next year because it was a bit of a shambles this year.

S: But with special topics as well they didn't start till week four but they also timetabled those for a Tuesday so it could be possible instead of saying Monday 3<sup>rd</sup> and 10<sup>th</sup> October for the training, you could just pick the 3<sup>rd</sup> and the 4<sup>th</sup> for training because you won't have anything on the Monday or the Tuesday. Obviously that would rely on the timetable.

RA: So that comes back to your comment about part of the scheduling is that of timetabling?

S: Yeah.

S: I think that would be the thing as well that if it was (unclear) that would only be if the timetable got nicely spread out this year because, or for next year's lot, because we did have it that the earlier bits were quite empty and therefore you probably could have fitted four, three or the second to fourth session probably in the first month without it actually having any effect whatsoever on the normal course running, but I think that will depend on what alterations they are doing to the timetable from our year to next year to whether it is appropriate or not.

S: They're only three or two hours, aren't they, so it's not like it's taking up a whole day so if it was done weekly it's not like it's going to take up a lot of your time if you did have other things, well that's how I feel.

S: As well with the timing on the consultation and feedback (unclear) but it would be really nice to have that before any OSCEs or anything like that which are timetable because I know it's at the end of term at the moment but in case they decided to change it and things like that, it would be nice to have the feedback before you went and sat that as well.

RA: Anyone else? Any thoughts on that? So can I follow through then, do we actually need this training before you do medication reviews?

S: I think so because you haven't done any since previous academic year and if you had four months off for the summer holidays.

S: I hadn't done any medication use reviews, I've only actually had, have I had two or a lecture?

S: No, in third year you do a couple and that's all you really do, in fourth year...

S: There's one patient.

S: ...you do your OSCE and that's it.

S: Yeah, so this is really beneficial but...

S: It could be nice to show the difference in (unclear), we've done patients' history taking, we've done counselling and symptoms, it could be nice to show how medication use review fits in, but also how it's different and therefore it shows another aspect of the difference in the community pharmacy patient history taking in some ways, isn't it?

S: And that's another selling point; it's a communication skill which links in to what you were do, but actually it's not the same as what you were already doing.

RA: So if we gave an explanation of what in fact a level three medication review is, what is this level three: talking to the patient, read the notes, etc. So we need to do that.

S: I think it's a good idea as well the timing, sorry at the beginning as well, is because a lot of people will have done placements over the summer where you may have had an opportunity to sit in and watch somebody do it in real life and then you can use that knowledge (unclear) lost it, but it also gives, well I did a placement for eight weeks but I never got to see a medicines use reviews because they were always too busy, so I think it would be nice to see that as well.

RA: And these are medication reviews they're a higher level than a MUR, so we need to explain that is, that a correct interpretation?

General agreement to this point.

S: I think as well with the medication reviews I think as well sometimes in fourth year you can actually lose sight of why you ever did this degree in the first place with what we get, if you're doing something clinical like this and something that you would be doing in real life, and I think that helps reinforce the facts, that's how I felt.

RA: Is there anything you would want to add to this training scheme?

S: I don't know if I'd add, like we were saying at the beginning with the self-directed parts, is maybe having to check their actual knowledge.

RA: Ok, yes, I'll take that one on board.

S: Maybe even if it was just something on blackboard like a self-assessment, particularly if it was over-subscribed.

RA: And would you actually be happy to do that? Because one of our concerns was to not overload the students, but I'm getting the feeling that you're saying...

S: (Unclear) question direct studying on diabetes would be a simple way you could be reassured that you know it, but also if it's online you access (unclear).



RA: So put it on blackboard as like an MCQ?

General agreement on this point.

S: Yeah, something like that and I don't know if you would want to put in you need to get a certain percentage or whatever to carry on with it because obviously if you put no effort into it whatsoever...

S: But rather than maybe scaring people off if you get the feedback that tells you what you've got wrong, and some of them can have like an explanation underneath, like why the other answers are correct and that might direct you to where your gaps in your knowledge are and you can look at them again.

S: Yes, so rather than it being a test it would be an assessment of the knowledge, like the differences in, not testing the student's but...

S: I think it would have to be worded well I think because a test would put people off.

S: Kind of like a review...

S: Yeah, an up to date review of your knowledge or something.

RA: Can I pick up on the words you used there, Kate, feedback, on some of these sessions, particularly ones for instance with actors or one with the GP, etc, we will be giving feedback in combinations probably of Paul, Debi and myself, how would you want that? Do you think just a verbal one to one or a group thing or individual written or what?

S: Personally I think one to one in a group, I think it all depends on the student, I think it could probably be really intimidating if you had you, Debi and Paul all giving feedback at once.

RA: No it would probably be one to one, but I'm asking you, would you want one to one?

S: (Unclear) on the student's ability or feedback on the place?

RA: It's the feedback on performance for reflective practice.

S: I think a one to one would be nice...

S: Because you're doing it in pairs, aren't you?

S: ...I think it would be nice and I personally wouldn't find a problem with it and I'd prefer to have it that way myself, but I think if you had a less confident student maybe like doing a group thing, so if anybody does something totally rubbish then say this is not the way you do it, they're not kind of (unclear).

S: If you do it as a group though they can pick up on little (unclear) things from other people and things that you as an individual might not have thought of but might do it at a later date you might not have done it next time but don't necessarily know it's not wrong or right to do it the next time.

S: Could you not pick up from other peoples experiences?

S: Could you just not have both?

S: You could do a group overall to start with but then you could break it down just because as a group, like you said, what Laura said is really good, but at the same time it's an impersonal sort of thing knowing what you're directly possibly doing wrong.

S: Or give the students an opportunity to get personalised feedback if they want it so do like a group for everyone then if you wanted more feedback about you individually then they could ask.

S: I think individual feedback is better for reflection but group feedback helps everyone then.

RA: So you're saying we would need to include a group one in order we can learn from other people's either good points or mistakes?

General agreement on this point.

S: But I think it's important to still have the opportunity, but prepare people individual feedback.

RA: And would you want the individual feedback, I'm getting two views I think, would you want the individual feedback as everyone gets individual or would you want it just if you want it?

S: The only problem is if it was optional you might get people just being a bit too lazy even though they might actually want it, people aren't always proactive.

S: I think as long as you do the feedback sandwich or whatever so you tell people positive things as well as negative, I think it's quite a positive experience, because you can say look you did this really well but you should probably work on that, that type of thing.

S: Could you do like just a small paragraph written about, or to the students to share, you've done well in this, the patients find this good, this is good, this is all right, maybe try and do a bit of improvement here but overall you're doing fantastically.

S: I think it depends on the student, doesn't it? Because some people would really want one to one feedback but I don't think we can say that for everyone, so I think that's why it maybe should be their choice.

S: Group feedback gives you anonymity so if done (unclear).

RA: So am I right in feeling you all want group feedback?

S: Yeah, but optional one to one.

RA: And then it's a matter of what we do about the (unclear).

S: Some people would find it uncomfortable I think having one to one feedback. I think as well who does it.

RA: I won't go too much into that.

S: Because some people scare me more than others, that's why.

S: Yeah which is why I think it should be maybe optional.

RA: Ok so are there any other issues? Any other thoughts you've got about the training package?

S: Why didn't you do it a year earlier?

(Unclear – over-talking.)

RA: Actually, that's a nice comment.

S: We would really like to have the opportunity to have done this.

S: The only other thing though is it says about the students working as pairs, how much working as a pair is there involved? Can you pick your pair?

S: Yeah, it's a mixture of quite often working as a pair when you read it you just think that's really nice, there'll be someone in the same boat as me and it'll be really good and then you get there and you're like that person's not pulling their weight, they're doing my nut in, and then being really slow, how can't they understand this and they're probably thinking exactly the same thing back.

RA: You will have close supervision.

S: Could you have an anonymous feedback thing, can't they put up for PBLs and stuff where you just write anonymously and go this person's being really rubbishly lazy or whatever?

S: Couldn't you put something in here about the pair?

S: Having said that, if they were a pair, you'd know it was the other person anyway, so you wouldn't be writing anonymous.

(Unclear – over-talking.)

S: If there is, because if there's problem with pairs (unclear).

RA: The only time the pair comes is at the GP practice. Two students to access four patients records.

S: I think that's not so bad.

RA: So can I then go on to in fact that, would you have any concerns about the working within GP practice?

S: No I think, especially we had GP placements this year, and I think as long as the GP practice is geared up for students or knows that the students are coming and what's expected of them, I don't think it's going to be a problem. The only time I think it's a problem is if maybe the GP practice is busy or they don't want you there or things happen.

S: Or they don't understand what pharmacists do and you're sitting there almost explaining why you're there and what you do and it is a bit annoying because you're like why have you accepted a placement when you don't know what pharmacists do?

S: And then they go so why have you picked medicine, and I'm like argggg.

RA: So you've all been to GP practices, yes, and what we would have is we would have designated rooms, for all the students, probably a consultation room, but they might be offices. We'll have access to a computer and you'll have supervision by either myself or a PCT pharmacist.

S: So you're not going to be there on your own anyway, are you? There's always somebody you can ask?

RA: And you'll be working as a pair at the time.

S: Will you actually end up having interactions with GPs over the notes?

RA: What will happen is that the students will compile care plans for at least four patients and each pair will then feedback to either a GP or a specialist nurse, depending on what the practice decides.

S: That sounds good, though, because it could leave the opportunity as well for you to ask the GP why did you choose down that path? Not in an accusation way but in a trying to learn how GPs, how they progress diagnosing patients and doing things.

RA: And there is a session in the training package at which you would do a consultation and feedback to a GP before you go out but you said it could be nerve racking (laughter), no it's an important issue, so is there a problem?

S: I remember when we went to the GP placement and that was quite nerve racking because you were like we're going to the GPs and it's a doctor and things like that, but I think it's always good, the nerve racking's good because that one of the reasons you do it, so next time you do it it's not.

S: I think it also depends on your own level of confidence in your own abilities as well and I think it's a good thing because you don't learn then you're going to have a big shock when you start doing your pre-reg year. I think as well it's quite nice because it forges links as well because you don't really get to see many health care professionals while you're doing your degree at the moment, I know we have inter-professional learning and stuff but that doesn't really cover that much and we don't think very much of it. It's nice because it would be something that you would be doing to actually in real life.

S: I think possibly explaining to the students that if you do say something slightly wrong, don't be worried about it, they're not judging you; because that would be my fear is sitting there going oh and this, this, this and this and then the GP looks at you like you're an idiot and you just like go oh I've said that wrong.

S: You could stress that you're not being assessed on this, it's not forming part of your mark so...

S: Yeah, it's all for a benefit.

RA: Would it help if we in effect mentored and could feedback but with myself or the PCT pharmacist to check your knowledge before it was put to the GP?

General agreement to this point.

S: Because it's true what you were saying when you go to a GP is when they ask you your opinion on something and you're just like oh god, maybe if I say something and then they just obviously look at you like you're completely up a tree or whatever.

RA: So as far as accessing the information and sitting in a room accessing the patient's data, do you have concerns about that or are you happy with that?

S: So long as we can't delete any of their stuff or do anything like crash their whole kind of system.

S: That's why you're supervised.

RA: You will have read only access.

S: That's fine then.

RA: I have checked this with IT and all students will have read only access, for which I think we'll all be happy.

S: Some of us are less IT loving than others.

(Unclear – over-talking.)

RA: So the feedback to the GP or nurse, would you have any particular ways you would want to handle this in terms of would you want to just sit down face to face and say my ideas are, do it all verbally or would you want to present them with a written plan or how would you want to do it?

S: I personally prefer talking to writing, so personally from my point of view, I would rather sit down over a cup of tea and biscuits.

S: Something quite relaxed...

S: Or more like to not have it as a formal situation when you're sitting there but like if you're having a cup of tea sit and do it then it's more of a chat instead of a (unclear).

S: When you have multi-disciplinary team meetings and stuff, you might have the brief outline and the major topics as you talk because you note it down, but it's not a big piece of paper and I suppose it would be nice to simulate that environment where you sit, you're discussing a patient and to get them to discuss back to you why you've chosen something as much as to discuss with them where you think the plan should go.

RA: So I have two definite verbals, what about any others?

S: Yeah if you do it verbal you can get their opinions of what they've done, the previous options that they're on at the moment and things and bounce ideas back and forth and see why different things work and don't.

S: Yeah I agree.

S: I think it should be verbal and not too formal but not just a chat, part of it should be...

RA: Ok and would you go, referring back to the previous conversation, would you want any feedback on this or would you feel that in effect you're, because it's dialogue rather than a marker log, you'd be getting automatic feedback?

S: I think yeah, it would just be automatic I think, wouldn't it?

S: Yeah, I think if there's a dialogue with doctor I think you're getting that feedback, but I think if the person that's supervising you has got useful things to add afterwards then it would be useful to have that.

RA: Ok.

S: You also want to make sure it's like it would be in real life practice so if this is what they do a certain way in a real life practice, make it that way, I suppose. I don't know what it is like in real life practice because I've never done it so...

S: To get the GPs to talk back to you like they would, not necessarily harshly or nastily or anything like that, but to get them to talk to you as if you were a professional doing it properly and what they would say back to you as long as it wasn't too nasty.

S: Maybe recruit only nice GPs basically.

RA: I'll do their moderating. Similar to the issue then, these patients will then be invited into the UEA for a clinic, in the clinical trials unit, and the students will meet them individually for a consultation and the idea is to actually get information but also to give advice and help as part of the medication review. Would you have any concerns about it?

S: So these are proper, real life patients?

RA: These are real life patients whose data you have already accessed.

S: Are you going to be supervised while you do it?

RA: Absolutely.

S: Ok, the only concern I have is if you gave them erroneous information but obviously you can't do that if somebody's in the room who actually knows what they're talking about.

RA: Where you going to say something there?

S: No, I just think that sounds good. As long as you're supervised, I was just thinking if you were just going to be the student and the patient but, yeah, that's fine.

RA: And you would be in a clinical situation so it would be as near as possible to real life, apart from the fact that either myself or another moderator will be sitting in. Would you think it was a good thing/bad thing to do?

S: A very good thing.

RA: Why?

S: Why is it they need to come here? Is this, could you not do it at the surgery? So we're going to the surgeries to access the notes...

RA: Could you give me your views on that?

S: ...so we're going to the surgeries to access their notes and talk to the GP about issues and then we're asking the patients to come here? I just feel like why? Why should they have to come here? Not to be rude.

RA: No – no, I want your views.

S: That could be good for us as well because we're then going even more into a real life situation if we're going to be going back to the surgery where the patient's more comfortable they're probably therefore more likely to tell you honestly stuff and act more like they would in a proper consultation, whilst if they come here, they might feel more out of place and less likely to open up because they're no longer (unclear).

S: They might just find it a bit odd.

S: (Unclear) feel uncomfortable in the student environment and not open up to you as they would a normal professional in practice, whereas if you're in their normal environment, it might be easier on them.

S: Or even do it in the GP consultation room.

RA: What do you think?

S: I just think about is it fair to make patients travel from somewhere like Aylsham to come to here? For something that they would normally just go to their GP surgery for, even though they are part of the clinical trial.

RA: So this is your issue, so you think it would be preferable for the students to travel out to the patient and meet them at the practice?

S: Yeah, (unclear), if the practice has space to accommodate it all.

S: I think it could be good because again if you're going, like when you go out on to the placement it's a bit like when you step in to the dispensary, it's like straight away you go into professional mode.

S: Definitely.

S: Whilst if you knew also it not going to your marks other than not wanting to say anything wrong to a patient you know deep down that it's not the end of the world like how you act entirely – like you still want to be good but if you go up into a placement you're in that environment you're more inclined to be more of a professional...

S: Yeah so what I think it works both ways doesn't it?

S: Yeah you're in a slightly unusual environment therefore I'm going to be on my best professionalism behaviour.

S: I think that's true, but I also think from a student's point of view and from a control point of view for a trial, if they all came to the same place the clinical trials unit then they've all had that same experience, they haven't all gone to their own practice so all the patients have been subjected to the same thing, they've all gone to the same place for it.

S: But you've got a problem as well I mean it depends I suppose on how you arrange it if, that would be better, because that would be better, are they doing the questionnaires at home or at their practice or are they coming here to do those as well?

RA: They will be given, in fact they will be posted the questionnaire and that's something I'll be talking to the patients' focus group about in terms of how they will complete it.

S: So the control group don't come to UEA at all?

RA: No, the control group only complete the questionnaires.

S: Ok, I was thinking maybe if there was like crossover.

RA: So do you think this is an issue I should take up with the patients' focus group?

S: Possibly.

S: If you could, you could ask them, because we seem quite concerned about travelling to get there just to look at patient records, if we're that concerned about it then are we not going to be really anxious and stuff about it if we're going to be actually going to be interviewing the patients and then have to travel to...

S: But then if you've done it once you know exactly what you need to do to do it again, it's usually only that initial "how do I get there? What time do I need to go?"

RA: If I could hypothesise then, being blunt I will be saving money on the clinical trials unit if I could spend that money on travel for students to get you out there to see the patient would that be easier?

S: Yeah, I think it just depends, if you're saying for the patients? What if patients don't turn up?

RA: Ok do you think we're more likely to get patients or are they more likely to come here?

S: I think they're more likely to go to their own surgery because it's a lot more convenient for them.

S: I think you're going to have to talk to them to be honest and double check because some people like my dad's a diabetic and he would be happy to if he would train up future doctors and stuff he'd be happy to trek all over the county but I know a lot of other people wouldn't.

S: I think most people are inclined, because your surgery is never usually that far away so to potter down to have a bit of an interview again from the patient's perspective they can see this is going to be someone else in here to see my problems from a different perspective on what I want, they might see this is as it's quite nice to have a fresh set of eyes on my situation, especially if any of them do have something they've not wanted ever to say to someone ever before, they might quite like it as well.

RA: Ok.

S: Can I double check, when we they go to the surgery to look at the records, is it another day that they would then go back to talk to the patient? Can that not be done at the same time?

RA: At the moment it's done at separate times for the simple reason that we want to be able to check the care plan to make sure there are no problems with it.

S: Ok, so it's just timing, yeah ok.

RA: Ok, now there is some work similar to this that's been done in America and they obtained feedback from the patients about the students' performance. Do you think that's a good thing or a bad thing?

S: Depends, I think that's probably a good thing because there are some things that you don't realise that you're doing as a person that can be really, like I didn't realise when I was in patient interview that I came across as apparently quite scary and abrupt and I didn't realise I was like that at all until somebody told me so I think that's quite good because none of my friends would have said Jane you're quite scary and abrupt but having a patient say that really makes you think about what the way you come across to people, and I think that's probably quite good as long as it was positive.

RA: What do the others think?

S: I think it would be good to have feedback from them.

S: I think they would maybe like to give feedback really, we've only ever been given feedback from like a pharmacy practice person point of view, the thing is then you're taking the view of are you trained, are you doing it suitably? At the end of the day you are saying that in a sense for the patient but you yourself, the pharmacy practice team themselves aren't patients. they aren't a real equivalent knowledge of the patient and therefore it's not the same as a patient turning round and saying to you something like why did you word it that way or yes you made me feel reassured or you say about those couple of side effects has really scared me now or something.

S: And also jargon like you don't sometimes notice that you're doing it because we all do it to each other so we all know what it means, something like that helps you think about it.

RA: If we did it, would you rather have a simple say five point questionnaire that the patient filled in or would you want it just a free form the patient writes their opinion?

S: Structured.

S: I think maybe a five point questionnaire but the option to write something at the bottom if they want to.

S: Yeah.

S: I think it would be more truthful if they can write something, otherwise...

RA: The kind of questions that I've seen in the American studies are things like was the person professional? Did you learn anything? Did they seem confident?, those sorts of things.

S: Were you comfortable? Something like that as well.

RA: Would you be happy to get that sort of feedback?

S: Yeah.

S: Sort of almost like the professional side of the feedback that we get on the current forms that we do in pharmacy practice those sorts of questions.



RA: So it's that sort of area, ok. Anything else about meeting the patients then? I've got one last very quick one: do you think this, do you have any thoughts about whether this training should be included in future MPharm courses?

S: Yeah

S: Yeah, I think it should, particularly in community pharmacy now our pharmacists aren't getting, pharmacists aren't paid just for checking prescriptions for clinical accuracy, pharmacists are only making their money through their enhanced and advanced services so pharmacists have to be doing things like this to actually make any money in community pharmacy and because a lot of students do go into community pharmacy, I'm going into hospital so I can't talk, but it applies to those as well they need to have skills like this to get anywhere in the future. And if they have a foundation in a lot of the skills that are involved here then they're a lot better in standing for the future.

S: And also you can say if you're recruiting a third year you can say at your pre-reg interviews and stuff well I'm involved in this thing, I'm going to do this study where I have to do all this training and stuff, medication reviews, that we said before was a really good plus point for you CV as well.

S: We've got an NHS contact.

RA: And you'll have a research passport contract which is transferrable. Any other thoughts on...

S: I think it's good because it's an opportunity to see some patients which is something we don't really get.

S: I think that's a real point to put in the MPharm degree.

RA: If it proved to be workable, effective or whatever word we want to use, I mean this is a pilot study, do you think stick with same number of patients or have more or what?

S: I think it would have to be dependent on how many students there were to be assessed.

RA: What do others think?

S: Depends how willing the patients are to repeatedly do it for different students.

RA: Now obviously for this one we are only looking at one condition, which is diabetes, which is partly scientific reasons and partly logistics in terms of the students that focus on one disease state...

S: It's the way it could develop though is that you could actually have, you could then have some diabetic patients, some cardiovascular and some slightly other and students could actually say "ooh well I'm particularly interested in cardiovascular, so can I go for the cardiovascular ones?" or something like and it's a study itself or the way this could develop for students is you could start them picking into, if you widen the disease ranges within the patients you could let students pick into areas that they are interested, if that makes sense.

S: And I think as well if you are going to do a lot of this in community pharmacies focussing on the patients that you are going to get, because at the moment that's like burgeoning diabetes obviously and cardiovascular stuff and focussing on all the big diseases that are going to come about and maybe doing all of them if you can fit them all in.

RA: Would you find that scary?

S: I'd be quite happy actually, I'd really like to do that.

S: Well that's part of what we've done this year with special topics, we got to pick in to things we were interested, we picked the project itself we got to pick it so it's another way that you are sort of dictating the way your education goes without it being completely realistically, you're still just getting that little bit more of a say of all I was interested or I'm not that good at it so maybe I should go over it again, I would be quite interested to.

S: There's a level of control then and you're taking charge of your degree to a certain extent, and that's quite appealing.

S: I think the more clinical based the report is the better, because I don't think we do enough clinical hands on stuff in the course.

RA: Ok, so, Kate do you have any thoughts on that?

S: The only thing would be because obviously diabetes works because that's something that everybody will have covered in their second year before they go out, you get too many different choices and people haven't covered the material like we did in the course, are they going to be less confident and able to perform?

RA: And one other thought there from right the way back, one comment there was that this will set you up for your future career, etc, I'm paraphrasing, should that then be fed back into the beginning into the paperwork to encourage students to participate?

S: Yeah.

S: Yeah, because if you see something that's going make you, because it's more competitive than ever to get anywhere...

RA: Is that us being judgemental, there's a fine line between selling it and...

S: No, because even if you go into hospital it's still involved because you talk to patients, there's an obesity epidemic at the moment and diabetes is increasing and stuff so whichever field of pharmacy you're going to go into, even if you don't go into pharmacy, you're going to come across people with diabetes and people that are taking medications.

S: And even like because it's split so all the people doing extra work on it like getting information about it is even though if you wanted not to do diabetes like learning the skills and where to find things and related studies and stuff will benefit you for other things as well.

S: But I quite like this as well in the sense, we're going into hospital having done something like this would reassure me I could go in community and start doing MURs, because you now don't really find the pharmacist who doesn't do MURs or medication reviews...

RA: This will be a higher level than MUR...

S: Yeah but again you've gone above, it give you that little bit of community area in some ways of to talk with patients, having gone for, it makes community a bit more clinical looking as well and then if you're in hospital it makes you don't feel stuck in hospital, that you can't go, if that makes sense, it just makes you feel like you can...

S: And I think if you're going to, because when we go into hospitals, one the reason I'm not so keen on community is it's less clinical so if you can enhance the fact that you can do this clinical stuff in the community as well I think you will help people choose their career paths as well, like where they want to go.

RA: We're just about on time, I promised I'd be about an hour so I should can probably justify going on off track at the end, in Australia there are 1,200 pharmacists qualified to give home medication reviews and they

don't dispense, they spend their time dealing with patients. Well in fact previously the issue was they'd all wanted to go into hospital, now they all turn round and say they want to go into the community and do that.

S: I think that's actually a really cool idea.

S: But this course has led away from being...

RA: I'll be turning off, but if I can just ask one other thing, is there anything, are there any other issues that you want to raise that I haven't asked about this training? About this project? If anyone wants to say anything, please say it now, or forever hold your peace.

S: It's a really good idea.

S: It's good, very good.

RA: I will switch off now.

## Focus Group Introduction - Pharmacists

### **Introduction**

Thank you for sharing your time with us and for attending today in order to help us make sure that the design of the research is the best possible.

We need to ask for your views and opinions in order to make sure that we do not miss anything or that we do not try and undertake activities which would be a problem for you or other participants. Our feeling is that it is important that as researchers we do not assume that we have got automatically it right, and your views will be used to help us decide if we need to make changes. If we do need to make changes we will go back to the research ethics committee (which approves research)

The Focus Group will last for 1 hour in total including this introduction. I will ask a series of 5 or 6 questions and may follow these up to check that I have understood correctly. There is no right or wrong answer, so do not worry about getting it right. Your views are what we want.

I will audio record the session so that I can go back and check what was said as it is very difficult to run the session and remember everything. Nobody will be identifiable from anything that we may later publish in relation to the research. I know that you have all signed consent forms but is everyone still willing to be recorded?

I will try to make sure that everyone has their chance to speak but please respect the views of other participants and if you want to speak but have not had a chance please just let me know.

Once again thank you for attending and now I will give a very brief overview of the study.

## Questions

1. Having read the 'lay summary' of the project what are your thoughts?

Follow up might include

Do you think there are any benefits for patients?

Do you think there are any concerns for patients?

Is there anything good?

Could you explain that (or give me more information) please?

Can you give me an example?

Why do you think that?

2. The study involves the students undertaking medication reviews for patients with type 2 diabetes (T2DM). What are your thoughts about the relative merits of recruiting random T2DM patients versus those with either well controlled or uncontrolled T2DM for this study

Follow up might include

Could you explain that further

What would be the relative benefits

Do you think that would produce clearer results

3. What are your thoughts about the student preparation training?

Follow up might include

Will it prepare them for the intervention?

Is the content of the correct level?

Is there anything missing

Any other thoughts?

Is there anything that needs missing out?

4. We need to ask PCT Pharmacists to help us with the supervision of students when in the GP Practice obtaining patient data and when they meet patients for one to one consultation. What are your thoughts about this?

Do you have any concerns?

What would encourage you to volunteer?

We would pay at your standard rate. What are your thoughts on that?

5. What are your thoughts about the session at a GP Practice where the students extract information from the patients' records?

Follow up might include:

What are your thoughts about confidentiality?

What are your thoughts about the ability of the students to achieve the task in the set time? (may need to explain the current plan)

How could that be made easier?

What are your thoughts on supervision?

Are there any other issues?

6. What are your thoughts about the session where the patients attend a 'clinic' for a consultation with a student?

Follow up might include:

All the usual questions above

What do you think about the location?

What are your thoughts about the likelihood of patients volunteering?

Do you have any particular thoughts about how the session should be run?

Do you think that this is something which should be done?

Pharmacy Focus Group

RA: Ok the tape is running, ok so you got a copy of the latest summary there, which is this one. I've sent a copy around before and I'll briefly describe the project. Have you any thoughts about the project? Open Question.

P: I think it's a very good idea, I think it'll focus people's attention on the ethic and sort of probably bring the pharmacist/patient interventions to a head.

RA: Ok, anyone else have any thoughts?

P: One thing I wondered to start with was just picking one topic would be too narrow so students would perhaps not bother concentrating on any of their other things but then I started thinking about it and actually diabetes is a really good one to cover lots of skills and because you've got lots of drugs, you've got devices and you've got to talk about diet and cardiovascular risk. There's a huge variety of things which they could then apply to other topics, so actually it's probably one of the best ones to do, I don't know what other...

P: Yeah I think that's true and also they may have conditions so they're unlikely to be just diabetic so students will have to discuss and presumably have training in other things as well as diabetes.

P: Now you've said about doing the medication reviews before seeing the patients I feel a bit more confident about that because I was thinking if I was a student I would be incredibly nervous if I was going in to sort of without much preparation or without the chance to chat it through with somebody else first before going in hitting the patient with that.

P: I think having read your background there is quite - I hadn't really thought about it before - but there is quite a gap in undergraduate training with patient contact, they only have the odd placements where they perhaps see one patient other than that they don't see what they real patients until their fourth year when they do their OSCEs and I just wanted to ask you about it says here they use the undergraduate schools of optometry and dentistry, is that the best model or what?

RA: They are simply - it's similar to medi schools and nursing where students meet patients who are real, so I just gave that example. Do you think they'll be any benefits for the patients at all? Or not?

P: Yes I think any opportunities to discuss the disease and I think hopefully they'll be quite open, especially with students as well, I think there's less, maybe they'll be much more open because it's a student, because they may be seeing it to be helping the students as much as them getting some benefit from it themselves.

P: I think that patients will probably treat them like they would one of us actually. I think they'll probably see them as sort of nearly pharmacists and I think they'll just tell them - and experience with community pharmacy when you have a pre-reg is, they're all willing to talk to the pre-reg as much as the pharmacist.

P: They don't always know the difference.

P: Like I said it depends but if they got supervision to make sure they don't do anything dangerous that should be okay.

RA: Do you have any concerns about it? Is there anything about it that worries you?

P: My only concerns were the practical ones of getting the qualified person and the student and the patient all together at the same time without having to make 32 different trips.

P: Yes consolidating the appointments you know into set times would make that a lot easier obviously.

RA: Would you think that's possible? Is it practical?

P: Well I was going to say I've managed to book clinics and have whole blocks, like a morning or an afternoon or whatever, I think if you can at least do several together rather than just dribs and drabs I think that's going to be much better.

RA: What kind of number do you think is practical?

P: How long are you going to allow them for a consultation?

P: 20 minutes.

RA: It's going to be somewhere like 20 minutes, half an hour.

P: Yeah so I think probably two an hour so you could potentially see six or eight people.

P: I think that's too many.

P: 20 minutes and let them have about half an hour afterwards to sort of digest it and write any notes, this is from my own personal experience and then see someone maybe the next hour so you have actually got chance to write up all the notes and all the bits and bobs and the questions you've got.

P: You're focussed on it.

P: Because once you've seen a second and a third patient, coming to write up the notes you've forgotten half the things that you'd seen.

P: They've got to look at the care plan for the patient coming in before the patient comes in as well.

P: They need a bit of preparation time and a bit of time for afterwards for note taking I think.

P: I agree.

RA: Okay, can I maybe come back specifically to those sessions later maybe? One thing that we have been thinking about and have an open mind about at the moment is we're talking about type 2 diabetes patients, and there's been debate as to whether we just take totally random patients or that we focus on patients who are uncontrolled or well-controlled and at the moment there is a not a consensus and I would appreciate your views on that.

P: Uncontrolled patients usually are shipped off to Bertrum so we wouldn't have any way of changing their medication.

RA: Okay.

P: A lot of the practices I go into the problem patients are immediately palmed off to Bertrum even if it's a Bertrum's nurse come out and do a session at the surgery.

P: You're very unlikely to get any changes at the GPs, are you?

P: So the GPs won't touch those ones.

RA: So are you saying that you would recommend that we went for a random sample but not particularly uncontrolled?

P: Is there going to be any exclusions on other co-morbidities or anything? Because sometimes if you did random you could get some really really complex patients in amongst that.

P: Something that would be too much for the students.

RA: Do you think there should be exclusions?

P: I think there should be, I don't know what off the top of my head but I think there should be some exclusions.

RA: Anyone else have a view on that?

P: I wonder if it's an uncontrolled patient, not a horrible complicated one, but if it might be an adherence issue or a misunderstanding on the patient's part, there is chance of talking to someone about it may actually make the problem better, don't know for definite but it's a possibility that talking to someone might help them.



P: Depends if you want a realistic situation as well because you know this is a pilot study and go further forwards so if you make your group too small you can't really replicate it in future if (unclear) there's too many exclusions.

P: I think it should just be random I...

P: It's also a more realistic exercise then for the students.

P: Students are going to face complicated patients, sometimes I know we run away from the really complicated ones...

(Unclear – over-talking).

P: You just need more time.

P: Yeah just more time.

P: But they got half a day and an opportunity to talk with a health professional so actually that's a great opportunity to tackle any patient.

P: So actually that's an opportunity for a referral, couldn't it? Because it could identify that or it could be that no one has done anything about it up until then and they just needed to be taken that further step.

P: The GP may be ignoring them as well a bit.

P: Well yes and nobody's checking whether they are actually re-ordering their medicines or having blood tests done or whatever.

P: Depends what time slot they've got (unclear).

P: How are they (unclear)...

P: How is the intervention thing being recorded because if we're going for like maybe complex patients are we going to be recording interventions on not their diabetes? Is that going to be part of the study?

RA: Can I put it back to you and ask you?

P: Well I think I sort of assumed at the beginning that it was just going to be the diabetes interventions and that's why I said if you have someone too complex the student's going to spend all their time in the med review not on the diabetes you know are they actually going to have enough knowledge to deal with everything else as well?

P: (Unclear) to be able to apply their skills.

P: They need to prioritise the main issues to talk about.

P: Do you think we should be just doing the interventions on the diabetes though or on anything else? Like if someone was asthmatic there might be an inhaler issue...

(Unclear – various points over-talking).

P: That's kind of all part and parcel of that patient, but the other thing is what sort of training are you going to give them before hand? Are you going to...

RA: We'll go through that in a moment, it's an important issue so...

P: If you are going to have to go through inhaler technique with patients and talking about asthma, that's a whole other 20 minute session.

P: Yes.

P: That might be a pathway to signpost them to the next specialist asthma session...

General discussion and over-talking – not able to decipher.

P: Well I was going to say it's going to be a balance because the patient's going to be there to talk about their medicines and it's a balance of saying to them actually I'm not going to do the whole asthma thing now and actually maybe say almost as you said briefly covering it to see if there's a simple intervention you can do fine and if not best go to see your respiratory nurse, go to speak to your community pharmacist.

P: But that's not going to be showing that they've improved care if we're going to be missing out huge chunks of patient's medication.

P: Surely you can almost have it almost as an other intervention, maybe not as in just simply rather than going...

P: How are you going to measure the way that they've changed? You know? Are you I mean it all depends what you're putting in your questionnaires, doesn't it?

P: Well it does you know I mean are they going to be - are you looking at how well they sort of comply with their regime? Are you looking at their general well being, all those sorts of things and they can all...

RA: The questionnaire currently is adherence, handling of medicines, satisfaction with the diabetes treatment and quality of life.

P: So it does take in diabetes, doesn't mention anything else...

P: I was just thinking did you pick diabetes as a disease to just concentrate on those patients or is it literally just a diabetes intervention?

RA: Our original thinking was to just hone it down to a particular group of patients, but I'm interested in the thoughts about whether we should focus on the diabetes or holistically?

P: I think as pharmacists we're all duty bound to look at the whole patient, otherwise we'd end up being specialist in each little individual thing, saying go to station number 1 to concentrate on diabetes, station number two concentrate on asthma, station number 3 your hypertension, so I think if they're going to be dealing with it as pharmacy students I think they need to look at it as a whole.

P: It takes us back to June's point though, doesn't it? About whether or not you have restrictive criteria because actually you are just looking at it the impact on the diabetic treatment on their well being then we would need to actually narrow it down and say a diabetic and just allow them to have I don't know just thinking off that top of my head one or two other drugs so you'd have to rule out people who have COPD and goodness knows what else because you're not questioning afterwards whether or not they've had any changes made in those things.

P: But are they being invited in for a diabetic review or a review with the pharmacist?

RA: A review.

P: If it's a review then you have to include everything, but if you have them in for a diabetic review then...

P: I think you will at the moment if they go in they see either the diabetic nurse or the respiratory nurse or you know whatever.

P: Nobody talks to their GP.

P: Nobody looks at the whole thing and they're also going to say how you getting on with your medicines and the general reply probably is "oh fine" and that's all that gets put down on the review.

P: It could be a very short interview.

P: Well yes except that the pharmacist will look at it from a different point of view from the doctor or the nurse.

P: Well I was thinking about the numbers if there's only 160 and there's five practices then it'll be fairly easy to limit the number diabetics that you ask so you would have to do some digging I think to find people who weren't on too complicated a regime because I think it would be impossible otherwise.

P: That's true, to get the numbers.

P: Yes and I think to if you restrict it too much you may find it difficult to get sufficient numbers, it depends.

P: It could be unrealistic to in the real world.

P: Well it depends how long you've got to recruit them, if you're going to send them letters then that's going to take a long longer to chase up. You can telephone them but you may not be able to get hold of them because they might be at work or they may not have a telephone number and all sorts of problems like that which means that you start off with potentially a very large pool that you could use and then find that at the end you're probably down to less than half of those who will actually come in or even think about coming in because you'll also lose some, you send them out the first set of questionnaires and they take fright and say oh no I don't want to do this or they suddenly discover they're going off and doing something else. So I think to a certain extent you probably don't need to, it might be as well not to be too limiting to begin with.

P: So if we're not too limiting it would be best to limit it for a diabetic review rather than a review, wouldn't it?

P: What about patient satisfaction at the end of the day? They'll probably come out thinking I didn't get that question answered or what about that medicine, I thought I was coming in for a...

P: Why don't you limit them to diabetes and maximum of one other co-morbidity on the QUAFF or whatever?

P: And it also depends how you pitch it to the patient when you're trying to recruit them, doesn't it?

P: There's the letter here, isn't there? That only mentions...

P: "Primarily we are looking at diabetes, we may have time to discuss other things if you have particular questions relating to your medicines, we will do your best to cover those as well".

P: Or possibly other co-morbidities, the supervisor could then deal with them.

P: Well I think it will skew the results.

P: No I think that skews the results.

P: I think to replicate it as well in other areas you could have to have a specific criteria, which co-morbidity (unclear) plus one other to get the results at the end of the day.

P: Or you have to produce a template for all of the particular things you're going to look at and stick to that to get your level playing field.

P: I suppose even if you have tried to simplify the patients, there is always the scenario that the patient is still going to throw something completely random at you in the consultation, well actually over the internet I buy six or seven medicines... My kind of experience shows that sometimes patients are more willing to tell the pharmacist something they would never tell their doctor. So even the simpler patients may end up being massively complicated and the poor student's going to fall apart.

P: It's going to be difficult for the students, isn't it? Because if they do throw in something like say they're taking a herbal supplement or something, they're not going to know about the interactions are they?

P: Surely this is what you're also trying to teach the students, how do you cope with the question when you don't know the answer, because it happens to everybody at some point, doesn't it?

P: Oh, yeah, without a doubt.

RA: And what do you think we ought to do in that situation? What does anyone do?

P: Normally I actually I say I'll get back to them.

RA: What do you think the student should do, more to the point?

P: I think the patient, it would be much better for them to honestly say to the patient you know I'm afraid I don't really know the answer to that at the moment, but I will find out for you and let you know or get back to you, because I think that's probably what we'd all do to a certain extent, isn't it, and you're trying to train them to do what other pharmacists would do.

P: It's the main skill, isn't? You don't need to know everything as long as you know where to look.

P: On the flip side of that, it'll teach the patient be open about what they're taking and have that on their records.

RA: So am I gauging the feel that we're moving towards a wider scope of conditions?

General agreement from pharmacists on this point.

P: (Unclear) doing a medication review and having the opportunity to pull off all the information before hand, there shouldn't be anything other than yes, if they're buying something of the internet, that is really thrown at them before hand, so they should have an opportunity to look at what's going on. And even if it is a patient who's maybe under a heart consultant and is problematic, actually even in a review they should learn to say that's something obviously we can look up or that really you need to flag that with your heart consultant because even the GP might not be able to handle that level of medication review.

P: That is true because they've got all the information on the doctor's record.

P: They can check that beforehand, it's not blind, with them coming through the door like we normally have.

P: You're quite right...

(Unclear – talking over each other.)

P: Well this is it, they're not going into it cold, are they? They have got you to refer to as well.

P: Yeah, exactly they can ask us before, can't they? Prioritise what they need to speak to the patient about.

P: Do we, as supervisors, need to discuss the case before the patient arrives? Or is it totally student-led?

RA: Can I do what I've been doing and say what do you think?

P: They already feed back to the GP don't they?

P: Do they feed back via the pharmacist before they feed back to the GP?

P: It says here discuss, agree and produce a prioritised list of required actions to feed back to the patient and GP.

P: But that's afterwards, isn't it?

P: But the pharmacist is with them when they are pulling the off data...

P: I'm talking about before the patient interview.

RA: There is a pharmacist with them at all times.

P: At which point in time it would be quite nice to encourage them, because there two of them pulling off the data from what I remember, so actually you probably need to encourage them to have that discussion by themselves and listen to it and then if you felt you needed to steer them and then intervene. Because they should, part of it is also learning to have a discussion with a colleague to make a way forward.

P: What we do want is to be the PCT pharmacist doing the review for them.

P: That's what I mean, listen to them encourage them.

P: It's like a coaching process I would think, how do you deal with or are there things you might like to if you think they've missed something?

P: And what do you think about this?

P: Tell me?

P: Directed studies...

P: The other thing too is that some of these patients may have already met medical students so it's not necessarily going to be a whole new thing for them either and they could well already have expectations or lack of expectations as to what may come out of this.

P: They should be expert patients.

RA: We're leaning towards the abilities of the student so can I maybe go on to the training? There's this paper, which you've got, which is apparently the draft training programme and you'll see that this is the programme we've put together that we think they will need so already we're into the area where we're sending out pre-course reading over the summer, but do you have any views about the training programme?

P: Do we know what they've read up on?

(Unclear – various comments too quiet to pick up.)

P: Do you think two hours pre-course reading for a student is sufficient to cover the whole of diabetes and cardiovascular systems?

P: Depends, it could take you two hours to read the notes.

RA: I don't want to give too many views here because I want your views, but one of the comments from the students' focus group was that they felt that needed to be larger and they suggested a MCQ to test the knowledge when the students came back at the beginning of term.

P: Oh, that's a good idea.

P: How much time have they spent learning about, because I'm not familiar with the undergraduate programme, how much have they spent doing diabetes by the time they get to this?

RA: I can't tell you that in hours, but they've spent a decent amount of time.

P: So it's something they have already covered, so this should be top up refresher making sure they're all in the same place.

RA: Obviously other parts of the course revolve around a session on how to use system one, then using the information that they've taken off that from dummy patients, how to incorporate that into an IT care plan and then using that care plan to have training in motivational interviewing, consultation and feed back to a GP and then a final session where currently the plan is that they will meet actors to play the key part of patients. That's the current plan, but obviously I'm open to suggestions.

P: Looks good.

P: Yeah.

RA: If you like it, what do you particularly like about it? Is it about the right level or does it incorporate the right things?

P: How is it going to fit in with their studies because these are fourth year students, is it tied to a project or is it something they volunteer for?

RA: It's volunteer time outside the course.

P: Oh right, so are they evening workshops then or because they're on Monday.

RA: They're day time when's a bit of a gap in the timetable.

P: So that does fit.

P: Is that when they would have their eight week project?

RA: Yeah.

P: (Unclear) then hopefully they'll be quite good students?

P: But then again, is that giving a real picture if you only get good students?

RA: We can only take volunteers.

P: I'm sure there will be some who just want to do it for their portfolios.

RA: Do you think is there anything particularly good or anything particularly bad about...

P: Do you think there's a place for having a patient, a session with a patient talking about their condition or anything? A real diabetic patient talking about their kind of views of diabetes so they get like a whole person view of it rather than just the drugs?

P: They do do that in an earlier module at the UEA.

P: Do they do that?

P: Someone's mum comes in so they can batter them with questions, but to fit that in with this, if there was time it would be nice, but I think this looks really comprehensive and if you've got an actor then as long as they're well practiced...

P: They're just as nervous with actors as with real patients, aren't they?

P: How many students do you need to volunteer?

P: 40 I think I saw.

P: Oh yeah.

P: I like the fact they are having to feed back to a GP because I think naturally they'll be quite nervous of that, but that's quite nice to have included that part as well.

RA: Do you think it's right, apparently the plan is for a real GP.

P: Yes.

P: Yeah, a real GP.

P: If it's going to be a proper practice exercise it's got to be a proper GP.

P: Are they nice?

P: Yeah, obviously choose a nice GP.

P: As they all are.

P: Oh yes.

P: I guess the GPs will be paid?

RA: Sorry?

P: I guess the GPs will be paid?

RA: The GP will be paid or anybody involved.

P: The practices will be paid.

RA: Yes.

P: Oh well they'll probably be quite nice about it then.

RA: And do you think other aspects of the training are right in terms of our training on system one or training on the IT, training on the care plan?

General agreement on training.

P: I was going to say we would all have that.

P: Can we come to this training?

P: The majority of this training we generally will get until deployment level or Uni or jobs training pretty much so it really introduces you to.

P: It's usually go out a there and sort it out yourself that's right, day one you're on the counter, somebody comes in and asks, that's it.

P: Consultation skills really isn't at all massively, I know Debi does some lectures, but that really is a good thing that they get that extra session out of that, it's really important.

P: So you've got four patients each student then, haven't you?

RA: Yeah so currently a pair of students access the records of four patients and then each student face to face sees two patients. Do you have a view on that?

P: That's a good amount.

P: I like the way that they've got a buddy as well, because I think even if they're not certain then they've got some support to ask.

P: A fellow student?

P: Which I think is quite nice, it's a non-threatening way just having somebody else there...

P: Yeah.

P: Is this right?

P: So this patient is facing two students and one supervisor.

RA: No - the patient will face one student. It'll be individual medication review as near as is possible to real life.

P: I think it'll be an opportunity they won't have had already and I think they'll really like seeing real patients and the feedback they get from them they'll really enjoy it.

P: I take it from here as well we've got the four student s discussing it, produce the prioritised list on their training so there'll maybe be two students (unclear) a little bit, it'll give them confidence.

(Unclear – buzzing.)

RA: That then leads us through to where they actually start doing things in practices; so again currently the idea, or our thinking, is that they will go out in pairs to GP practice, in fact what we'll probably do four students at a time to a practice, they work in pairs, access records and take information off. What are your thoughts about the practicalities of that session?

(Unclear – over-talking.)

P: Who gets the Smart card?

P: Smart cards, you'll have to think about that.

P: (Unclear) the practice, could you do it with me?

(Unclear – very quiet.)

RA: Do you think it will be better in the practice or Lakeside?

P: I think it would be better in the practice, particularly if you bump into some of these other people that in coffee rooms and things you get a little bit more confidence in approaching when you've got to do your official reviews, but then get, I think computer access if they go out four at a time, I know they only need two computers between them but a lot of the places that's, it's hard to just get one sometimes.

P: I don't know any of these practices.

P: The other thing about Lakeside as well is obviously if there's two of them they're going to be discussing what they see as well so that's not very confidential because there's other people going to be sitting next to them.

RA: That's a good point.

P: And Lakeside, the access is slow, isn't it, some of the computers?

P: Can't have full access.

(Unclear – too quiet.)

P: What about smart card as well? Are they going to get their own?

RA: That is part of the training that they would receive a smart card. So when the students are out there they will need to be supervised by the PCT pharmacist and or possibly myself...

P: If that's the case, then again you've got computer access problems because we can't be getting on with everything else if we need three computers.

RA: This would be, this is one of the questions I ought to ask, is it practical either to get part time people to do extra or if we're paying the PCT to say that people do a day as a set session?

P: Block out half a day sort of thing?

P: They don't do any other work while they're there?

P: No.

P: Because it would...

P: Either way really.

P: You could do half.

P: Is it a bit of a waste of our time twiddling our fingers while they do that, I know they can ask you questions and things but the idea is they do their initial part themselves, isn't it? I don't, that's just poking...

P: I have always got things that I can do.

P: Even if it's just reading / catching up on something there is always something.

P: A pile of PJs or something.

P: And is the supervising pharmacist going to supervise them for every minute that they're there?



P: Yeah, how much supervision would you expect, would you want them watching exactly what they're doing?

P: How much do we think, yeah?

RA: I think it's a two edged thing, it's supervision and giving information, do you think they need all the time or...

Not clear, over-talking about the above point.

P: We could be on our laptop doing some work.

P: They don't really want you sit there and watch.

P: I think that's maybe where you'd use your judgement, you'd sit in the corner of the room and actually have an eye on that screen so you could soon tell whether they're pulling off all the writing and the relevant information because in some ways you always need to check that they have got everything.

P: If you've got two different rooms you've only got half your time with each one anyway.

RA: If we were asking for volunteers either part timers or people maybe on a half day off, that way we can pay them, would people be likely to volunteer do you think?

General agreement to the above point.

P: We could write it up as CPD as well, couldn't we?

P: That's true.

P: Doesn't have to be directly in work time, if it's going to be paid for anyway then you can do it as extra, can't you?

RA: And do you think paying people at their current standard rate is reasonable?

P: What's the alternative?

P: What you offering?

P: Sessional rate, I don't think you can argue with that really.

P: We can't do that if it's coming through the PCT.

P: Oh right yeah.

P: Ordinary rate don't really know.

P: I don't think you'd get many volunteers if you did less than the standard locum rate.

RA: So by standard locum rate, what do you mean?

P: Is it about £23 an hour during the week and £25 during the evening and weekends?

P: Usually.

P: Is it really?

P: Yeah.

P: I think that's a rough, but some would go up and down, but...

P: Depends what you get.

P: Depends how much you've asked for.

RA: So I'm getting different views, and that's fine I'm quite happy with different views, but I'm getting views about yes to current rate, whatever that is, yes to locum rate, so what about (unclear).

(Unclear – over-talking.)

P: It would depend whether you're paid through the NHS or yourself, doesn't it?

RA: It doesn't have to be a consensus.

P: Depends if we've been released from our day job or more full time rather than part time, if we're being released from that job then would you bill the PCT as part of that, or the PCT bill you?

P: Because I'm part time I'd rather be paid as an extra as a locum, rather than my PCT time because I still feel I need to achieve things in normal PCT hours.

P: I think it might be better as an extra, but we're all paid through the PCT.

P: But then we don't do any PCT work if we're doing this which again reflects on the end of the month and showing the PCT what we're actually doing, the fiasco which we had at the beginning of the year, it'd be better if we did it as extra.

P: Do you have the facility to pay us as self employed? Or does it have to go through the PCT?

RA: I genuinely don't know at the moment. What is the preference?

P: I think you'll get a mixture just because some people are already full time and they'd have to come out of PCT.

RA: So if people were full time, do you think any full timers would be likely to take say a half day and do the project and be paid for it, if that makes sense?

P: I think half day's annual leave and being paid instead.

P: I wouldn't.

P: It depends on how much I got paid, I might as well be honest.

P: I wouldn't take annual leave, but that's just me.

RA: That's what I want to know, that's fine.

P: Most of us are part time though, aren't we?

P: I was going to say there are very few, just the three of us, but Marion's not full time, are you?

P: I do Mondays for the University, but the PCT four days a week.

(Unclear – very quiet.) General discussion follows on what days each work where.

P: As most of us are part time, it would probably be easier to do it outside our PCT.

P: When is it likely to go ahead, anyway, when is it likely to be?

RA: We are looking at the intervention in November.

P: It's going to be December, isn't it?

P: Because they won't finish their training until 14<sup>th</sup>...

RA: As soon as they finish this training which completes 14<sup>th</sup> November, we would hope to start accessing records.

P: Doctors won't like being busy just before Christmas.

RA: Do you think we should wait till after Christmas?

P: No, because once you've done your training you need to do it.

(Unclear – over-talking.)

P: They get paid just before Christmas as well.

P: Well the 14<sup>th</sup> November's not so close, it depends, if you've got them all recruited and ready to go, then it's (unclear) fine but yes if it drifts into December then you'll probably have a poor attendance rate.

P: If they're getting double doses, they'll be ordering double of everything anyway.

P: Are the students going to be recruiting the patients? Or is that part of what the practices will do?

RA: No GP practices. In terms of ethics GP practices will have to do recruiting.

P: Will the GPs just find a list of patients and just send letters at random or will they pick patients that they think oh actually that'll save me time? What do you reckon what best, because if you get a patient that feels they're singled out they might feel a bit grumpy and not willing to, they might feel perhaps I've been singled out because I'm not really controlling my diabetes or if you get only willing ones then students will never meet an awkward patient. They'll think that they're all lovely.

P: The unwilling ones won't turn up, will they?

P: I think you'll find with all studies that you get the willing ones and I think people will really like going to UEA (unclear) for other things, they really think they're special if they're invited to take part in research at the UEA, so there is that.

P: It's a bit like the expert patients, isn't it, that get recruited, is it almost the same ones that drop in every year to (unclear).

P: My practice system is (unclear) coded for patients willing to see medical students, so I know they are always regular patients there.

RA: So can I just follow on this session at the practice then. The students, in effect they're be four students and in that time they'll have two computers and each pair will have to access four records, do you think that's doable in an afternoon?

P: Yeah.

P: Yes.

P: Should be.

P: You could even just have pharmacists there for the day if you can't get two computers you could just have a day so one lot in the morning and one in the afternoon depending on their timetable of course.

P: Do they come back a week later to do the appointment?

RA: That would depend on the patient.

P: It can't be too long otherwise it may have changed.

P: That's what I was thinking.

RA: How long do you reckon is enough? How long is it reasonable to leave between the consultation on the computer and seeing the patient face to face?

P: Two weeks?

P: No more than four weeks.

P: Because then it will be Christmas day.

P: Well, yes, you'll want them seen before Christmas.

P: You can get the dietary advice in then.

RA: We will have to span Christmas.

P: June's point is quite good about all the dietary advice you give before Christmas because when you do your HbA1cs...

P: They're not going to listen at that time of year, are they?

P: You might want to put that in as swaying your results.

P: At least you've not got Ramadan.

P: Yes.

P: That will be out of the way by then.

RA: Beginning of September this year. What about confidentiality?

P: I presume they will all sign practice agreements of confidentiality and you'll have your own one?

RA: They will have signed agreements and obviously there is the data on the computer which I will take away, but it's something that I know will be discussed and I'm just checking that you don't have any worries about it?

P: Is there a bit on information governance training as part of their training package, or do they already have that?

RA: Go back, do you think they should have had it?

General agreement in the affirmative.

P: My med in particular wouldn't let any of the care plans out of the practice for confidentiality reasons, I've hit that one before.

P: Even if it's anonymous?

P: Anonymised, yes of course they could.

P: Surely, that's part of the valuable lesson of this is how do you handle confidential...

P: We need to trust the students really, they're fourth years, not to go away and talk to their family about, it's having an element of trust in your students really, that they know what confidential means and it's drilling it into to them what will happen to them, because there's fitness to practice, isn't there?

P: They couldn't even discuss it amongst themselves out of the practice.

P: Exactly, they'll just go straight to the next practice (unclear) breaches.

RA: Ok then so having seen the records, then we invite the patients, I've heard various views about not leaving it too long which make sense...

P: Will the surgery, or could you ask the surgery to give the patients a ring and remind them to turn up the next day because if the student's having to travel quite a long way and you've got supervisory pharmacists as well to organise, that might be useful.

RA: That's a good idea...

P: To make sure they turn up.

P: Who's going to organise the appointment with the patient?

P: Hopefully the GP surgery, you think?

RA: Do you think the GP practice? Or do you think the student?

P: Well I thought the student could do that, they've got to ask the patient when they could come in and then they've got to book them in on the practice system.

P: I suppose the only problem with that is relying on the patient being at home when the student is doing that, and again if you're taking information like that if everyone's out of the practice then again, there's the confidentiality side of it, so it may well be that could try and do it but it may well have to be somebody within the practice just for the practicality side of it.

P: The practice are going to have a list of dates when everyone can make it, aren't they? And then phone the patient saying you've got this option or that option, that's probably about it really in reality.

P: I think it's probably going to have to start with the practice finding out, saying we need so many slots within this period because the practice will know how many patients they've recruited from their practice, won't they? And that's got to then be translated into sufficient time to see all these people.

P: Well that what I would have thought.

P: You said there are five practices, so there'll be 16 patients per practice on average?

RA: There will be 32, 16 intervention, 16, so that what you're concerned about here is 16 interventions?

P: I suppose if they could book, did you say they'll be seeing patients at that practice or at UEA?

RA: That's my next question.

P: Oh, sorry, if they could book half a day or whatever in a clinic room at the practice, for example, then you could just send them out letters saying this is your time slot, if you cannot make this then, sometimes that works.

P: What about, so who's going to decide which ones are interventions and which ones are...?

RA: It will be completely random.

P: So not the ones that could actually attend and not the ones who couldn't, because that would skew it?

RA: No, I'm afraid in research terms we have to random that's what we've said to ethics.

P: So if we did the med review in the UEA with the patient, all of the student's going to have in front of them is the notes that they've taken and that's not going to be like real life if they're going to be doing med reviews in a practice, because the patient may say something and they think "ah" I think I remember seeing that but I didn't take it down, so I think it's better in to be in the practice.

RA: Can I come to my next question which was, our original thinking was: you book rooms in the clinical trials unit at the UEA, invite the patients in. At the students' focus group they very strongly said they didn't think the patients should have to come all the way in that we should either go to a central place near the practice or to the practice, so which way do you go?

P: I think you're looking at the radius of the surgeries...

(Unclear – over-talking.)

P: And you might come across something else you need to talk to the GP about, which you're not there so you know somebody might tell you something and you think "oh my word" (unclear).

P: (Unclear) more comfortable in the practice.

P: Yeah.

P: And how would they record the consultation if they're not...

RA: So you're saying, in the practice with access to a PC?

General agreement to this point.

RA: Does it need to be in the clinic room or can it be another room?

P: Would they have to have a PC?

P: It would be useful.

P: It would be good if they could access record while talking they're talking to the patient.

(Unclear – over-talking.)

P: I think they're going to have an awful lot to concentrate on, aren't they?

P: Oh no, they don't have to access it, say if they go two or three weeks later and the patient just says oh I got started on something new then you can look at it.

P: You could have it open but not necessarily have to be looking at it.

P: It's just there in case they need it for something because they may have missed something when they pulled the records that the patient then brings up in the consultation.

P: Also, surely, it would be good for them to look at the computer record just before or in the five minutes before they saw them just to check whether there had been any consultations since they looked at the record last.

P: That's true.

P: I think to, having it in a proper room actually concentrates the student and the patient and I think the patient will probably view it somewhat more seriously if they're in a clinical setting, and the students as well.

P: Yeah.

P: I think the students will find it's more real than if it was just an exercise at the university.

P: I think the patients'll just see it more as a learning exercise for the student as well if they're in the UEA rather than something for them.

P: Statistically a lot of them will be older people and it's a long way for a lot of them to go.

P: Could you give them a choice? If they wanted to come to the UEA? I don't know if that's an option?

P: But it's not easy to get to a lot of places in the UEA if you can't walk, is it?

P: No, there's nowhere to park.

P: I think the doctor's surgery will probably be a lot more accessible than going to UEA.

P: I don't know these practices...

P: And it'll cost you more as well for travel and parking. It depends how you're going to incentivise the patient to come in.

RA: Cost is not particularly an issue, it's what is best for the patients.

P: Wymondham, Dereham, Paston, they're miles away.

P: It's a long way out.

P: If it was, it wouldn't be quite so bad if they were all here these practices, but considering especially where they are...

RA: Ok and probably my last question, do you think patients are likely to volunteer?

P: I think diabetes patients are quite used to being asked.

P: Yeah

P: Quite possibly.

(Unclear – over-talking.)

P: Well yes it is.

P: It might even be worth actually speaking to the diabetic nurses within these practices to identify potential ones that might actually volunteer, and they could easily probably go down the list and say, no he works, he's not going to come in, he's not got...

P: Then it ceases to be random, doesn't it?

P: But you're going to have to choose patients somehow, aren't you?

P: And the patients need to be asked anyway, don't they?

P: It is the practices who are going to select the patients, isn't it and recruit them? Fair enough you're going to give them parameters that they're going to search for them on and give them their starting pool but basically it will be the practices who do that, so it's not going to necessarily be a question for the students to go and speak to everybody and get them in.

P: No that's why I just thought that the diabetic nurses would have...

P: They know more about their diabetic patients than the GPs to be honest, so I mean they're doing all the changes, so they will know.

P: Oh they do.

P: That's right.

P: I would think so, I'm just trying to think how easy or difficult it was, but quite often people are interested to come in, particularly if you're going to give them a rather longer time to have a talk about something than they'd normally get their five or 10 minutes slot with the GP.

P: Would it be worth putting down, if you can, the hours that the students would be willing to see them in between? Because if you got a letter saying the student will see you between and if it only goes up to say half past four in the afternoon or whatever, you're not likely to get those who work, it depends when the surgery's open because I know Theatre Royal opens late.

RA: Do you think we ought to do afternoon and evening sessions?

P: If it's possible.

P: They need to be prepared to do that to get...

P: (Unclear) students substitute (unclear).

P: What about Saturday morning?

P: It's us pharmacists that could do it then, actually, full time in the week but then us doing it as an extra.

P: There are some.

(Unclear – too quiet.)

P: Surgeries have either late nights or Saturday mornings when they're doing their extended hours, aren't they?

P: They're more likely to be an extra room on those days.

P: Yeah, quite possibly.

P: I know on Saturday.

P: And you're getting a cross-section of patients then rather than just the elderly ones...

P: You'll get the people who are at work.

P: Nine till four or whatever, yes.

P: How many of these practices are open Saturday mornings?

P: (Unclear) Costessey I'm not too sure of...

P: Well Costessey's a 100 hours, isn't it?

P: That's the pharmacy, not the surgery.

P: The surgery hours are on that board we came past...

P: I don't think they're late...

P: Can I just say, they all have to do one late night, don't they?

P: They have to do one out of normal surgery hours, don't they, so they capture a wider section?

RA: Ok then well, I'm just about at the end of my time, are there any other questions that you think I should have asked? And if so, what is the answer? Or is there anything that you want to say that you haven't had a chance to say?

P: Just one thing and it's probably not relevant, but I remember when I was writing the letters to invite patients in for a med review for my diploma, it's just whether or not talking about whether patients would agree to it or not is making it, in the letter, apparent what they will get out of the session. So I know I included lots of things about well you'll have a chance to talk about medication. I don't know whether that will make it clearer to the patient what they can actually get out of the session with the pharmacy student, it might be different to a session that they would have with, so you can talk about all your medicines, all the side effects, or obviously depending on what's decided, I don't know...

P: You've got to find their USP.

P: Do you think we'll have to make a distinction between the MUR that maybe they've had in the community pharmacy as well?

P: Possibly.

RA: There is something that I had thought about, do you think we need to make that distinction?

P: I don't know if the patients will (unclear).

P: Depends who's done the MUR...

P: I think because patients are used to pharmacists doing a review then they might think it's just the same sort of thing.



P: And not a clinical...

P: Yeah, it's a possibility although with it being in the surgery and their GP sending it out perhaps not.

P: Is there any reason you couldn't actually, because I mean this is a learning experience, isn't it? So you could relate it MURs and say this is a step on or you could even, if you get stuck, use a room in a pharmacy and because you have got a lot information although we've said that it would be nice to have access to the notes at the time but theoretically it's all pharmacy and medication reviews at different levels...

P: So if Roundwell pharmacy is open longer, you could borrow (unclear)...

P: (Unclear) just before the surgery closes or whatever to go and look on the computer that afternoon, don't you?

P: And then use the pharmacy, well if you get stuck for rooms.

P: If they're open.

RA: Does anybody else think a pharmacy is a suitable location?

P: They're very small usually the consultation rooms. You couldn't get the four of us in there.

P: I think we should try and keep them at the surgery.

P: It would be nice.

P: That would be better because then you are then definitely putting it on a different footing from an MUR...

P: You're muddying the water, aren't you?

P: If you're saying we'll have it at the pharmacy then they're going to think it's going to be the same, you might even say in your invitation letter that this will be looking at your medicines in probably be greater depth than you would have a review within a pharmacy, so you help to make the distinction.

RA: Is there anything else that you would like to say? Or you think that I've missed out?

P: I know we're not talking about devices as such but what about device training? I know we're not really testing for finger cracking for type 2 generally but there may be a patient who is and there may be some insulin involved as well so are the students going to have training in devices or will that be digressing a bit too much?

RA: To be honest we haven't.

P: Referral to nurse for that.

P: That's probably beyond the scope of this study, do you think?

P: But it's a point though because they may well say I can't use my pen...

P: Exactly, or can you explain the units or can you explain the reason for uping and downing (unclear).

P: You can't ignore it.

P: Why did they change my pen over (unclear).

P: How do they clock that up or at that point in time they'd want an answer pretty much?

P: You can't ignore it.

P: But then if they are having two weeks between pulling off the information, if they know that somebody's on a pen, surely they should have some initiative to go and find out about these things.

P: Could be good opportunity to (unclear).

P: Or we're back to the thing which we discussed at the beginning if it's not something they've got an answer to because it won't necessarily be apparent from the notes, will it?

P: But I agree with Katie, they should have the initiative to look up anything they don't know about really.

P: If they're in the Roundwell surgery, well there's a pharmacy next door, they can just go and ask the pharmacist to let them have a play with and have a look at a pen, they are year four and we should treat...

P: That's true.

RA: It's a useful issue.

(Unclear – over-talking.)

P: I would expect them, if I was paying for a review of diabetes I would expect them to be able to talk about that type of thing.

P: Or at least try and understand the level of (unclear).

P: Knowing what the pen looks like.

RA: Are there any other issues, because that was a very useful one, one which we hadn't thought of? Thank you very much for your time. That's brought out quite a number of issues and it's brought out some issues that genuinely we hadn't thought of and it's possibly changed my thinking on some of them, so thank you. I have to go away and do a lot of thinking now. But thank you very much, I am in your debt. End of tape.

## Focus Group Introduction - Patients

### **Introduction**

Thank you for sharing your time with us and for attending today in order to help us make sure that the design of the research is the best possible.

We need to ask for your views and opinions in order to make sure that we do not miss anything or that we do not try and undertake activities which would be a problem for you or other participants. Our feeling is that it is important that as researchers we do not assume that we have got automatically it right, and your views will be used to help us decide if we need to make changes. If we do need to make changes we will go back to the research ethics committee (which approves research)

The Focus Group will last for 1 hour in total including this introduction. I will ask a series of 5 or 6 questions and may follow these up to check that I have understood correctly. There is no right or wrong answer, so do not worry about getting it right. Your views are what we want.

I will audio record the session so that I can go back and check what was said as it is very difficult to run the session and remember everything. Nobody will be identifiable from anything that we may later publish in relation to the research. I know that you have all signed consent forms but is everyone still willing to be recorded?

I will try to make sure that everyone has their chance to speak but please respect the views of other participants and if you want to speak but have not had a chance please just let me know.

Once again thank you for attending and now I will give a very brief overview of the study.

## **Summary of the Project**

Medication reviews are an evaluation of an individual patient's medication by a health care professional (usually a doctor, pharmacist or nurse). The aim is to check that all the medication is the best possible for that person and that for example all the doses are ideal (not too high to cause problems or too low as that would not give the best benefit), and that nothing is missed out or left on the list of medicines when it should be crossed off. A very high percentage of patients already receive a medication review from their GP each year.

In the consultation or discussion as part of the medicines review the pharmacy student will try to find out what the patient thinks about their medicine and how they take them. The student will provide information on medicines where needed and asked for and will use methods for improving medicines taking.

The aim of this study is to determine whether pharmacy students can affect patient care by reviewing medicines during the consultation with the patient.

We are not trying to show that the students are better than doctors, but by taking more time and speaking to the patient we hope that they can identify and help to solve issues such as making sure that all the medications are taken correctly, as well as how to identify and deal with or even prevent some bad effects of medicines. In addition we hope that they will be able to answer questions and provide more information to patients to enable them to make more informed decisions and to feel more in control of their medicines.

## Questions

1. Having read the 'lay summary' of the project what are your thoughts?

Follow up might include

Do you think there are any benefits for patients?

Do you think there are any concerns for patients?

Is there anything good?

Could you explain that (or give me more information) please?

Can you give me an example?

Why do you think that?

2. Do you have any thoughts about the letter and information leaflet?

Follow up might include:

Who do you think that the letter should be from (currently GP)

Is the presentation alright?

Is there any content missing?

When should we post it to get the best response from patients – beginning, middle or end of the week

What might make (whoever??) likely to participate?

What is likely to make (whoever???) less likely to participate

3. Where would you rather have the consultation?

Follow up might include:

Would travelling be a problem?

How could that be made easier?

How does that compare to going to see your GP

4. What is your opinion of the questionnaire and invitation letter?

Follow up might include:

All the usual questions above

What do you think about the amount of time taken to complete it?

What do you think about the ease or otherwise of completing the questionnaire

Do you find the questions too personal ?

5. Do you have any concerns about the patients having a consultation with a student?

Follow up might include:

Could you explain that?

6. If there is time – Could you say what things would make a good consultation by a pharmacist?

*Follow up might include*

*Could you explain that?*

*Could you explain why?*

*Is that different to a doctor?*

*Is that based on previous experience?*

Patients Focus Group.

Recorded comments

N.B. Discussion started amongst the patients before the recording was started hence the abrupt start.

Sorry maybe a stupid question but I mean out of the practice is that practice one of your five?

RA: I can't say. I don't know, but in defence what - the reason we want views from yourselves is an overview, we don't actually want to get to the stage where we've recruited patients and then start talking about the study design so at the moment it doesn't really matter which practices we recruit.

So, the point is, my doctor won't know if I'm part of the study.

RA: No.

Okay, that's fine.

RA: Because in effect you're participating in this study will not impact on your medication, we will not do medication review with you. The involvement ends at the focus group. There are five studies - sorry five practices who have agreed to take part and assuming we recruit patients through those practices, those are the patients who will be entered into study and will be given medication reviews, so today is simply about the design of the study.

RA: The terrible picture here is - what is where we are - we're right at the beginning here so in effect we are doing focus groups where we are looking at the design of the study with different people. Our next step is if we find things which we think we are to amend the study then we hope to recruit patients and there will be two arms of the study. Of the patients we recruit, 50% will be randomised in control, where they will simply undertake the questionnaire at the beginning and end and they will not have any other intervention. The intervention group, they will complete a questionnaire at the beginning and end, then the students will access their medical records with supervision by either myself and/or a pharmacist from the PCT and then the patient will be invited to meet the student for a face to face consultation. So that is the study in a nutshell, can I maybe go on to some specific questions?

RA: Did anybody have a chance to read this paper which was the background to the study?

PT: At one stage.

RA: Can I ask what everyone's thoughts are about the study? I will come to more specific things later but can I ask general questions about thoughts about - what do you think?

PT: Well one of I think it's good in the respect that a pharmacist would probably have more specific information on a drug regime than maybe a practice nurse or even a GP in some cases, because GPs are covering a wide of gamut of people. If for instance, the pharmacist I would imagine that he would be more in touch with the current medications, the side effects of medications and possibly long term effects with that type of thing so I think to have a good understanding, because I mean as a patient, I think it's important that you're at least offered even if you don't take on board as much education and understanding as you can about your condition which is going to help you to control that condition long term, so I think - I personally like as much information as I can, I mean because you'll often pick the paper up and read such and such a drug has been found to cause this, that or the other, if you know what I mean, which I found out at a meeting only a few weeks ago, which was one of the drugs that I was on, so I thought that's interesting so I shall be having a chat when I go back for my review over this, so I mean if we find that the pharmacists are more in touch with the medication regimes and that - I think and the patient can be educated in either the side effects or the risks involved in taking that particular medication, then I think it gives you a more informed choice.

PT: Yes and I agree and I think if one thinks back over my time as a person with diabetes, the number of times I've been a given drug by the doctor which when you read - of course one carefully reads the little bit of paper that comes with it - and it says this is contraindicated to people with diabetes and you think why have they given it to us? And I think that's something that a pharmacist would perhaps be more aware of, possibly,

hopefully.

PT: Seems like a very good idea because obviously there are more and more drugs being developed as there are more diabetics being diagnosed and the drug companies are developing more drugs because they make money by developing the drugs, so it becomes harder and harder if you like for the GP to be on top of what is the best remedy for the patient given the other conditions they may have, which may make it difficult to prescribe. But the question is I mean okay pharmacists will get training as part of their courses, will they then have time to actually interact with patients, I mean will the system provide that flexibility if you like, that time, to do the job that they've been trained to do - or the additional job.

RA: That to be honest is a totally separate question, but it's a very important question but one which to be honest I can't answer here...

PT: But also they're doing blood pressure and blood tests for various things aren't they? You're right they could end up with too much on their plate just like the doctors are.

PT: In instances where somebody's on medication long term, you're going into a cycle of repeat prescriptions, repeat prescriptions, repeat prescriptions, the patient, if they are aware (can't make out this bit) you're looking at the information actually on the container, etc. etc., lots of times the GP ignores what the patient asks and says and reports back simple things. I've been on medication for years on two tablets and for years I've been saying why don't you just give me one (not clear)? Ignored totally. Eventually they got round to it and said we had a medicines review and we are giving you one large tablet 32mg, but you know it took literally four or five years to get to that point and if I had had a review with somebody and I could have actually flagged that and we may have gone further down the road and saved money, corrected it.

RA: So how would you feel about being part of a study with a student doing the review for you?

PT: I think that's fine, I mean at the end of the day whether they be a GP, a practice nurse or a pharmacist, the end product is the patient, it's not the packet of pills that sits on the shelf, if you know what I mean and really that's fine for people to interact right across the medical spectrum with the patient and it gives the patient more confidence as well.

PT: It would depend on how confident the student is, of course. If they come over as being confident and competent then I don't think there'll be any problem at all, even excepting that they are final year students?

RA: Final year, yeah.

PT: Final year students, so I don't see it as a problem but if they come through as being very timid and not sure of their grounds then yes it could upset a few people.

PT: I just can remember what (unclear) said about reading the packet or the instructions on the packet, I think - I'm sure people around the table would do that but then we're a sort of sub select group of people who have volunteered to be part of a study I don't think we should assume that the average person if you like (unclear) and because it's you know either complicated...

PT: But then that is, that could be quite worrying that they're not aware.

PT: Quite worrying if their GP doesn't give them the advice which is on the paper, if you like. I worry about, the GP's busy, even so I think having a pharmacist involved who has read all the paperwork and a lot more as well probably and understands what will harm (unclear) in the terms of biochemistry, I think it's a very good thing and we shouldn't assume, I mean what people read on food in supermarket, we have all these contents one or two per cent of people actually read the contents, most people just buy it and eat it.

PT: I guess the ones that will be reading it would be the ones with the medical condition that they need...

PT: Well maybe or maybe not, but the point is we I suspect this group is not typical in that sense of the general population.

PT: No but we're all aware of who's liable to getting any type of medication, are more have the benefit the drugs company to cover themselves should anything happen from a bruise appearing to somebody collapsing



and whatever so I mean I think the whole point of the matter is, I was speaking to somebody about this the other day, you sometimes see a scare story appearing in the paper and it says 'x' drug causes so and so in 30% of the population or something like that but when you actually break it down into percentages of percentages, you usually find a lot of these problems occur in about two thirds of one per cent of the entire people who are taking the drugs, but it's just the initial thing, and I think sometimes this is where the pharmacist would you know explaining the drug in more detail, which they may have the information to do because even when I go to my practice nurse she say let's have a look at so and so and she'll flick her book open and oh yeah that might do this, that and the other, she's not conversant with every drug on the market, whereas I would hope that when the students finish and go into practice they will carry on learning about that product and - I don't know how it works in pharmacy, I know that possibly GPs and practice nurses go to refresher courses, they're updated and that type of thing, perhaps some aren't, but I don't know what happens in pharmacy whether they move on to what you might call further product education as the years go on.

PT: It's another line of defence for eradicating errors and that does happen. I was prescribed something for an internal problem and when I got the packet it was for rosacea, it was not connected to what I needed it for whatsoever, the drug sounded very similar but the GP had made a mistake. Well I guess I'm intelligent enough to read it and think there's something wrong here and ask the pharmacist. The pharmacist said oh no you shouldn't be on that, but I guess having another level will give people confidence that what they're being prescribed is the right thing.

PT: To answer the question basically yes it's good to get them involved.

PT: THIS PATIENT IS TOTALLY UNCLEAR – 01:18:53 to 01:18:10 on recording.

RA: So would you have any particular concerns about sitting in front of a student and having this consultation?

PT: The only way this information is going to be attained by the student is from the questionnaire, I assume, initially?

RA: The questionnaire is really to validate what has happened...

PT: So therefore it's actually face to face consultation?

RA: So the student will look at the medical records of the patient at the GP practice, make a plan and then communication face to face.

PT: How much training will they have had to consult with actual patients?

RA: We are introducing as part of this study an additional course.

PT: Is it a counselling type of approach?

RA: That's included in the course.

PT: So they will have the skills to actually talk to somebody?

RA: We hope.

PT: Would they do a dry run before they actually get on to a real patient?

RA: They're doing dry runs with professional actors, with scenarios we have set up.

PT: So they won't actually go straight in and actually sit with a real patient initially, they will have several attempts at talking to people? With that particularly approach, so they're doing dry runs is there going to be a formal feedback within the group so that they can all experience what they've found, what the person felt, etc. so they get some additional feedback from the group that they're with?

RA: Can I possibly bounce that back do you and say do you think they should?

PT: I think so because you get more information out of networking with a team of people than you would ever actually just doing one to one, because it's the incidental spin offs which are the gems, we found that

whenever you are talking in a group of people with a similar problem, it's the incidental little comments that pop off which are absolutely critical because it's the syndrome when you say I never realised that, I wasn't aware of that and you only get it by actual group discussion.

PT: I think that works fine for a group like this who are self-selected speaking but maybe quite a lot of people in society who actually would only talk freely in a one to one situation because they will be inhibited in discussing what is a medical issue with other people they don't know.

PTS: Talking over each other.

RA: Can I maybe go onto some other specifics then? I have passed round information leaflets and these are the leaflets that the students, sorry - I apologise, the patients will receive; so each patient will receive from the GP practice an invitation letter, an information leaflet and a consent form. Do you want a few minutes to look through them? Have you had a chance to read them?

PT: In actual fact one comment I wanted to make...

RA: Yes I would like your comments on it.

PT: The letter itself explains (unclear) but then actually points you to the information they'll send you. When I read it, I'm trying to put myself in the position of the patient that gets lots and lots of stuff through the post, that basically reads something and if doesn't hit them within two or three lines, the eyes fold up and it ends up in the bin. What I was wondering was, or I may have missed this, but would it be beneficial to have a very brief summary about what this study is about within the first two or three lines of the letter?

PT: Yeah, there is, as Tony's pointed out, there is that question now, I mean it says supervised pharmacy student-led medication review for patients with diabetes in primary care, but that doesn't really sort of say the aim of this study is to...

PT: Then again it doesn't need to be complex, just a very brief, very simple because you'd read that and say yes I'm interested in this and then read the rest of the information. At the moment, when I read this, I put myself - I've got to read everything here to understand what this thing is about.

PT: You might get some people who may think that it's some devious way of taking their treatment away from their GP, or whatever like that, you know what I mean, because a lot of people, especially like the old people do have very great faith in the GP or their practice, so I think that perhaps take a few lines to explain.

RA: Anybody got any comments on the information contained in this? So we're talking about this particular one and the letter and the consent form.

PT: I thought this information leaflet was confused, complex and detailed and I read it all and I thought oh yes I read all of that...

RA: Is there anything on it you would think therefore should be left out?

PT: I don't know, I think personally that level, I just felt many people wouldn't be bothered reading this and then might decide not to take part because of that, which seems a shame (unclear) for selection.

RA: Does anyone else think that this might put people off? It's an important comment.

PT: Yeah, trouble is you walk a fine line between what ethics expect of you and then what you've got to do and what you'd like to do, if know what I mean, so if we amend things as such and it goes before ethics and so on, and they say we're not having this, so it just gets thrown back again.

PT: Maybe the way to do it is to have some key part of the information up in bold and then all the legal, ethical whatever stuff later on so that most people don't read it at all but it's there and no-one can complain (unclear).

PT: I agree, a sort of ethics-light really, that would be the way to do it, get your salient points over and get the

patient on board - if you see what I mean.

PT: The invitation to patients I thought was pretty good, except my bug bears is things that are abbreviated; and there is something that is called a PCT, I don't have a clue what it is, so I would make up my own version of what that actually means, I couldn't find it anywhere.

RA: So cut out abbreviations?

PT: Oh yeah, that is a big thing with a lot of these studies, we had over at the medical school there was so much doctor speak in the thing that went through there, I mean unless you knew what the abbreviate...

PT: Patients talking over each other.

PT: We know what it is but it does say it there but sometimes these things can go into all manner of abbreviations and not read from the ordinary man in the street's point of view and there isn't probably going to be a PCT by the time they read it anyway is there, or there might be it might be reinvented again by then.

RA: Do you know what (unclear) means?

PT: Did you include a glossary of terms?

RA: No.

PT: That would be quite useful, you know, so that something like the intervention on its own, someone who wasn't quite sure what it actually meant - you know? Generally speaking there are some technical sort of medical terms in there which many people...

PT: You could put abbreviations in there too which would make the form not quite so long looking...

PT: More user-friendly.

PT: ...but you've still got an explanation sheet.

RA: So - is there anything you think is likely to make people more or less likely to participate with this? I've already have some comments what would improve it?

PT: The feeling I get is that if you want somebody to participate, first of all you've got to get their attention; so your initial letter in effect sort of highlights what the thing is about and then let them have the information at a simple level and then still provide more information at a slightly higher level as they require it. So what you're doing is you're drawing them in, giving the basic information and then if they want more information you go up or they can actually ask you for information so it's making it...

PT: You build a level of importance then to the patient so as...

PT: That's it similar...

PT: Saying how much you appreciate their help, and you know you've got to make them feel like you can't do it without them if you know what I mean and that particular respect in just a few words you know that they're partaking in a study which is going to benefit not only their self but the whole of the diabetic community long term, but if you give people a bit of sense of self importance as I said it's the whole traffic warden's hat sort of thing then they're more likely to take, certainly looking at the marketing thing, but that can help them sort of draw them in and they may take the trouble to read it.

RA: So trade on self interest (unclear)?

PT: Yeah.

PT: But does that mean that following, if you're selected to be the active half of the study rather than the control, that when the student interview, does the student come to some conclusion about your medication, that will be fed back to your doctor/GP? I mean I think that needs to be stressed because actually that is the benefit of the patient if the student thinks there's a case for changing medication or some other change of

treatment, then that's potentially very useful to the patient.

PT: To let the patient know the outcome of the study.

PT: Patients talking over each other.

PT: There might be a good outcome for them if they (unclear) in the control group and it happens, but that's the nature of experimental science, but I think that's good if people have the idea, or actually personally (unclear)...

PT: (Unclear) need to clearly specify the time frame (unclear), for how long you will be involved in the study, eight months, nine months, eleven months, twelve months, that has not been shown here basically, so (unclear) because it is a short duration study, maybe there will be less drop out but if it is a longer duration there may be (unclear) so (unclear)...

PT: One minor point that I've noticed, you're talking about two final year students doing your drugs assessment, I assume you mean that they'll be working together, but not individually so that you do one with one and then another one with a second student, so I just wondered whether it was an idea to put working together?

RA: Do we need to clarify that?

PT: Yes, that's what I wondered because somebody might think oh well that means I've got to have two lots of 20 minutes and oh I don't know if I can spare that much time, so I just thought, it's a simple thing just because working together is...

RA: In effect, it's an important point then, two students would access the records of a patient, but then only one student would meet that patient, so is that your understanding from what we've written or is it not?

PTS: In chorus: No, it's not.

PT: And that's why asked whether they were together or individually.

PT: I think that's good, I mean now I understand what's proposed because I think you know the one to one interview is much less inhibiting than two students to one patient.

PT: So you could say that two students working together will assess your results, your criteria, whatever and you will have an interview with one of them, or something like that, just to make it clear that it's only one that you're needing to see.

RA: Right, that's obviously not clarified. Thank you.

PT: You mentioned about the students liaising with the GP would have (unclear), have you set a protocol for this?

RA: Not as yet.

PT: Do you think you should have the protocol giving the the framework of how that will actually be done?

RA: Can I possibly bang it back to you and say there's the issue, do you think we should?

PT: I think it would clarify it for the students that would give them the limitations of where they should not step out of, the parameters would be actually marked out for them. And also they need to be able to sort of, when they're not sure, get to somebody who can give them advise, obviously the person supervising would be that person, but I think you need to for the students point, you need to have some sort of format that they are going to follow there.

PT: Presumably the students will have to complete some paperwork during and after the interview with patient, presumably the paperwork will define what the questions are, that they are supposed to be asking (unclear).

PT: If the paperwork hasn't been put in to some sort of format....

RA: Currently we have a care plan to be used, but beyond the care plan, do you think there should be a further protocol for the student?

PT: I'm just thinking you agree to an area where you've got a GP who is having students possibly discussing with him/her the medication that they have prescribed to his/her patient or he/she has prescribed to his patient, well that could be very, very sensitive, that's where I think the protocol should be. It's tackling that problem.

PT: Can I go back on my previous point which was a load of rubbish because you have got it here quite clearly in black and white that after four weeks you will be invited to UEA for a consultation with one final year pharmacy student – so I apologise, it does say that.

RA: It's not about apologising, because it obviously wasn't clear first time.

PT: I just didn't read that bit, went on to the next bit I think.

PT: I think that's because the paperwork is information dense and so it may well be there but are we (unclear) going to read is another (unclear). That's why I say you need the bold messages, then you need all the fine detail later on when people have agreed that's their choice.

RA: Any other comments on this particular paperwork? Can I ask one more specific question there? The letters will actually be sent out from the GP practices and we've had comments that we might get a better response at a particular time of the week, does anybody think that is an issue, or not?

PT: I think the letter has to go from the GP that will be their responsibility to each recipient, but (unclear) the response rate is poor but once the GP (unclear).

PT: I suppose you could argue that patients might have more time at a weekend to read through and if you send it at the beginning of the week they might have lost it by the weekend, but that's different.

PT: I think if you get a brown envelop from the doctors you'll rip it open in about two seconds flat to see what the hell's going on, you know. I can't see the time of the week making a great deal of difference, I suppose theoretically if you had to pick a time of the week, then send it so it arrived on the Monday or Tuesday so you wouldn't be tied up with the constraints of the weekend, you might have the chance to see the other way round, a lot of people (unclear – patients talking over each other)...

PT: That's completely opposite to the way I would send it out...

PT: A lot of people may plan things for the weekend, if you know what I mean, whereas Monday and Tuesday is a fairly sort of...

PT: You are doing the bowel cancer screening evaluation programme so in which case they are sent out mainly in colour and most of people's just throw them just (unclear) unless they have put the NHS logo, they are changing the colour, they normally (unclear) to see the address has come from NHS, this is about our health, they should read and should have a look at it otherwise our (unclear) like that.

PT: This may sound a bit spaced out and daft, but what I would suggest is that once you've got a package ready, you know say like a dummy package which is going out to a patient, you sit and read it, you personally, and then try and fill it out, because when I read this, I had to sit down for at least half an hour, I actually when through looking at the questionnaire as well and that took quite a bit of time. I mean you say 20 minutes on that because I think you'll find that once you've actually tried it yourself you will find things yourself which may need tweaking, purely because of the amount of paperwork, one thing that, a silly little thing, the names that you refer to on these bits of paper, I couldn't relate that to the letter necessarily. I can't remember exactly what the actual specific thing was, but you know when I was saying have I got all the bits, I don't know because they're not listed there, have I got to read them in this order, that type of thing. In the end I had them spread out on the table whilst I'm rummaging through them. I think that when I've been involved in these things before, very few people attempt to do it themselves, as you know. Get all the documentation

ready and then you do it yourself and maybe a couple of your colleagues do it as well and just see what you find.

RA: Okay, thank you. Can I go on then to another thing? The consultation, where do you think it should happen?

PT: In their doctor's surgery.

PT: Yeah, I would have thought so.

PT: Yes, I agree, because patient is close to that place, so (unclear).

PT: Yes, it's got to be at the GP's centre.

PT: Because it's local, presumably to most of the patients.

PT: They're familiar with it, I mean to come up to a place like this in some people it would be a little bit intimidating, if you know what I mean, it's like you're going to go on the slab in Dr Frankenstein or you could get lost like we did, so I think they'd feel under less pressure and they wouldn't have all the rigmarole of coming up to find the place, you've got to find them, and they'll just go to the surgery, they'll know where to park, they'll know who to ask for and they'll have a little room that they can go in and do what they normally do really. So they're doing exactly what they do, the only thing that's different is the student.

RA: And should we give any assistance with travel?

PT: Not to the surgery I don't think because most people, as Dave says, go to the surgery any way.

PT: And potentially it's for the benefit of those involved.

PT: Plus, it's the paperwork (unclear) small sums of money.

PT: (Unclear) some pay scheme like giving Boots voucher to participate in the study, it will (unclear) expenses (unclear).

PT: Now that's a good idea, that is, just a little sweetner.

PT: Give out £20 or £10 Boots voucher (unclear).

PT: To be spent at your local pharmacy.

PT: Of course that's the other place, most people's pharmacy is also very close to where they live so I suppose that could be an alternative place, but my first thought would be to the doctor.

PT: (Unclear) attached and I think most of the ones where you go into are going to be in that case aren't they? Have they got a new one at Costessey?

PT: Yes.

PT: Yes, you see a lot of the patients will be joined to the pharmacy or very, very near indeed.

PT: (Unclear) depending consulting room, basically (unclear).

PT: I mean there's a Co-op in my local town and they do have a room set aside that you can go and talk in private with the pharmacist, so that's a possibility, but I think my first thought was still with the doctor's surgery.

PT: I think it's got to be done at the surgery because I mean the very elements you need, the proximity to the patient, the very fact that the GP or practice nurse is going to be present, otherwise you are going to be transporting people all over the show all the while aren't you?

PT: Plus documentation, which they would be very reluctant I would think to leave the premises.

RA: So I think that's a universal GP practice?

PT: And as for the voucher, that's an idea but I suspect it's, you haven't got the money for that?

PT: It adds to the expense.

PTS: Unclear as patients talking over each other.

PT: You could emphasise that this could be to your benefit.

PT: (Unclear) pay for travel you've got to have the incentive (unclear).

PT: Well you could give us an option I suppose, you tick a box if you want the voucher and hopefully most people will not bother, I don't know.

PT: The practices are not slow in coming forward the minute you suggest anything, it's all how much are we going to charge you for the room and all this sort of thing and I mean they're straight out there with their hands out GPs now, there's no two ways about that.

PT: I think that I would just emphasise that it could be to your benefit, to your long term health benefit.

PT: When a patient joins they don't know whether they are going to be in the intervention group or the control group, will they be told eventually?

PT: Oh yes.

PT: Does it become apparent because they won't have the interview?

PT: Well you didn't use the word control group, you used something else, what was it?

PT: (Unclear).

RA: Well we've referred to a control group but we want to check with the paperwork (unclear)...

PT: One thing you'll have to address, and you will get asked because we did on our last project, is the fact that the people who don't get allocated to the control group will feel that they are second class citizens by just getting the same treatment that they are getting already and...

PT: Sorry, Dave, you've just said the same thing but getting confused, it's the intervention group...

PT: The intervention group are getting the extra treatment, if you see, the standard group which are getting their standard care, like we're all getting we tended to find that they thought they were second class citizens to a certain extent.

RA: Do we need to deal with that?

PT: I think they need to have a good understanding, the fact that their role in the study is just as important as the other, that's got to be very much emphasised the fact that just because they are not getting, because people were saying well why can't I have the extra help? Why can't I have the exercise sessions? Why can't I have this, you know?

PT: You could say, I mean I assume that it will be names out the hat to produce which group they go into?

RA: It will be randomised.

PT: So you could actually say that, that the selection will be randomised and whilst you might not be in the medication review both roles are incredibly important to us, something like that.

RA: We obviously need to communicate with people to inform them whether they are standard care or intervention, do we need to...

PT: Intervention is not a very good word, I think assessment or something...

RA: I'm using that phrase...

PT: Put it in your glossary at the end...

PTS/RA: Unclear as all speaking over each other.

PT: Medication review group is written down, so stick with that.

RA: So if they are control or standard care, do we need to think about a different form of letter to them to emphasise their role?

PT: When they are initially informed what group they are in, yes, I think that's quite important to give the people the understanding that they are still part of the study even if they don't feel like they are doing anything, if you see what I mean.

PT: They fill out the questionnaire don't they?

PT: They do, yeah.

RA: But that's all.

PT: So you want them to do that before you tell them that they're not part of the study?

PT: No, but you need to draw them into the study.

PT: They are part of the study, they're as important as they other people who are in the intervention.

PT: Yeah, but I think that sentence that...

RA: That's an important issue there. Okay, now I think as you've earlier mentioned, the questionnaire, what do people think about it? Is it easy to complete, or not, do you think? It's too long, too short?

PT: Will it come in the mail this questionnaire? Because when I downloaded it, I couldn't download it properly.

NOT CLEAR HERE AS PEOPLE TALKING OVER EACH OTHER.

RA: There should be a copy in your pack.

PT: Yeah, I've got a packet there.

PT: I'm assuming that UNCLEAR is merely a glitch on the computer and not an indicator to the patient?

RA: It's actually because that's a sample version, we have to get a licence to use it and so that mark will not be there.

PT: On question number seven, I'm assuming it's seven to 23 the questions, these tick boxes, I merrily started filling it in thinking oh yes how do you take your medicine, and then what's your medicine called, I immediately wrote down the name of the medicine and when I actually looked at what I was supposed to do and then I finally figured it out but it did take me three or four questions before I actually understood how I was supposed to fill that thing in.

PT: The think it should say something like do you know what your medicine is called, too much, about right, too little, none received, amount of information – what your medicine is for, amount of information received...

PT: Yes that's relevant, it's what your medicine is called because you can only be told once and it can't be too much, too little or whatever if you've been told once.

PT: What you're actually saying is the amount of information received about your medicine.

PT: The key word is the heading of the column is this information about needs to be in bigger type or



emphasised in some way.

PT: Or perhaps you should pluralise that to medicines because (unclear) are on more than one.

PT: But we can only be told what the medicine is called once, it's neither too little, too much or anything else. The name of your medicine, so I tell you you are on sugar lumps today, it's sugar lumps tomorrow, it'll be sugar lumps in three weeks' time, it's not going to change.

PT: Well you see that's not one hundred per cent true, because I've found that the drug companies change the names of the medicines, they use the common names by which you refer to them and that does help cause some confusion, even to pharmacists I've found.

PT: Well in which case the question needs to be changed.

PT: Maybe that's what the question is getting at, I don't know. I mean but you're right if the name never changes, once you know it, you know it. But if it does change, it can cause some problems.

PT: It can.

PT: I've had people even showing concern about the fact that the colour of the pack has changed or they use a different type of statin, do you know what I mean, and they don't look at the instructions they don't even read the name, I had an orange box last time and now I've got a blue one, that's how people tend to look at their medicines initially.

PT: (Unclear) type 2 diabetes and here you stick to the (unclear) studies and there I have shown that diabetes people are taking at least two drugs only for diabetes besides that they have another three drug that they are taking for hypertension and also for (unclear) five or six drugs and if you're asking what the general (unclear) the side effects vary from one drug to another so how are they going to summarise, unless you specify diabetic drug then we can understand whether you are talking about (unclear) so we have got five or six (unclear) so we are talking about only three or four (unclear) there is more side effects all over the world (unclear). So suppose the patient (unclear) only about statin and not about (unclear) then this comes a very (unclear) response (unclear).

TALKING OVER EACH OTHER.

PT: Because the further questions go on about diabetes, how satisfied are you with your diabetic treatment so basically we are talking about diabetic medicines and they are on medication so why don't we stick to diabetics medicines?

PT: It does talk about ALL your medicines.

PT: Yes because you cannot (unclear) how you can tell about the side effect of (unclear) separately, or I'm taking Ramipril for my (unclear) so are you to (unclear).

PT: If they have had two drugs that both had side effects and they were different, or different levels of side effect, you've got not ability to fill the forms.

PT: Yes.

PT: That's obviously going to be sorted out in the form, the questionnaire, because clearly we have some differences of opinion as to what the form is talking about, is it about diabetic medicine or is it about all your medicines.

PT: Well it says about all your medicines.

PT: The thing that again may be beneficial to you is to sample the forms and then just send them out random to a few, half a dozen people, a dozen people, get them back and have a look, just analyse them before you actually include them into a main study.

UNCLEAR TALKING OVER EACH OTHER.

PT: If somebody actually fills it out and realises there are a few...

PT: No I'm thinking of actual patients that would actually fill all of these things in.

PT: I think possibly you should change that to say take your medications or what were your medications called, if you see what I mean, because otherwise if someone says how do you take your medicine, someone's going to say which one? there's usually five, you know...

PT: But it does say above, it says one medicine but if you take more than one then give your overall feeling about information you have received about all of your medicines. Of course it might not be so easy to give an overall feeling if you've got one drug that gives you small side effects and one that gives you horrendous side effects.

PT: (Unclear).

RA: Okay, any other thoughts?

PT: Question 44, I put a word in, your treatment to be lately.

RA: What specifically do you find a problem with it?

PT: When I read that I thought am I reading that right?

PT: So it doesn't need the to be lately you think?

PT: Yeah.

RA: What about the time taken to complete it?

PT: It was fairly quick, twenty minutes.

PT: Within twenty minutes I think, but you do need to read it.

RA: Would you feel, if you were a patient in the study, you would be happy to complete it though?

PT: Yeah.

PT: Yeah, because by the time I've got to filling that in I should have, in theory, should have understood the information, the letter, the invitation, etc, etc.

PT: Your comment about lately, it also applies to number 45, recently – how flexible have you been finding your treatment – you don't really need the recently because it has to be the current treatment, doesn't it?

PT: True.

RA: I will look at those.

PT: I think currently would be a much better word to use if that's what (unclear) styles.

PT: Yeah.

PT: It could be that it has changed...

PT: That a little while ago it was really good and now it's not.

UNCLEAR – TALKING OVER EACH OTHER.

PT: (Unclear) because I'm also use the same questionnaire it is called the DSQ questionnaire, but in my questionnaire in my reply that word, last word, is recently but here it is lately, I don't know why (unclear).

PT: It's 44 and 45, that one's lately and 45's recently.

PT: (Unclear) how flexible have you been finding your treatment to be recently, it is fine the wording. In the 44

question in the original questionnaire it is currently.

PT: I think current, current treatment.

PT: Exactly.

PT: Currently is a much better...

PT: Current, yeah, I think currently would be a much better there.

UNCLEAR – TALKING OVER EACH OTHER.

PT: (Unclear).

RA: I will go back to the person who felt the questionnaire because obviously these are validated (unclear) and we can't actually change them but I take your comment also that we've (unclear).

PT: (Unclear).

RA: I'm in contact with Clare at the moment.

PT: (Unclear) basically diabetic medicine so I do not know that it is useful for this type of questionnaire also. In same trial basically that trial was related to intensive care for diabetic area so (unclear) who has been having a GP (unclear) those are special interest diabetes, sending patients to the hospital for care (unclear) a specialist GP (unclear) in the local area so there you basically (unclear) because I am a health economist so I do the cost effective manual analysis, so that is quite, but for the patient point of view (unclear), satisfaction then we have a separate quality of life questionnaire for the diabetic people so that is called (unclear) procurement and (unclear) because (unclear) is basically more like a health department (unclear) other clinicians or other people who are (unclear) quality of life so you might consider that. Another is the pain question study review was in that trial (unclear) basically using my previous trials as it were, you want to look at it (unclear).

RA: Thank you.

PT: Yeah, you can have a copy of that.

PT: I would think about question 47 at all... would you recommend this form of treatment to someone else with your kind of diabetes.. that's asking the patient to say, give information, that they've got no medical knowledge absolutely whatsoever and unfortunately if you do, the last thing you want is somebody saying, that's just like asking would you use this soap powder again, but I wouldn't like to think that was a leading question as to where someone's sitting in the pub with someone they say well I'm diabetic and I'm getting off, well I wouldn't do that, I'd go ask for this, and that and the other, you know what I mean, that's a bit of a question which suggests to see if they're happy, but it's also the sort of thing that you really got to have a tremendous amount of understanding of your condition to answer that question.

PT: And different people react differently anyway as we all know from drugs that we might all have been on at some stage, what suits one person doesn't necessarily suit another.

PT: Question 41 is really the heart of the matter, is how satisfied are you with your current treatment. It's a question that you can answer and that's what's really necessary for the study, whether you'd tell others or recommend it to someone else is irrelevant, and a bit pretentious really.

PT: It is really.

PT: The questionnaire is designed to be filled in by a patient who has diabetes, would it be beneficial, and I can't remember if we've actually included it in here now, to find out how long they've been diagnosed diabetic because you're asking them questions on the performance of their medication but you don't know how long they've been actually taking them.

PT: It might be in the criteria to the GP who's going to produce the patients.

PT: The analysis of this is going to be separate from (unclear) because this will be a document which will be

analysed on its own.

RA: One of the criteria is they will have been diagnosed for at least two years.

PT: Is that mentioned in here?

RA: Nothing in there, no.

PT: They mention about long-term diabetes treatment (unclear) two years not a long time, sometime for the first two years you are on diet control not on medication, but if you say at least two years on medication then one can see all the side effects.

PT: So in actual fact a question about how long you've been diagnosed would be a good control question in here to make sure you don't pick up someone who's recently been diagnosed.

PT: (Unclear) from the GP's report because GPs record information about since when it has been diagnosed as a diabetic and then he has been put on a medication so these two indicators are already there in GP's report.

UNCLEAR – TALKING OVER EACH OTHER.

PT: (Unclear) would remember anyway when they started taking medication. If you asked me, I couldn't tell you how many years ago, it's about several but it's not...

UNCLEAR – TALKING OVER EACH OTHER.

PT: It's more than you think actually.

PT: I remember.

PT: You are saying five years or six years or ten years (unclear) but we know if it is more recent they can say easily okay I was diagnosed on such and such (unclear), so I am saying the two years is quite a short period if you are looking for long term (unclear) then maybe at least two years on medication that would be a more appropriate indication...

PT: Yes, it's the time on medication that's ...

PT: (Unclear) because (unclear) better information of medication (unclear).

RA: Can I ask specifically about consultation? It will be a one to one with student and patient with pharmacist, possibly myself, as a invigilator or to check there are no particular problems. Would you have any concerns about that?

PT: Only if the student made a, dropped a real clanger at the interview that the fact that the patient was informed that the mistake had been made and we wouldn't want the patient to go away with the wrong impression of something and rush off to the GP and said the student told me this which was totally different from what you've done. So they may well make a horrendous mistake, they may well not do so, but we hope they don't, but as long as people don't go away with the wrong impression of things, that's the main thing.

PT: Are the students being directly supervised during the interview?

RA: Yes.

PT: So that's three people in a room?

RA: Yes.

PT: Would you have already explained to the patient of what the process is, of what they are going to be subjected to?

RA: Can I throw it back to you and say what do you think we ought to do?

PT: Well first of all you need to make sure the patient is aware of the process, you need to make sure that

they're aware of who the people are and identified and three you need to actually get their verbal consent to actually do it.

RA: Well we will actually have written consent.

PT: But at least a verbal consent, okay and then also is if the patient will also have to have more space to actually ask any questions within the parameters of the actual time that you've allowed. I think that would cover.

PT: And emphasise that it's for the educational purposes of the student, that again reinforce the importance of what it's all about.

PT: Their partaking.

PT: Would be the role of you or (unclear) welfare pharmacist in this threesome which is going on in a room in the GP's surgery?

RA: The role of these supervisors, supervising pharmacists would be to ensure safety, really.

PT: So they wouldn't say anything basically until something went wrong?

RA: We would hope to be able to be to one side and not say anything, but we're there to ensure safety.

PT: So the student doesn't give mis-information or, I don't know, something they shouldn't be telling the patient (unclear – over-talking)...

PT: So would the student been preparing, I mean when we worked with the second year students down there, they usually come in with the pre-written list of the questions they'd like to ask us?

RA: The course of events: they go to the GP practice, access patient details from the screen or from the computer, compile a care plan, have that checked by a pharmacist, feedback to GP or specialist nurse. Then that care plan is taken away and retained safely. Next time students then will meet a patient and have access to that care plan and will talk to the patient, so yes they will have time to prepare.

PT: And they've already, the information in that care plan, has already been vetted in effect.

PT: So they'll basically be looking via the care plan and a set of questions that they've formulated in their head to see if they can offer the patient anything to improve the condition or to just check the patient is getting the maximum benefit from his medication.

PT: So at that stage it's rather more how they relate to the patient than anything else.

PT: So when they're actually about to discuss with the patient they have got a format of the care plan?

RA: The student will have formulated their care plan.

PT: Is that standardised?

RA: It will be standardised, I'm currently working on it.

PT: So everybody will be approaching it from the same angle?

PT: That care plan will take into account all the patient's conditions, diabetes plus whatever else they may have?

RA: That's our current thinking, so you think that's right?

PT: Well I think not to do it that way is sort of half the job, isn't it?

PT: It'd be a waste of time.

PT: Because obviously there's an interaction between the medicines.

PT: No, you've got to look at the whole thing, especially if someone...

PT: Just say purely by chance someone had got some drugs that did have contra indications that they'd been given mistakenly or that the student could see that possibly there was in the conversation that came up that someone was having a particular problem and that the student could recognise that there was probably a better type of medication that could be on to control that condition, you know they've got to look at the whole package because that's what it is all about.

PT: Sorry, there's one thing that I wanted just to mention, when they're looking at the care package and evaluating basically medication, will they take constraints of finance into account? Because some of the GP centres will actually not prescribe that particular type of drug because of expense and want to substitute another type of drug which does the same thing but is cheaper.

RA: They will have access to all the national guidelines, things like NICE, etc.

PT: (Unclear) to put more and more people on insulin so insulin is becoming more and more cheaper and it's more effective than a tablet to manage diabetes (unclear) control for that factor within six or eight months period for the patient in their information group or control group(unclear)...

PT: But then when they go onto insulin the added complications of the insulin...

PT: (Unclear) that's the primary way, so people at the hospital think that way.

RA: You asked about financial aspects, is that because you have a concern about it?

PT: Yes, it's just that over the years I've noticed that as drugs, generic drugs, come more and more to the forefront, GPs are tending to use that particular type of drug because it is actually cheaper. Also, out there there maybe two or three drugs, one more expensive than insulin. I've had instances instead of having insulin they've gone the other way and used the (unclear) instead of the insulin, but that's a lot more expensive, but it does work the other way round as well you know with other types of drugs, they've decided to use a cheaper type of drug.

PT: Like Metformin and slow release as well, they'll try and ram the basic, cheapest Metformin down you until they know it's not going to work before they put you on slow release.

PT: I'm just wondering whether there is a financial consideration there.

PT: There is financial, I give my example, when I was (unclear) high level of cholesterol so you are (unclear) on statin, but my GP said you to take, I am prescribing you 40mg tablet but you are to take 80mg tablet, make it half because there is no price difference between 80mg and 40mg and the guidelines suggest that PCT guidelines has told you basically to do this way because it would save us 10 million pounds over a period so they keep on doing that and he was literally doing for almost one year 80mg then making half and I am taking that way because the company, the NHS is getting the same price whether it is a 40mg or 80mg from the company.

PT: But that's where it all gets very silly, because I had a very similar thing, I was put on 40mg and it affected me, it didn't make me feel wonderful, put it that way, and I went back to the doctor and I said why have you started me on 40mg, which I thought was the biggest dose they're likely to give you and he said because they're the same price as the 20mg and I said, so you've put me on 40, wouldn't it be better to start me on 10mg and increase it until it achieves the correct result, but no it's this financial bit, oh they're the same price so I've got to put you on the biggest dose.

PT: Putting business head on then, theoretically, the students would have to take the business side of the cost of medicines into consideration because of the, especially when they know we're going to move to the which is now virtually private practice which is the PCTs and that, what are they calling them now? Whatever it's called now, they're really going to be looking at handling their own budgets and the doctors are certainly going to have a way of thinking as to the type of medications that they are going to be taking on board and what

their drugs' budget is going to be so there's going to be that thing between what the pharmacist or even what the patient may research and say well I want (unclear) and things like that, people will want the very best they can get, but as you know full well you can't get it in some places.

PT: And authorities are already sending out letters to the GPs aren't they suggesting that they use x or y instead of a and b because x and y are cheaper, so that's already happening.

RA: So what's the feeling, do you think that we should get the students to ignore the financial things and just go for a quality based drug or completely financial?

PT: I think you need to lead the students to where they live in the real world.

PT: Yeah.

PT: Even if they spoke to the GP afterwards and said look I recommend Mr Smith should be on such and such a thing like that, I mean what would your opinion be and if the doctor is totally honest with him he'll say well look at the end of the day if we put every patient in the practice on this, that would cost the practice x amount more and all this type of thing because there's this balance between the well being of the patient and obviously the cost of running a business which is what practice groups are now going to be becoming and that's going to be but the doctor isn't going to say oh well I shalln't get the Audi A6 next year I'll get the A4, he'll still want his car and I'll have the Metformin.

PT: GP consortia, I've thought of the word now.

PT: There is a business aspect that has to be looked at from that understanding because if we are looking long term for somebody to walk into a pharmacy like they may do in Germany or somewhere like that and say look I'm felling x, y, z what can you recommend, and he'll go that's so many euros, that isn't work if they do it for a medicine review at the pharmacy and the pharmacist said you're obviously suffering these side effects on this, you'd be a lot better off on that drug, the patient then goes back to doctor and says look the pharmacist said I should be on this and that's ten times the cost of the other one, that could cause a conflict, if you know what I mean, so I think that's where there's got to be a business understanding in the review there somewhere.

RA: I have one more question, time's getting on, do you have time for one more question? It's as simple as this: what do you think, what elements would make up a good consultation by a pharmacist, I mean what about the difference to a GP's consultation?

PT: Yes, I think there's an opportunity when people go for their medical review there to the GP or to the practice nurse in the practice, there's always that thing of you'll go in there, if you're type 2 you'll go once, perhaps twice, a year to the GP, maybe more if you're having problems, but you probably go in there with the idea of how you feel, what you need to ask and what you want to do and you come home and you've probably forgotten half of what you want to ask in the first place...

PT: Or you've run out of time...

PT: Or you've run out of time or whatever like that and you know you'll get asked your standard questions but sometimes a consultation or a review, well it is a consultation basically with a pharmacist making people the opportunity to...

PT: Talk specifically about their drugs rather than about how they're feeling...

PT: ...their mental well being, or their blood pressure or anything like that.

RA: Are there any particular things you would want to find in the consultation, or are there particular ways that you want it presented?

PT: Dave's actually made a very good point there is that once you've been into a doctor and had a consultation with the doctor, as you walk out you've sometimes got so confused you've forgotten exactly what was said and how it was said. If you have a consultation about medication review, would it be beneficial to give a feedback sheet to the patient which the student could then keep as a record, as a reference, to his documentation. For example, a list of medication, because if this review is going to be done again you've then

got a base to look at. Two, any comments the person wants to make about particular medication, oh this one gives me the trots, this one, you know, etc. It can be recorded and any other further follow up that the student should think the patient should possibly do recorded. That way if the GP starts complaining about what's going on, you've actually got proof as well, you've got an audit trail basically of what actually went on in that particular consultation. Also the patient's actually got something to go home with.

PT: If the patient has just seen the GP and he walks into the pharmacy to pick his tablets up on the same day and the pharmacist says how are you getting on with your medication, would you like to have a pharmaceutical review then there's a second chance for the patient there, and sometimes if you went to the GP and the GP said that we're going to have to get your blood pressure down a bit or you're going to have to lose a bit of weight, you know the usual sort of thing, or you've got to cut your drinking down or you've got to cut the smoking out, there may be instances there where the pharmacists can, just say for smoking for instance, you can get certain things on the NHS to help you with all that sort of thing, but there may be other things that the person again may want to speak, we find this because we have people ringing us up with concerns and you wouldn't have a help group for patients if they were having all bases covered when they saw the GP they wouldn't be ringing us up and asking us things that they do, if you understand what I'm saying, so how that format should take place sometimes if you sit that person down you don't really have to say that much at all, once that person opens up, and I think that's one thing you've got to tell the students is the fact we don't want them, one says how you getting on with that medication, how you getting on with that, is this one giving you any problems, if you fire the questions at them that isn't necessarily going to work. Whereas a more relaxed approach is saying I can see you're on so and so, so and so, so and so, so and so, are you having any problems with anything at all, and they'll problem come out with something completely nothing to do with the medication whatsoever, but there could be a lot of things that would come that would be quite, may signpost to other problems that that person's got that he's not mentioned to the GP.

PT: Will all the interviews be time limited? Obviously ultimately it will be time limited, but I mean will it be like ten minutes, twenty minutes and then you're out?

RA: Currently we don't have plan to limit, do you think we should?

PT: More probably that depends on resourcing it (unclear – talking over)...

PT: Eventually if it were to come to fruition it would depend on the uptake, if everybody and his wife want to see the pharmacist, if you don't limit the time, then...

PT: Well I was thinking about the interviews for the study, but as long as is reasonable I suppose, but if it's twenty minutes and you're out and someone's got things they still want talk about (unclear – talking over)...

PT: Considering it's a student doing the interview, they've got to be given as much time as they need to do it because really and truly their brain's going to be working through things to try and get, if it all hopefully comes to fruition in ten or fifteen years' time it gets put into practice by the NHS then yes there will have to be a constructed way of doing it and a time limit in it, and who's going to do it, and who's going to get paid for doing it and all this sort of thing...

PT: I think you would have to have some time frame purely to concentrate the student's direction because if you don't then what's going to happen is somebody out there the direction can go anywhere, but by having a time constraint you're going to focus certain things, once those things are done then it gives them space to do what they want.

PT: But I think that should be a generous sort of time, at the end of the day if you give them twenty minutes or half an hour even and if you see after fifteen minutes you conclude the student has completed all the information that they need to do so and all it's going to be is fifteen minutes of waffle you could say of well I think you've done very well there and we can bring the interview to an end now and then we'll talk (unclear) end of thing, I mean you can always jump in at any time if the student's struggling or the you see they've actually come to as far as they're going to go with the thing. I mean obviously there's going to be people who simply can't do it or may not wish to do it in practice.

PT: There is a consultation between the student and the GP basically the student has one recommendation



and the patient goes to the doctor and he has said like this and GP's own experience clash (unclear)?

RA: The student's information will be fed back to the doctor and at least he will know what is happening.

PT: How many patients are these students dealing with?

RA: This is a pilot study so they will actually only see two patients face to face.

PT: But you've got 168 patients...

RA: 160...

PT: That means that by my maths you've got about 150 students?

RA: No, there will be 80 control and 80 intervention, if we can use those terms.

PT: Two students per patient, that's (unclear) students.

RA: No, it's two patients per student.

PT: Oh right, it's only 40 students.

PT: And they've been, this is voluntary...?

RA: It's voluntary, it's outside their normal course time.

PT: And they're not marked on it?

RA: It doesn't form part of the qualification of their course.

PT: So in fact they are all going to be people who think they can cope any way because they wouldn't volunteer otherwise?

RA: You'd hope so.

PT: Are the students going to get credits for their course?

RA: No.

PT: Why?

RA: Well partly, we can't do that for ethical reasons but they were informed prior to volunteering that there would be no evaluation and credits for their course.

PT: Could they use it for part of their thesis towards the end, the study information?

RA: What they can do obviously is put it on their cv and so far they've volunteered because they feel that there will be benefit to themselves.

PT: That's good.

PT: What's the uptake rate by the students, you've got 40 students, how many students in total do you have in that year?

RA: In that year, that's about half the year. We did actually over-recruit but we've had to stick to 40.

PT: I think that Norfolk is not a diverse population so you may have been only having English patient because the diabetes among Asians is eight times higher and they have a language problem, they cannot read this questionnaire, so you won't be recruiting them or you (unclear).

RA: To be honest even the local population there's not a large population of people who don't speak English, although in some areas (unclear).

PT: (Unclear) in Coventry because I come from the Coventry area so (unclear – over-talking).

PT: Even Coventry how diversified is your study?

RA: In terms of?

PT: Ethnic groups.

RA: To be honest we have said that the students will be seeing patients whose prime language is English (unclear), this is a pilot study and also the assessments don't have (unclear) for languages. So, for instance, if we meet somebody whose first language is German or Norwegian or Gujarati or whatever, we can't expect the assessor to automatically know (unclear) initiate that.

PT: I'm just thinking, every national health thing I've seen has got this ethnic thing stuck on the front of it, I didn't see it.

PT: As long as they can speak English then they could still be put forward, it's just non-English speaking ethnic minorities that wouldn't be included for obvious reasons.

PT: But then if you had the study as you said in a different ethnic group, this would be useless if they couldn't speak English.

PT: (Unclear) UK (unclear) different patient language acknowledge that (unclear).

RA: So if this trial proved to be successful and was then developed as a full trial, should we take that on board?

PT: Definitely, for a national level the diversity (unclear).

PT: I think you should consider it purely because when you start analysing this, if you start getting flagged up areas and ethnic groups that are having difficulty doing it that should be telling you something.

PT: Is this the only study that's been (unclear) pharmacist course?

RA: To be best of my knowledge it's the only one. So, is there anything else about the consultation, anything we should learn from this telling us what we should or shouldn't do? (Unclear).

PT: Not really, as long as they get a good grounding on the people skills side of things, because I'm not saying you're asking a boy to do a man's job, but you are in respect that they're going to sit down in front of a patient with an understanding of their condition long term, who's probably had diabetes longer than they've been born and in some cases and they're going to...

PT: They're bound to be nervous, aren't they? I think any patient involved in something like this will take that on board.

PT: But I think they're pretty damn good from the second year students we work with, they're an intelligent lot and I really enjoy working with them and they're good.

PT: I think it would be beneficial that once you have had a certain number of students go through the consultation process with the patients, is to get those students to feedback to the rest of the group and then have a sort of brain storming session amongst themselves under supervision so that the people who haven't done it are going to be able to get ideas and some benefit and some pointers and also that the people, the students, who have done it are able to talk amongst themselves and compare what they have actually done because I don't think they have the opportunity.

PT: I expect you would have done that anyway?

RA: No, the point is to find out from yourselves what you think. Can I ask is there anything that you felt during the course of this that you wanted to say and didn't the chance or are there any questions that I should've asked do you think?

PT: (Unclear) research question where (unclear) is going to capture your changes in quality of life, there is a

different issue basically (unclear) frequently challenged that it has to be once the consultation is done then he has to be (unclear) with the doctor six months that only need to be (unclear) basically for this questionnaire because less than six months' time for the quality of life questionnaire is not acceptable (unclear).

PT: Did I understand from what you said earlier that the questionnaire is set in stone and can't be changed?

RA: What could be changed?

PT: It could be, okay.

RA: Is there something you think that should be changed?

PT: Well no, I mean, I think we covered most of them, but I got the impression from the way you responded at one stage that it was unlikely that it would be changed.

RA: It is compiled from validated tools, in other words, questionnaire which have been used in other trials. You have to go back to the people who produced those questionnaires and discuss it.

PT: Do you have to go through your ethics committee as well?

RA: Yes, you would, but that's not a problem.

PT: So you could one off, add to it and not replace it and that would be okay?

RA: As long as we then write to ethics.

PT: So you still have to go back to ethics?

RA: Yes.

PT: Because I still think, have you received enough information about what your medicine is called is a daft one, and I'd be really cross when I read that and I'd think what do they mean, of course they know what they're called.

RA: Sorry, which?

PT: It's number eight, we mentioned it earlier. I just find it annoying, but then I'm reasonably intelligent and I accept that not everybody that you'll be talking to are necessarily intelligent but I just think that's an insult, sorry, I'm a bolshie whatsit aren't I?

RA: What I wanted to hear was your views.

PT: And the two 'recentlys' should be cut.

PT: Yes, we both felt...

PT: That's a less important issue.

PT: So I take it by the fact that the initial letter there if you have any questions about taking part please contact Rick Adams, that if they do find that if they do struggle with filling in the questionnaire that they are very likely to give you a ring anyway.

RA: Any other comments?

PT: (Unclear) is actually that the letter goes out to them, they consent, you then send them a questionnaire?

RA: Correct.

PT: Then they will send the questionnaire back to you, then you will then arrange with them to have a consultation with a pharmacy student, and then you need them to after six months to do another questionnaire?

RA: Correct.

PT: Is that (unclear) concise bit of information put down some place nice and simple that (unclear) that?

RA: It is in there, but maybe not in the words you have said.

PT: Because that is what you want to do...

PT: (Unclear – over-talking) the information, timeframe for the study...

PT: When you get the initial letter you can look at that and say oh that's what they want me to do, pretty straight forward.

PT: And presumably the control group don't do the second questionnaires, is that right?

RA: They do.

PT: They do? Okay, before and after the non-treatment, the non-intervention.

RA: (Unclear – over-talking).

PT: They may have changed their opinions anyway for other reasons.

PT: Well the obvious question, do you feel during the course of this study has your condition changed and your opinion and such, because you say things in six months, a year, two years can be totally different than they were at the beginning of the study.

PT: Just a sort of technical question here, because that questionnaire looks like it can only be actually analysed manually, is that correct?

RA: It is.

PT: You hadn't thought of actually doing it so that it could be scanned and run by a matrix of some sort?

RA: We do have the technology and it's something we can look at.

PT: (Unclear) when you have more than 1,000 cases then you (unclear – over-talking) break even...

PT: It's purely the numbers, is that...

PT: (Unclear) the quality of paper and the design of questionnaires is very strong because it has to scan in such...

PT: Relatively small numbers...

RA: (Unclear).

PT: Are we having another meeting at any stage or is that it now?

RA: That is it, but if anybody would like, nearly everybody's ticked they'd like results of the study, because we obviously will be, we hope to publish and if we do then you will certainly get copies. You didn't actually tick, would you like that?

PT: Sorry, it's because I ticked the other... I sent it in the post, please tick it for me.

RA: Thank you so much because I've actually got a lot of things there that I need to go away and think about. I'll need to go through, I'll need to get that transcribed and go through it in depth, but there are a lot of issues (unclear) will help us to either improve the quality directly or to stop us going down a blind alley, so certainly, okay it's a one off but from our point of view it was well worth while and I'd like to thank you very much.

PT: Is this your project, your idea and your project?

RA: To be honest, it's the project I'm working on, the original idea is from my professor and I'm the one who's actually carrying it out with his supervision, but it's an area that I believe in and.... Tape finishes.

# Appendix D: Ethical Approvals and Approved Documents

Appendix D1: Ethics Committee Correspondence

Appendix D2: Ethics Approved Documents – Development

Medical Practices

Students

Pharmacists

Patients

Appendix D3 : Ethics Approved Documents – Intervention

Medical Practices

Students

Pharmacists

Patients

Appendix D4 : Ethics Approved Documents – Review

Medical Practices

Students

Pharmacist

Patients

Appendix D5 : Ethics Approved Documents – UEA

## **Appendix D1: Ethics Committee Correspondence**



Professor David Wright  
Head of Medicines Management  
School of Pharmacy  
University of East Anglia  
Norwich  
Norfolk  
NR4 7TJ  
[d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)  
01603 592042

Mrs Lynda McCormack  
Cambridgeshire 3 Ethics Committee  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

6<sup>th</sup> November 2010

**Supervised pharmacy student led medication review in primary care:  
A pilot study to ascertain the potential costs and effects: REF 10/H0306/77**

Dear Mrs McCormack

Please find enclosed copies of paperwork relating to the above trial, which has also been submitted as an online application for review at the meeting on the 2<sup>nd</sup> December.

Papers enclosed.

Printed IRAS form

Six copies of each of the following:-

- Annex 1 Protocol
- Annex 2 Development Phase Focus Groups



- 2.1 Consent form and Information leaflet for G.P.s
- 2.2 Consent form and Information leaflet for Patients
- 2.3 Consent form and Information leaflet for Students
- 2.4 Consent form and Information leaflet for Pharmacists

Annex 3 Intervention Phase

- 3.1 Invitation letter, consent form and Information leaflet for G.P.s
- 3.2 Invitation letter, consent form and Information leaflet for Patients
- 3.3 Invitation letter, consent form and Information leaflet for Students
- 3.4 Questionnaire for patients

Annex 4 Review Phase Focus Groups

- 4.1 Consent form and Information leaflet for G.P.s
- 4.2 Consent form and Information leaflet for Patients
- 4.3 Consent form and Information leaflet for Students
- 4.4 Consent form and Information leaflet for Pharmacists

Annex 5 CVs for Professor David Wright and Rick Adams

Annex 6 Funding Approval letters and Peer Review Documentation

- 6.1 Provisional approval
- 6.2 E mail with final approval
- 6.3 Peer reviewer No. 1
- 6.4 Peer reviewer No. 2
- 6.5 Peer reviewer No. 3
- 6.6 Peer reviewer No. 4
- 6.7 Peer reviewer No. 5

With your agreement we plan to attend the meeting in order that we can answer any questions which might arise.

Yours faithfully

Professor David Wright



**National Research Ethics Service**  
**Cambridgeshire 3 Research Ethics Committee**

Victoria House  
Capital Park  
FULBOURN  
Cambridge  
CB21 5XB

Telephone: 01223 597597  
Facsimile: 01223 597645

08 December 2010

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study Title:** Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects  
**REC reference number:** 10/H0306/77

The Research Ethics Committee reviewed the above application at the meeting held on 02 December 2010. Thank you for attending to discuss the study. Please pass on the Committee's thanks to Mr Adams for attending as well.

**Documents reviewed**

The documents reviewed at the meeting were:

Document	Version	Date
Investigator CV: Prof. David Wright		08 November 2010
Protocol	1	03 October 2010
Summary CV for student: Richard (Rick) Adams		09 November 2010
Letter from Funder		09 August 2010
E-mail from Funder		01 October 2010
Letter to accompany questionnaire	1	19 October 2010
REC application: 63837/163432/1/533		17 November 2010
Covering Letter: Prof. David Wright		08 November 2010
Questionnaire: Intervention Phase: Patient Questionnaire	1	24 October 2010
Letter of invitation to participant: Development Phase, GPs	1	14 October 2010
Letter of invitation to participant: Development Phase, Patients	1	14 October 2010
Letter of invitation to participant: Development Phase, Students	1	14 October 2010
Letter of invitation to participant: Development Phase, Pharmacists	1	14 October 2010
Letter of invitation to participant: Intervention Phase, Medical Practices	1	14 October 2010
Letter of invitation to participant: Intervention Phase, Patients	1	24 August 2010
Letter of invitation to participant: Intervention Phase, Students	1	24 August 2010

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England

Letter of invitation to participant: Review Phase: GPs	1	14 October 2010
Letter of invitation to participant: Review Phase: Patients	1	14 October 2010
Letter of invitation to participant: Review Phase: Students	1	14 October 2010
Letter of invitation to participant: Review Phase: Pharmacists	1	14 October 2010
Participant Information Sheet: Development Phase: Invitation for a GP to join a Focus Group	1	03 October 2010
Participant Information Sheet: Intervention Phase: Invitation for a Medical Practice to join a Research Project	1	03 October 2010
Participant Information Sheet: Review Phase: Invitation for a GP to join a Focus Group	1	03 October 2010
Participant Information Sheet: Development Phase: Invitation for a Patient to join a Focus Group	1	03 October 2010
Participant Information Sheet: Intervention Phase: Invitation for a Patient to join a Research Project	1	03 October 2010
Participant Information Sheet: Review Phase: Invitation for a Patient to join a Focus Group	1	03 October 2010
Participant Information Sheet: Development Phase: Invitation for a Student to join a Focus Group	1	03 October 2010
Participant Information Sheet: Development Phase: Invitation for a Pharmacist to join a Focus Group	1	03 October 2010
Participant Information Sheet: Intervention Phase: Invitation for a Student to join a Research Project	1	03 October 2010
Participant Information Sheet: Review Phase: Invitation for a Student to join a Focus Group	1	03 October 2010
Participant Information Sheet: Review Phase: Invitation for a Pharmacist to join a Focus Group	1	03 October 2010
Participant Consent Form: Development Phase: Focus Group for GPs	1	10 October 2010
Participant Consent Form: Development Phase: Focus Group for Patients	1	10 October 2010
Participant Consent Form: Development Phase: Focus Group for Students	1	10 October 2010
Participant Consent Form: Development Phase: Focus Group for Pharmacists	1	10 October 2010
Participant Consent Form: Intervention Phase: On behalf of Medical Practices	1	08 October 2010
Participant Consent Form: Intervention Phase: Patients	1	08 October 2010
Participant Consent Form: Intervention Phase: Students	1	08 October 2010
Participant Consent Form: Review Phase: Focus Group for GPs	1	10 October 2010
Participant Consent Form: Review Phase: Focus Group for Patients	1	10 October 2010
Participant Consent Form: Review Phase: Focus Group for Students	1	10 October 2010
Participant Consent Form: Review Phase: Focus Group for Pharmacists	1	10 October 2010
Referees or other scientific critique report: RFPB Programme, Reviewer 1		
Referees or other scientific critique report: RFPB Programme, Reviewer 2		
Referees or other scientific critique report: RFPB Programme, Reviewer 3		
Referees or other scientific critique report: RFPB Programme, Reviewer 4		
Referees or other scientific critique report: RFPB Programme, Reviewer 5		

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the National Patient Safety Agency and Research Ethics Committees in England

After the Committee's initial deliberations, you were invited to join the meeting to clarify some issues. You kindly provided the Committee with the further information and clarifications set out below.

1. The Committee asked whether the main aim of the study was to determine if patient care was improved or to pilot a change to Pharmacy students' training. You said that it was hoped that both would be achieved: having taken up the participants' time, you felt there was a need to demonstrate benefit to the participants.
2. The Committee asked if Pharmacy review was already used. You replied that it was, but at varying levels. Evidence that it saves money has been demonstrated but the issue of patient benefit is less clear.
3. The Committee asked what would happen if every student wanted to take part and would those unable to do so feel disadvantaged. You replied that this had been considered but you don't feel that all will want to take part. It will be made clear that their course grades won't be affected by not having taken part and that the benefits are expected to be long-term improvements to students' training. Furthermore, when you asked informally about interest, a number of students who had initially expressed an interest, became less enthusiastic when they realised how much work was involved on their part.
4. The Committee asked whether patients would be required to undergo an additional blood test for the purposes of the research. You replied that this is the case and this will be included in the Participant Information Sheet.
5. The issue of indemnity was raised by the Committee. You thought that this would be covered by the Primary Care Trusts (PCTs) but members pointed out that this would be the case only for PCT-owned practices. It was agreed that this required clarification.
6. The Committee asked whether the search of medical records was to be undertaken by researchers or GP Practice staff. You replied that it will be done by the Practice Pharmacists. The Committee said that the GPs' consent must be sought and you agreed that this would be done.
7. Members explained their concerns about the patient Participant Information Leaflet where, in answer to the question 'Will I benefit from participation in this study?' the information states that it 'may further enhance your medical treatment' and you agreed to remove this wording.
8. The Committee mentioned that a flowchart would have been helpful and, while they will not make it a requirement for this application, it might be useful to include one for any future projects.
9. The Committee raised the point that the fact that the study was to focus on patients with diabetes was not mentioned until quite a long way in to the protocol and it was felt that this should be made clear earlier on. You agreed to amend this.
10. The Committee asked about the requirement for the patient to be stabilised on their therapy for at least two years: the implication is that you are looking for a stable group but diabetes tends not to be stable. You replied that they understood that diabetics are a dynamic group in terms of their medication but want to avoid

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newly-diagnosed patients in the acute phase of illness as they understand that this is the period in which major changes will be made with up-titration of medications and the addition of new medications to control not only diabetes but hypertension and cholesterol levels as well.

11. Members noted their concern over wording in the Invitation Letter to Patients, where it mentions that the patient has 'shown an interest in participating in this study' and asked how this is known at this point. You responded that subjects will have been recruited via their membership of Diabetes UK. Members advised that they felt that the wording in the Invitation Letter to Patients should be amended as the patients will have shown an interest in taking part in research generally rather than this study in particular.
12. The Committee asked who will sign the Consent Form on behalf of Medical Practitioners. You expect this to be the Senior Partner.
13. Regarding the health scale which has a marker at point 7.0: you explained that the scale provided in the application is a sample version but the licensed version to be used in the study will not have the marker.
14. The Committee asked about what would happen to participants who lose capacity to give consent during the study: you confirmed that the incorrect box was ticked on the application form and that, while data collected up to that point will be included, the patient will be withdrawn.
15. The Committee suggested that, while taking a blood sample to test HbA1c levels, perhaps they could also test cholesterol levels and you agreed to do so.
16. The Committee mentioned the use of the term 'main study' and you will clarify this where necessary in the study documentation.
17. Regarding the Patient Information Sheets, members pointed out that some of the terminology in the PIS for GPs and students was not appropriate. They would also like the students' PIS to make it clear that their degree grade will not be affected if they do not take part in the research. There is reference to the Hertfordshire REC which needs to be changed to Cambridgeshire 3 Research Ethics Committee.

After you left the meeting, the Committee discussed your responses further and felt that you had provided a number of useful clarifications.

#### **Provisional opinion**

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Vice Chair.

#### **Further information or clarification required**

##### *Administrative issues:*

- (i) As discussed, while taking a blood sample to test HbA1c levels, you should also test cholesterol levels.

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- (ii) Study Title  
The title should be amended to reflect that the study is looking at patients with diabetes. The Committee suggests 'Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects'.
- (iii) Protocol:  
The protocol should be amended so that it clear from the start that the patients will have diabetes.
- (iv) IRAS Database:  
A35 should be amended to reflect that participants who lose capacity to consent during the study will be withdrawn.
- (v) Indemnity:  
You should ensure that there is suitable indemnity in place for the GP practices.
- (vi) Health Questionnaire:  
There is no option for the use of pill dispensers (Dossit boxes) or to indicate that extra doses are taken. You are asked to consider this.
- (vii) Letters of invitation:  
Many of the letters start We are writing on to ....
- (viii) Development Phase; Invitation Letter to Patients  
The sentence '...and has shown an interest in participating on this study.' should be amended. These potential participants have shown an interest in taking part in research studies but not this study in particular.
- (ix) Information Sheets:
- The use of the term 'main study' should be consistent.
  - Confirmation that there is suitable indemnity in place for the study should be given.
  - The name of the reviewing committee is the Cambridgeshire 3 Research Ethics Committee.
- (x) Information Leaflet – Invitation for a GP to join a focus group:
- The section Will I benefit from participation in this study? starts 'You will may benefit...'. 'Will' should be deleted.
  - Confirmation that there is suitable indemnity for the study should be given.
- (xi) Information Leaflet – Invitation for a patient to join a research project Intervention Phase
- Participants should be advised that an additional blood test may be required
  - In Will I benefit from participation in this study? the part of the sentence 'and may further enhance your medical treatment.' should be deleted.
- (xii) Information for students  
Additional reassurance should be given for students who do not take part in the study.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the Committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 07 April 2011.

The REC nominated Co-ordinator, Lynda McCormack, to be the point of contact should you seek further clarification upon receipt of this decision letter.

#### **Membership of the Committee**

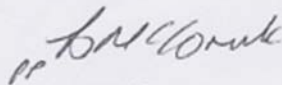
The members of the Committee who were present at the meeting are listed on the attached sheet.

#### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H0306/77	Please quote this number on all correspondence
-------------	--

Yours sincerely



**Mr Stuart Kent**  
Vice-Chair

Email: [lynda.mccormack@eoe.nhs.uk](mailto:lynda.mccormack@eoe.nhs.uk)

*Enclosures:* List of names and professions of members who were present at the meeting and those who submitted written comments.

*Copy to:* Ms Clare Symms,  
Research Governance Manager  
NHS Norfolk  
Lakeside 400, Chapel Way  
Broadland Business Park  
Thorpe St. Andrew  
Norwich  
NR7 0WG

**Cambridgeshire 3 Research Ethics Committee**  
**Attendance at Committee meeting on 02 December 2010**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr John Richardson (Chair)	Lay member	No	Apologies given
Mr Stuart Kent (Vice-Chair)	Retired Consultant Surgeon	Yes	
Dr Sati Ariyanayagam (Alternate Vice-Chair)	Consultant Physician	No	Apologies given
Mrs Anna Eden	Lay Member	No	Apologies given
Mr David Lewin	Research Officer	Yes	
Dr Stella Lowry	General Practitioner	Yes	
Ms Sue McIntosh	Lead Nurse Theatres, Day Surgery & Procedural Areas	Yes	
Revd David Parkes		Yes	
Mrs Nikki Phillimore	Senior Pharmacist	Yes	
Mrs Ingrida Robinson	Clinical Governance Team Manager	Yes	
Professor Michael Simmonds	Retired academic pharmacologist	Yes	
Mrs Madeleine Wang	Lay member	No	Apologies given

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Lynda McCormack	REC Co-ordinator
Mrs Charis Bailey	REC Co-ordinator

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
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the National Patient Safety Agency and Research Ethics Committees in England



Ref: 2010IC02 (CSP 63837)

**Mr Richard Adams**  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**Research & Development**  
NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

Tel: 01603 257283  
Fax: 01603 257292  
E-mail: [paul.mills@norfolk.nhs.uk](mailto:paul.mills@norfolk.nhs.uk)  
[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

1 February 2011

Dear Richard,

**Re: 2010IC02 (CSP 63837). Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects**

**REC Number:10/H0306/77**

**Chief Investigator: Professor David Wright, University of East Anglia**

**Sponsor: NHS Norfolk**

Further to your submission of the above project through NIHR CSP your project has now been reviewed in accordance with the NIHR CSP Operating Guidelines and all the mandatory research governance checks have now been satisfied. I am therefore pleased to inform you on behalf of **NHS Norfolk** that NHS permission (R&D approval) was granted on **26<sup>th</sup> January 2010** for your study to take place at the following sites:

- NHS Norfolk

Please note that NHS Permission is granted on the basis of the information supplied in the application form, protocol and supporting documentation, if anything subsequently comes to light that would cast doubts upon, or alter in any material way, any information contained in the original application, or a later amendment application there may be implications for continued NHS Permission.

You may now begin your study at the above sites.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework. I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign and return one copy to the R&D office at the above address. Failure to return the standard terms and conditions may result in NHS permission being revoked.



Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan

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NHS Norfolk hosts the Research Management and Governance Services for NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust

Please note, under the agreed standard terms and conditions you must inform the R&D Office at NHS Norfolk of any proposed changes to this study, whether minor or substantial, and to keep the Committee updated on progress.

Please note also, if you wish to extend approval to any sites other than those listed above you must apply for this through NIHR CSP.

If you have any queries regarding this or any other project please contact Paul Mills, R&D Officer, at the above address. Please note, the reference number for this study is 2010IC02 (CSP 63837) and this should be quoted on all correspondence.

The following documents were reviewed:

Letter of Favourable Opinion from Cambridgeshire 3 REC, dated 18<sup>th</sup> January 2011

- Protocol, Version 2, 5<sup>th</sup> January 2011
- Letter of Invitation – Development Phase, GPs, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Development Phase, Patients, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Development Phase, Students, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Development Phase, Pharmacists, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Intervention Phase, Medical Practices, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Intervention Phase, Patients, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Intervention Phase, Students, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Review Phase, GPs, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Review Phase, Patients, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Review Phase, Students, Version 2, 6<sup>th</sup> January 2011
- Letter of Invitation – Review Phase, Pharmacists, Version 2, 6<sup>th</sup> January 2011
- Participant Information Sheet – Development Phase, GPs, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Development Phase, Patients, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Development Phase, Students, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Development Phase, Pharmacists, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Intervention Phase, Medical Practices, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Intervention Phase, Patients, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Intervention Phase, Students, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Review Phase, GPs, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Review Phase, Patients, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Review Phase, Students, Version 2, 7<sup>th</sup> December 2010\*
- Participant Information Sheet – Review Phase, Pharmacists, Version 2, 7<sup>th</sup> December 2010\*
- Participant Consent Form – Development Phase, GPs, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Development Phase, Patients, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Development Phase, Students, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Development Phase, Pharmacists, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Intervention Phase, Medical Practices, Version 2, 6<sup>th</sup> January 2011
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- Participant Consent Form – Intervention Phase, Students, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Review Phase, GPs, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Review Phase, Patients, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Review Phase, Students, Version 2, 6<sup>th</sup> January 2011
- Participant Consent Form – Review Phase, Pharmacists, Version 2, 6<sup>th</sup> January 2011
- Letter to Accompany Questionnaire, Version 2, 6<sup>th</sup> January 2011
- Patient Questionnaire, Version 2, 6<sup>th</sup> January 2011

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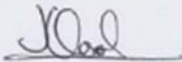
- CV – Professor David Wright
- CV – Mr Richard Adams
- Evidence of Peer Review – RfPB reviews 1-5
- Letter from Funder, 9<sup>th</sup> August 2010
- Email from Funder, 1<sup>st</sup> October 2010
- Clarification of Insurance/Indemnity – Email from Paul Mills, 5<sup>th</sup> January 2011
- Clarification of Insurance/Indemnity – Email from Sue Steel, 22<sup>nd</sup> December 2010
- Revised Answer for Question A35

Other Documents Reviewed

- Signed R&D Form, Lock Code 63837/166464/14/507
- Signed SSI Form, Lock Code 63837/177926/6/367/75666/201368

**\*Note:** It has been noted that, although the version numbers are the same, the version dates on all supplied patient information sheets are different to that listed on the REC approval letter. In your email of 27<sup>th</sup> January 2011 you stated that this was an oversight, but the documents provided to the R&D office are the same as given to the REC. We suggest you notify the REC of the difference in version dates for audit purposes.

Yours sincerely



Jonathan Cook  
Director of Corporate Services  
NHS Norfolk

cc: Professor David Wright, University of East Anglia  
Tracy Shalom, NHS Norfolk, Sponsor Representative  
Heien MacDonald, PCRN East of England  
File

Enc

**Research & Development**

NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

**Mr Richard Adams**  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

Tel: 01603 257283

Fax: 01603 257292

E-mail: [paul.mills@norfolk.nhs.uk](mailto:paul.mills@norfolk.nhs.uk)

[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

2 February 2011

**Re: 2010IC02 (CSP 63837). Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects**

STANDARD TERMS & CONDITIONS ATTACHED TO NHS PERMISSION FOR RESEARCH IN  
NHS NORFOLK, NHS SUFFOLK, NHS GREAT YARMOUTH & WAVENEY AND NORFOLK  
COMMUNITY HEALTH & CARE NHS TRUST

NHS Permission from NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust is conditional upon acceptance of these standard terms and conditions. It is the investigators responsibility to ensure that these are disseminated to all parties involved in the study.

**1. Validity of permission**

NHS Permission is only valid if the research commences within one year of the date NHS permission was granted. NHS Permission is only granted for those sites listed on the NHS Permission letter(s) for the above study.

**2. Safety and conduct of research**

The Investigator will notify the R&D Office at NHS Norfolk immediately if they are or become aware of any information which would cast doubts upon, or alter in any material way, any information contained in the original application, or a later amendment application, such as to raise questions about the safety and/or continued conduct of the research.

The investigator or Sponsor may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health & safety, however the R&D office must be notified that such measures have been taken, detailing the reasons why such measures were taken and the plan for further action. This notification should take place at the



Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan

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NHS Norfolk hosts the Research Management and Governance Services for NHS Norfolk, NHS Suffolk,  
NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust  
ST&C of approval NHSNorfolk Jan2011  
Review date – April 2012

same time as required notification to the Research Ethics Committee and any regulatory authorities.

### 3. Confidentiality

The investigator and all members of his/her team are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. The investigator is responsible for ensuring that all members of his/her team understand and comply with the requirements of the NHS Confidentiality Code of Practice

(<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>) and the Data Protection Act 1998, and to be made aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

The investigator is also required to adhere to the NHS Norfolk guidance "Access to Patient Notes for Research Purposes – Guidance Notes for Primary Care" November 2009 which are available on the R&D website (<http://www.norfolk.nhs.uk/node/1480#confidentiality>).

### 4. Interventional Studies

The granting of NHS permission for this study does not commit the PCT to ongoing financial support for any intervention trialled.

Where excess treatment costs are to be incurred on a study, written agreement must be obtained from the Trust in advance of the study starting.

### 5. Observational or Non-Interventional Studies

If the research is classified as an observational or non-interventional study, NHS permission is contingent on the following:

- (a) the assignment of any patient involved in the research to a particular therapeutic strategy is not to be decided in advance by reference to the study protocol;
- (b) the clinical care, management, investigation and supervision of any patient involved in the study must be determined by the clinical judgement of the treating clinicians and in accordance with the normal practice of the treating institution; it must not be influenced by or contingent upon the patient's involvement in the study.

### 6. Documentation to be supplied to NHS Sites

It is the investigator's responsibility to provide all participating sites or participant identification centres with all relevant study information to enable them to fulfil their role within the research. This will include as a minimum:

- (a) Final approved protocol
- (b) Copies of REC favourable opinion (including list of approved documentation), NHS Permission letter covering that site, any other approvals necessary (e.g. MHRA)
- (c) Participant information sheets, consent forms, invitation letters, posters/adverts and any other documentation given to the participant

It is the investigator's responsibility to update the information held at each site with any amendments made to this documentation and all approval letters applicable to those amendments.

### 7. Protocol and Protocol amendments

The Investigator must conduct the research in accordance with the Protocol. All amendments made during the study should be notified to and discussed with the R&D office at NHS Norfolk prior to implementation (except in cases of emergency where the welfare of the subject is paramount – see clause 2) and in parallel with any necessary regulatory or ethical review. This applies both to substantial and non-substantial amendments.

### 8. Serious Adverse Events

The Investigator will inform the R&D Office at NHS Norfolk of any serious adverse events relevant to any local participants in the research within 24 hours of such events happening or of the investigator learning about them if later. This requirement is in addition to any duties the

Investigator has to the Ethics Committee or the Sponsors of the research. The Investigator must also comply with relevant Trust incident reporting mechanisms.

#### **9. Ethical favourable opinion**

The Investigator will adhere to any applicable Research Ethics Committee terms and conditions of favourable opinion.

#### **10. Monitoring**

The Investigator will provide the R&D Office at NHS Norfolk with details of the progress of the research. This should be submitted on the Annual/Final Monitoring Report Form (available on request), at intervals of one year unless otherwise specified in the letter of NHS Permission, and on conclusion of the research. This will include details of numbers of patients screened and recruited from all NHS Norfolk, NHS Suffolk and NHS Great Yarmouth & Waveney sites.

If a research project is discontinued, the R&D Office at NHS Norfolk must be informed and an Annual/Final Monitoring Report Form submitted. This is in addition to any requirements from the Research Ethics Committee.

#### **11. Payments to Practices / Directorates**

The investigator will co-operate with the R&D office to facilitate payments of support funding to practices / Directorates for work incurred in the conduct of this study. This may include, but is not limited to, provision of screening and recruitment figures, numbers of bloods etc on an ongoing basis.

#### **12. Smartcards**

Where an investigator or a member of his/her team has been issued with a Smartcard for the project allowing access to SystemOne clinical databases each individual is required to notify the R&D office at NHS Norfolk when their involvement in the project is complete on a site by site basis to allow deactivation of the smartcard at that particular site.

#### **13. Research Audit**

NHS organisations are required to monitor research projects to ensure adherence to the Research Governance Framework and other legal and regulatory requirements. This is achieved through routine audits. The Investigator agrees that the research project may be subject to audit, either as part of routine or 'for cause' audit activity. The Investigator agrees to cooperate with any audits or investigations undertaken by the host institution or regulatory authorities as required.

The investigator is required to contact the R&D office at NHS Norfolk if they receive notification of any research audit or inspection to be conducted at any NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney or Norfolk Community Health & Care NHS Trust site.

#### **14. Dissemination**

The investigator is responsible for disseminating information on study progress and any findings/issues etc to all sites on an ongoing basis throughout the study and at study conclusion.

#### **15. Roles and responsibilities**

The Investigator will comply with the roles and responsibilities of the researcher, as described in the DH Research Governance Framework for Health & Social Care. In particular they will ensure that all members of the study team are able by knowledge, experience, training and supervision to undertake the roles assigned to them and are made aware of these standard terms and conditions of approval.

Where the research is being conducted in full or in part within general practice the principles outlined in NHS Norfolk "Good Practice Guidelines for researchers working with General Practice" must be followed. These are available from the R&D website (<http://www.norfolk.nhs.uk/node/1427>).

#### **16. Intellectual property rights**

ST&C of approval NHSNorfolk Jan2011  
Review date – April 2012

NHS responsibilities for intellectual property are defined in the NHS Executive's Policy Framework for the Management of Intellectual Property (HSC 1998/105). Copies of this document, are available from the Research and Development office and the investigator is referred to the Intellectual Property Policy of their relevant Trust(s).

Intellectual property (patents, copyright, design rights, trade-marks, know-how) which arise in, or during, the course of an employee's employment, belong to their employer, unless an existing contract overrules. By agreement to these terms and conditions the Investigator confirms his/her agreement to the allocation, treatment, management, handling and assignment of any intellectual property arising from the research in accordance with the intellectual property policies of the relevant host Trust.

In particular, where a research agreement relevant to the research requires that a relevant Trust should assign the rights to intellectual property arising from the research to the Sponsor of that research, the Investigator will cooperate to make that assignment effective in accordance with the terms of that agreement.

**17. Publications**

The investigator will inform the R&D office of any publications or publicity arising from the study and, at the request of the R&D office will use his/her best endeavours to ensure that the role of the host NHS organisation is acknowledged in any such publication or publicity.

**18. Health and safety**

It is the responsibility of the Investigator to be familiar with and comply with the Health and Safety Policies of the relevant Trust(s) copies of which may be accessed via the R&D office.

**19. Research outside the NHS**

The Investigator recognises that agreements and 'permission' granted by NHS Norfolk and/or on behalf of NHS Suffolk and NHS Great Yarmouth & Waveney apply to research activity on NHS premises involving patients and their tissues or records, clients, staff and NHS services. They do not apply to patients who are being treated privately nor does it extend, for example, to social services (except those working within Norfolk Learning Difficulties Service) or local education services. Separate agreements and approval for research access to these sectors will be required.

I confirm that I accept the above terms and conditions of approval.

Signed:.....

Name:.....

Date:.....

Please copy this document returning the original to the R&D office at NHS Norfolk and retain the copy for your files.



Dr David Wright  
Professor in Pharmacy Practice  
School of Pharmacy  
University of East Anglia  
Norwich  
Norfolk  
NR4 7TJ

Mr Stuart Kent  
Vice-Chair  
Cambridgeshire 3 Research Ethics Committee  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

3<sup>rd</sup> February 2011

**REC Reference number: 10/H0306/77**

Dear Mr Kent

Whilst discussing the project with representatives of GP Practices at recruitment meetings we have received some useful suggestions. Following this I am writing to seek permission to make a minor amendment.

It has been suggested that GPs may find it difficult or be unwilling due to pressure of work to attend a Focus Group and that accordingly attendance may be low, whilst Specialist Nurses may be better able to attend. We already have stated in the protocol that the students will feedback to a GP or Specialist Nurse during their session at a Practice so it would be sensible to include them at this stage as well.  
I am therefore asking that the GP Focus Group should be amended to be a Focus Group for GPs or Specialist Diabetic Nurses.

Enclosed:  
Annex 2.1

Consent Form Focus Group for General Practitioners and Specialist Diabetes Nurses  
Invitation for a General Practitioner or Specialist Diabetes Nurse to Join a Focus Group  
Participant Information Leaflet  
GP/Nurse Invitation letter

Please contact me if you require any further clarifications.



Patient Invitation Letter 1 v3 14.6.11  
Patient Invitation Letter 1 v4 10.8.11

In addition the same focus group and a PPIRes representative recommended the removal or explanation of abbreviations and that the consultation should take place at the patient's GP Practice rather than at the University.

Enclosed:

Annex 3.2  
Patient Invitation Leaflet v3 14.6.11  
Patient Invitation Leaflet v4 10.8.11

Please contact me if you require any further clarifications.

Thanks in advance for your consideration.

Yours sincerely

David Wright

Thanks in advance for your consideration.

Yours sincerely

A handwritten signature in black ink, appearing to read 'David Wright'. The signature is fluid and cursive, with a large initial 'D' and 'W'.

David Wright

Rick



**National Research Ethics Service**  
Cambridgeshire 3 Research Ethics Committee

Victoria House  
Capital Park  
FULBOURN  
Cambridge  
CB21 5XB

Tel: 01223 597685  
Fax: 01223 597645

15 April 2011

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

**Amendment number:** Amendment #1 07.01.11

**Amendment date:** 30 March 2011

The above amendment was reviewed at the meeting of the Sub-Committee held on 11 April 2011.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	Protocol and Flowchart, 3	30 March 2011
Notice of Substantial Amendment (non-CTIMPs)	Amendment #1 07.01.11	30 March 2011
Participant Information Sheet: Intervention Phase: Invitation for a Medical Practice to Join a Research Project	2	07 January 2011
Participant Information Sheet: Development Phase: Invitation for a Pharmacist to Join a Focus Group	2	07 January 2011
Participant Information Sheet: Development Phase: Invitation for a Student to Join a Focus Group	2	07 January 2011
Participant Information Sheet: Development Phase: Invitation for a Patient to Join a Focus Group	2	07 January 2011
Participant Information Sheet: Development Phase: Invitation for a GP to Join a Focus Group	2	07 January 2011

This Research Ethics Committee is an advisory committee to the East of England Strategic Health Authority  
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Participant Information Sheet: Intervention Phase: Invitation for a Student to Join a Research Project	2	07 January 2011
Participant Information Sheet: Intervention Phase: Invitation for a Patient to Join a Research Project	2	07 January 2011
Participant Information Sheet: Review Phase: Invitation for a Pharmacist to Join a Focus Group		
Participant Information Sheet: Review Phase: Invitation for a Student to Join a Focus Group	2	07 January 2011
Participant Information Sheet: Review Phase: Invitation for a Patient to Join a Focus Group	2	07 January 2012
Participant Information Sheet: Review Phase: Invitation for a GP to Join a Focus Group	2	07 January 2011
Participant Information Sheet: Intervention Phase: Invitation for a Student to Join a Research Project	2	07 January 2011
Covering Letter		

#### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

#### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

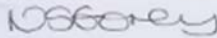
#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H0306/77:

Please quote this number on all correspondence

Yours sincerely

pp 

**Mr Michael Sheldon  
Chair**

E-mail: Nicky.Storey@eoe.nhs.uk

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Ms Clare Symms,  
Research Governance Manager  
NHS Norfolk  
Lakeside 400, Chapel Way  
Broadland Business Park  
Thorpe St. Andrew  
Norwich, NR7 0WG*

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**Cambridgeshire 3 Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 11 April 2011**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Michael Sheldon (Chair)	Retired Clinical Psychologist	Lay
Dr Robert Stone	General Practitioner	Expert

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
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2010IC02 (63837)

Mr Richard Adams  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**Research & Development**  
NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

Tel: 01603 257283  
Fax: 01603 257292  
E-mail: [paul.mills@norfolk.nhs.uk](mailto:paul.mills@norfolk.nhs.uk)  
[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

9 May 2011

Dear Richard,

**Re: 2010IC02 (CSP 63837). Supervised pharmacy student led medication review of patients with diabetes in primary care: A pilot study to ascertain the potential costs and effects**

**REC Number: 10/H0308/77**

**Chief Investigator: Professor David Wright, University of East Anglia**

**Sponsor: NHS Norfolk**

**Amendment 1 (30<sup>th</sup> March 2011)**

Further to your submission of the above amendment through NIHR CSP this has now been reviewed in accordance with the NIHR CSP Operating Guidelines.

I am pleased to inform you on behalf of **NHS Norfolk** that we are able to accommodate the above amendment and the amendment may be implemented under the existing NHS permission at **NHS Norfolk**

Please note that continued NHS Permission is granted on the basis of the information supplied in the amendment notice/letter and supporting documentation, if anything subsequently comes to light that would cast doubts upon, or alter in any material way, any information contained in this or any other amendment, or the original application, there may be implications for continued NHS Permission.

If you have any queries regarding this or any other project please contact Paul Mills, R&D Officer, at the above address. Please note, the reference number for this study is **2010IC02 (63837)** and this should be quoted on all correspondence.

The following documents were reviewed:



Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan

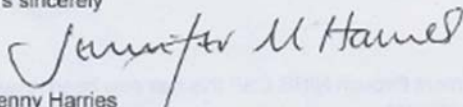
Visit our website: [www.norfolk.nhs.uk](http://www.norfolk.nhs.uk)

NHS Norfolk represents the Norfolk Primary Care Trust  
NHS Norfolk hosts the Research Management and Governance Services for NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney  
and Norfolk Community Health & Care NHS Trust

- Cover Letter to REC, 3<sup>rd</sup> February 2011
- Protocol version 3, 30<sup>th</sup> March 2011
- Annex 2.1 - Participant Information Sheet – Development Phase, GPs, Version 2, 7<sup>th</sup> January 2011
- Annex 2.2 - Participant Information Sheet – Development Phase, Patients, Version 2, 7<sup>th</sup> January 2011
- Annex 2.3 - Participant Information Sheet – Development Phase, Students, Version 2, 7<sup>th</sup> January 2011
- Annex 2.4 - Participant Information Sheet – Development Phase, Pharmacists, Version 2, 7<sup>th</sup> January 2011
- Annex 3.1 - Participant Information Sheet – Intervention Phase, Medical Practices, Version 2, 7<sup>th</sup> January 2011
- Annex 3.2 - Participant Information Sheet – Intervention Phase, Patients, Version 2, 7<sup>th</sup> January 2011
- Annex 3.3 - Participant Information Sheet – Intervention Phase, Students, Version 2, 7<sup>th</sup> January 2011
- Annex 4.1 - Participant Information Sheet – Review Phase, GPs, Version 2, 7<sup>th</sup> January 2011
- Annex 4.2 - Participant Information Sheet – Review Phase, Patients, Version 2, 7<sup>th</sup> January 2011
- Annex 4.3 - Participant Information Sheet – Review Phase, Students, Version 2, 7<sup>th</sup> January 2011
- Annex 4.4 - Participant Information Sheet – Review Phase, Pharmacists, Version 2, 7<sup>th</sup> January 2011
- Letter of favourable opinion from Cambridgeshire 3 REC for Amendment 1, 15<sup>th</sup> April 2011

Please can you also send a copy of the Notice of Substantial Amendment to the R&D office at the above address for our records.

Yours sincerely



Dr Jenny Harries  
**Joint Director of Public Health**  
**NHS Norfolk & Norfolk County Council**

cc: **Professor David Wright**, University of East Anglia  
 Tracy Shalom, NHS Norfolk, Sponsor Representative  
 Helen MacDonald, PCRN East of England  
 File

**Mr Richard Adams**  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**Research & Development**  
NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

Tel: 01603 257283  
Fax: 01603 257292  
E-mail: [paul.mills@norfolk.nhs.uk](mailto:paul.mills@norfolk.nhs.uk)  
[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

24 May 2011

**Re: 2010IC02 (CSP 63837). Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects**

STANDARD TERMS & CONDITIONS ATTACHED TO NHS PERMISSION FOR RESEARCH IN  
NHS NORFOLK, NHS SUFFOLK, NHS GREAT YARMOUTH & WAVENEY AND NORFOLK  
COMMUNITY HEALTH & CARE NHS TRUST

NHS Permission from NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust is conditional upon acceptance of these standard terms and conditions. It is the investigators responsibility to ensure that these are disseminated to all parties involved in the study.

**1. Validity of permission**

NHS Permission is only valid if the research commences within one year of the date NHS permission was granted. NHS Permission is only granted for those sites listed on the NHS Permission letter(s) for the above study.

**2. Safety and conduct of research**

The Investigator will notify the R&D Office at NHS Norfolk immediately if they are or become aware of any information which would cast doubts upon, or alter in any material way, any information contained in the original application, or a later amendment application, such as to raise questions about the safety and/or continued conduct of the research.

The investigator or Sponsor may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health & safety, however the R&D office must be notified that such measures have been taken, detailing the reasons why such measures were taken and the plan for further action. This notification should take place at the



Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan

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NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust  
ST&C of approval NHSNorfolk Jan2011  
Review date – April 2012



same time as required notification to the Research Ethics Committee and any regulatory authorities.

### 3. Confidentiality

The investigator and all members of his/her team are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. The investigator is responsible for ensuring that all members of his/her team understand and comply with the requirements of the NHS Confidentiality Code of Practice

(<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>) and the Data Protection Act 1998, and to be made aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

The investigator is also required to adhere to the NHS Norfolk guidance "Access to Patient Notes for Research Purposes – Guidance Notes for Primary Care" November 2009 which are available on the R&D website (<http://www.norfolk.nhs.uk/node/1480#confidentiality>).

### 4. Interventional Studies

The granting of NHS permission for this study does not commit the PCT to ongoing financial support for any intervention trialled.

Where excess treatment costs are to be incurred on a study, written agreement must be obtained from the Trust in advance of the study starting.

### 5. Observational or Non-Interventional Studies

If the research is classified as an observational or non-interventional study, NHS permission is contingent on the following:

- (a) the assignment of any patient involved in the research to a particular therapeutic strategy is not to be decided in advance by reference to the study protocol;
- (b) the clinical care, management, investigation and supervision of any patient involved in the study must be determined by the clinical judgement of the treating clinicians and in accordance with the normal practice of the treating institution; it must not be influenced by or contingent upon the patient's involvement in the study.

### 6. Documentation to be supplied to NHS Sites

It is the investigator's responsibility to provide all participating sites or participant identification centres with all relevant study information to enable them to fulfil their role within the research. This will include as a minimum:

- (a) Final approved protocol
- (b) Copies of REC favourable opinion (including list of approved documentation), NHS Permission letter covering that site, any other approvals necessary (e.g. MHRA)
- (c) Participant information sheets, consent forms, invitation letters, posters/adverts and any other documentation given to the participant

It is the investigator's responsibility to update the information held at each site with any amendments made to this documentation and all approval letters applicable to those amendments.

### 7. Protocol and Protocol amendments

The Investigator must conduct the research in accordance with the Protocol. All amendments made during the study should be notified to and discussed with the R&D office at NHS Norfolk prior to implementation (except in cases of emergency where the welfare of the subject is paramount – see clause 2) and in parallel with any necessary regulatory or ethical review. This applies both to substantial and non-substantial amendments.

### 8. Serious Adverse Events

The Investigator will inform the R&D Office at NHS Norfolk of any serious adverse events relevant to any local participants in the research within 24 hours of such events happening or of the investigator learning about them if later. This requirement is in addition to any duties the

Investigator has to the Ethics Committee or the Sponsors of the research. The Investigator must also comply with relevant Trust incident reporting mechanisms.

#### **9. Ethical favourable opinion**

The Investigator will adhere to any applicable Research Ethics Committee terms and conditions of favourable opinion.

#### **10. Monitoring**

The Investigator will provide the R&D Office at NHS Norfolk with details of the progress of the research. This should be submitted on the Annual/Final Monitoring Report Form (available on request), at intervals of one year unless otherwise specified in the letter of NHS Permission, and on conclusion of the research. This will include details of numbers of patients screened and recruited from all NHS Norfolk, NHS Suffolk and NHS Great Yarmouth & Waveney sites.

If a research project is discontinued, the R&D Office at NHS Norfolk must be informed and an Annual/Final Monitoring Report Form submitted. This is in addition to any requirements from the Research Ethics Committee.

#### **11. Payments to Practices / Directorates**

The investigator will co-operate with the R&D office to facilitate payments of support funding to practices / Directorates for work incurred in the conduct of this study. This may include, but is not limited to, provision of screening and recruitment figures, numbers of bloods etc on an ongoing basis.

#### **12. Smartcards**

Where an investigator or a member of his/her team has been issued with a Smartcard for the project allowing access to SystemOne clinical databases each individual is required to notify the R&D office at NHS Norfolk when their involvement in the project is complete on a site by site basis to allow deactivation of the smartcard at that particular site.

#### **13. Research Audit**

NHS organisations are required to monitor research projects to ensure adherence to the Research Governance Framework and other legal and regulatory requirements. This is achieved through routine audits. The Investigator agrees that the research project may be subject to audit, either as part of routine or 'for cause' audit activity. The Investigator agrees to cooperate with any audits or investigations undertaken by the host institution or regulatory authorities as required.

The investigator is required to contact the R&D office at NHS Norfolk if they receive notification of any research audit or inspection to be conducted at any NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney or Norfolk Community Health & Care NHS Trust site.

#### **14. Dissemination**

The investigator is responsible for disseminating information on study progress and any findings/issues etc to all sites on an ongoing basis throughout the study and at study conclusion.

#### **15. Roles and responsibilities**

The Investigator will comply with the roles and responsibilities of the researcher, as described in the DH Research Governance Framework for Health & Social Care. In particular they will ensure that all members of the study team are able by knowledge, experience, training and supervision to undertake the roles assigned to them and are made aware of these standard terms and conditions of approval.

Where the research is being conducted in full or in part within general practice the principles outlined in NHS Norfolk 'Good Practice Guidelines for researchers working with General Practice' must be followed. These are available from the R&D website (<http://www.norfolk.nhs.uk/node/1427>).

#### **16. Intellectual property rights**

ST&C of approval NHSNorfolk Jan2011  
Review date – April 2012

NHS responsibilities for intellectual property are defined in the NHS Executive's Policy Framework for the Management of Intellectual Property (HSC 1998/106). Copies of this document, are available from the Research and Development office and the investigator is referred to the Intellectual Property Policy of their relevant Trust(s).

Intellectual property (patents, copyright, design rights, trade-marks, know-how) which arise in, or during, the course of an employee's employment, belong to their employer, unless an existing contract overrules. By agreement to these terms and conditions the Investigator confirms his/her agreement to the allocation, treatment, management, handling and assignment of any intellectual property arising from the research in accordance with the intellectual property policies of the relevant host Trust.

In particular, where a research agreement relevant to the research requires that a relevant Trust should assign the rights to intellectual property arising from the research to the Sponsor of that research, the Investigator will cooperate to make that assignment effective in accordance with the terms of that agreement.

#### **17. Publications**

The investigator will inform the R&D office of any publications or publicity arising from the study and, at the request of the R&D office will use his/her best endeavours to ensure that the role of the host NHS organisation is acknowledged in any such publication or publicity.

#### **18. Health and safety**

It is the responsibility of the Investigator to be familiar with and comply with the Health and Safety Policies of the relevant Trust(s) copies of which may be accessed via the R&D office.

#### **19. Research outside the NHS**

The Investigator recognises that agreements and 'permission' granted by NHS Norfolk and/or on behalf of NHS Suffolk and NHS Great Yarmouth & Waveney apply to research activity on NHS premises involving patients and their tissues or records, clients, staff and NHS services. They do not apply to patients who are being treated privately nor does it extend, for example, to social services (except those working within Norfolk Learning Difficulties Service) or local education services. Separate agreements and approval for research access to these sectors will be required.

I confirm that I accept the above terms and conditions of approval.

Signed:.....

Name:.....

Date:.....

Please copy this document returning the original to the R&D office at NHS Norfolk and retain the copy for your files.



**National Research Ethics Service**  
NRES Committee East of England - Norfolk

Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

Tel: 01223 596907  
Fax: 01223 597645

18 August 2011

Professor David Wright  
Professor in Pharmacy Practice  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

**Amendment number:** Amendment 2 (minor)

**Amendment date:** 10 August 2011

**Amendment detail:** For user benefit, an extra paragraph has been added to the GP letter summarising the study while explanations of the abbreviations 'PCT' and 'UEA' have been added to the Participant Information Sheet

Thank you for your letter of 10 August 2011, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:

Document	Version	Date
Covering Letter	David Wright	10 August 2011
Notification of a Minor Amendment	Amendment 2 (minor)	10 August 2011
Annex 3.2 Patient information letter (GP)	4	10 August 2011
Participant Information Sheet: Annex 3.2 Participant	4	10 August 2011

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information sheet

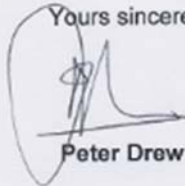
**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H0306/77:

Please quote this number on all correspondence

Yours sincerely



**Peter Drew**

**Assistant Committee Co-ordinator**

E-mail: peter.drew@eoe.nhs.uk

*Copy to:*

Ms Clare Symms  
Research Governance Manager  
NHS Norfolk  
Lakeside 400, Chapel Way  
Broadland Business Park  
Thorpe St. Andrew  
Norwich  
NR7 0WG

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NRES Committee East of England - Norfolk

Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

Tel: 01223 596907  
Fax: 01223 597845

14 September 2011

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

**Amendment number:** Amendment #3 (minor)

**Amendment date:** 13 September 2011

**Amendment detail:** An extra sentence has been added to the last paragraph of the GP letter advising participants that they will be contacted by the Practice to ensure they have all relevant information

Thank you for your letter of 13 September 2011, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:

Document	Version	Date
Covering Letter	Richard Adams	13 September 2011
Notification of a Minor Amendment	Amendment #3 (minor)	13 September 2011
Annex 3.2 GP letter	5	01 September 2011

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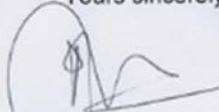
**Statement of compliance**

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10/H0306/77:

Please quote this number on all correspondence

Yours sincerely



**Peter Drew**  
**Assistant Committee Co-ordinator**

E-mail: peter.drew@eoe.nhs.uk

Copy to:

Ms Clare Symms  
Research Governance Manager  
NHS Norfolk  
Lakeside 400, Chapel Way  
Broadland Business Park  
Thorpe St. Andrew  
Norwich  
NR7 0WG

Rick Adams  
Research Pharmacist  
School of Pharmacy  
University of East Anglia  
Norwich Research Park  
Norwich NR4 7TJ

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
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**National Research Ethics Service**  
NRES Committee East of England - Norfolk

Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

Tel: 01223 597733  
Fax: 01223 597645

24 October 2011

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy,  
University of East Anglia  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects  
**REC reference:** 10/H0306/77  
**Amendment number:** Amendment 1 (REC Amendment #4)  
**Amendment date:** 28 September 2011  
**Amendment summary:**

Following a literature search it became apparent that a number of studies in related areas in USA and Australia use questionnaires at the end of student consultations with patients to give a measure of the student's performance in terms of clinical knowledge and consultation skills. The content of the questionnaires is the result of a consultation process. We feel that not only will these questionnaires give students feedback, but that they will allow us to assess the value and effectiveness of the process in addition to the measures approved previously.

- The patient questionnaire will allow us to evaluate the acceptance to patients and the value to patients of the consultation.
- The student version of the same questionnaire allows us to evaluate the student's perception of their own performance compared to that given by the patient.
- The student's questionnaire will enable student participants in the study to give feedback to the researchers on the process in the study.

Thank you for submitting the above amendment, which was received on 20 October 2011. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

**Documents received**

The documents to be reviewed are as follows:

Document	Version	Date
Covering Letter from Professor David Wright		18 October 2011
Covering Letter from Professor David Wright		22 September 2011
Notice of Substantial Amendment (non-CTIMPs)	Amendment 1 (REC Amendment #4)	28 September 2011
Email from Clare Symms (Sponsor Contact) confirming		19 October 2011

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agreement		
Questionnaire: Questionnaire for Students - Course	1	22 September 2011
Questionnaire: Questionnaire for Students - Consultation	1	22 September 2011
Questionnaire: Questionnaire for Patients	1	22 September 2011
Protocol	4	22 September 2011

**Notification of the Committee's decision**

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

<b>10/H0306/77:</b>	<b>Please quote this number on all correspondence</b>
---------------------	---

Yours sincerely



**Miss Anna Bradnam  
Committee Co-ordinator**

E-mail: Anna.Bradnam@eoe.nhs.uk

*Cc: Ms Clare Symms,  
Research Governance Manager  
NHS Norfolk  
Lakeside 400, Chapel Way  
Broadland Business Park  
Thorpe St. Andrew  
Norwich  
NR7 0WG*

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NRES Committee East of England - Norfolk

Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

Tel: 01223 597507  
Fax: 01223 597645

09 November 2011

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy,  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

**Amendment number:** Amendment 1 (REC Amendment #4)

**Amendment date:** 28 September 2011

**Amendment summary:** Following a literature search it became apparent that a number of studies in related areas in USA and Australia use questionnaires at the end of student consultations with patients to give a measure of the student's performance in terms of clinical knowledge and consultation skills. The content of the questionnaires is the result of a consultation process. We feel that not only will these questionnaires give students feedback, but that they will allow us to assess the value and effectiveness of the process in addition to the measures approved previously.

- The patient questionnaire will allow us to evaluate the acceptance to patients and the value to patients of the consultation.
- The student version of the same questionnaire allows us to evaluate the student's perception of their own performance compared to that given by the patient.
- The student's questionnaire will enable student participants in the study to give feedback to the researchers on the process in the study.

The above amendment was reviewed by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Questionnaire: Questionnaire for Students - Course	1	22 September 2011

This Research Ethics Committee is an advisory committee to the East of England Strategic Health Authority  
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19 December 2011

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy, University of East Anglia  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

**Amendment number:** Amendment #4 (Minor)

**Amendment date:** 16 December 2011

Thank you for the email from Rick Adams of 16 December 2011, notifying the Committee of the above amendment.

The amendment has been considered by the Chair, who has observed that providing no voucher is offered to those being asked to complete the questionnaire again, it can be processed as a minor amendment. (If the £10 voucher had been accepted as compensation for wasted time, this would have constituted a substantial amendment.)

As described above the Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:

Document	Version	Date
Notification of a Minor Amendment – Email from Rick Adams	Amendment #4 (Minor)	16 December 2011
Annex 3.4 Explanatory Letter - to accompany the questionnaire	3	14 June 2011

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/H0306/77:

Please quote this number on all correspondence

Yours sincerely



**Miss Anna Bradnam**  
**Committee Co-ordinator**

E-mail: [Anna.Bradnam@eoe.nhs.uk](mailto:Anna.Bradnam@eoe.nhs.uk)

Cc: *Ms Clare Symms,*  
*Research Governance Manager*  
*NHS Norfolk*  
*Lakeside 400, Chapel Way*  
*Broadland Business Park*  
*Thorpe St. Andrew, Norwich*  
*NR7 0WG*

19 April 2012

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy, UEA  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

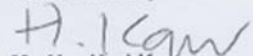
Thank you for sending the progress report for the above study dated 14 March 2012. The report will be reviewed by the Chair of the Research Ethics Committee, and I will let you know if any further information is requested.

The favourable ethical opinion for the study continues to apply for the duration of the research as described in the application and protocol agreed by the REC, taking account of any substantial amendments.

**10/H0306/77:**

**Please quote this number on all correspondence**

Yours sincerely



**Ms Har Hari Kaur**  
Committee Co-ordinator

E-mail: Recofficetemp@eoe.nhs.uk

Copy to:

*Ms Clare Symms,*  
Research Governance Manager  
NHS Norfolk  
Lakeside 400, Chapel Way  
Broadland Business Park  
Thorpe St. Andrew  
Norwich NR7 0WG

**NRES Committee East of England - Norfolk**

Nottingham REC Centre  
The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0115 8839436

14 May 2013

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy , UEA  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77  
**Amendment number:** 2: 14/03/2013  
**Amendment date:** 14 March 2013  
**IRAS project ID:** 63837

The above amendment was reviewed at the meeting of the Sub-Committee held on 13 May 2013.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter	Email from Rick Adams	01 May 2013
Notice of Substantial Amendment (non-CTIMPs)	2: 14/03/2013	14 March 2013

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

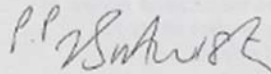
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

10/H0306/77:

Please quote this number on all correspondence

Yours sincerely



**Dr Michael Sheldon  
Chair**

E-mail: [NRESCommittee.EastofEngland-Norfolk@nhs.net](mailto:NRESCommittee.EastofEngland-Norfolk@nhs.net)

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Clare Symms, NHS Norfolk  
Ms Clare Symms, NHS Norfolk*



Professor David Wright  
Head of Medicines Management  
School of Pharmacy  
University of East Anglia  
Norwich  
Norfolk  
NR4 7TJ  
[d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)  
01603 592042

Dr Paul Mills  
R&D Office  
NHS Norfolk  
Lakeside 400, Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew, Norwich  
NR7 0WG

19<sup>th</sup> November 2010

**Supervised pharmacy student led medication review in primary care:  
A pilot study to ascertain the potential costs and effects: REF 10/H0306/77**

Dear Dr Mills

Please find enclosed copies of paperwork relating to the above trial, which has also been submitted as an online application for review at the meeting on the 2<sup>nd</sup> December.

Papers enclosed.

Printed IRAS form

Six copies of each of the following:-

- |         |  |
|---------|--|
| Annex 1 | Protocol                                       |
| Annex 2 | Development Phase Focus Groups                 |
| 2.1     | Consent form and Information leaflet for G.P.s |



- 2.2 Consent form and Information leaflet for Patients
- 2.3 Consent form and Information leaflet for Students
- 2.4 Consent form and Information leaflet for Pharmacists
  
- Annex 3 Intervention Phase
  - 3.1 Invitation letter, consent form and Information leaflet for G.P.s
  - 3.2 Invitation letter, consent form and Information leaflet for Patients
  - 3.3 Invitation letter, consent form and Information leaflet for Students
  - 3.4 Questionnaire for patients
  
- Annex 4 Review Phase Focus Groups
  - 4.1 Consent form and Information leaflet for G.P.s
  - 4.2 Consent form and Information leaflet for Patients
  - 4.3 Consent form and Information leaflet for Students
  - 4.4 Consent form and Information leaflet for Pharmacists
  
- Annex 5 CVs for Professor David Wright and Rick Adams
  
- Annex 6 Funding Approval letters and Peer Review Documentation
  - 6.1 Provisional approval
  - 6.2 E mail with final approval
  - 6.3 Peer reviewer No. 1
  - 6.4 Peer reviewer No. 2
  - 6.5 Peer reviewer No. 3
  - 6.6 Peer reviewer No. 4
  - 6.7 Peer reviewer No. 5

With your agreement we plan to attend the meeting in order that we can answer any questions which might arise.

Yours sincerely

Professor David Wright

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

#### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter: Prof. David Wright		08 November 2010
Investigator CV: Prof. David Wright		08 November 2010
Participant Information Sheet: Development Phase: Invitation for a Student to join a Focus Group	2	07 January 2011
Participant Information Sheet: Development Phase: Invitation for a GP to join a Focus Group	2	12 January 2011
Participant Consent Form: Development Phase: Focus Group for Patients	2	06 January 2011
Protocol	2	05 January 2011
Evidence of insurance or indemnity: Email from Paul Mills		05 January 2011
Evidence of insurance or indemnity: Copy of email from Sue Steel		22 December 2010
Referees or other scientific critique report: RfPB Programme, Reviewer 1		
Referees or other scientific critique report: RfPB Programme, Reviewer 2		
Referees or other scientific critique report: RfPB Programme, Reviewer 3		
Referees or other scientific critique report: RfPB Programme, Reviewer 4		
Referees or other scientific critique report: RfPB Programme, Reviewer 5		
Summary CV for student: Richard (Rick) Adams		09 November 2010
Letter from Funder		09 August 2010
E-mail from Funder		01 October 2010
Revised answer to A35 of the IRAS Application Form		
Letter to accompany questionnaire	2	06 January 2011
Participant Information Sheet: Development Phase: Invitation for a Patient to join a Focus Group	2	07 January 2011
Participant Information Sheet: Development Phase: Invitation for a Pharmacist to join a Focus Group	2	07 January 2011
Participant Information Sheet: Intervention Phase: Invitation for a Medical Practice to join a Research Project	2	07 January 2011
Participant Information Sheet: Intervention Phase: Invitation for a Patient to join a Research Project	2	06 January 2011
Participant Information Sheet: Intervention Phase: Invitation for a Student to join a Research Project	2	07 January 2011
Participant Information Sheet: Review Phase: Invitation for a GP to join a Focus Group	2	07 January 2011

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
*The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England*

Participant Consent Form: Intervention Phase: Students	2	06 January 2011
Response to Request for Further Information		07 January 2011
Participant Information Sheet: Review Phase: Invitation for a Patient to join a Focus Group	2	07 January 2011
Participant Information Sheet: Review Phase: Invitation for a Student to join a Focus Group Review Phase: Invitation for a Student to join a Focus Group	2	07 January 2011
Participant Information Sheet: Review Phase: Invitation for a Pharmacist to join a Focus Group	2	07 January 2011
REC application: Submission Code 63837/163432/1/533		17 November 2010
Participant Consent Form: Development Phase: Focus Group for GPs	2	06 January 2011
Participant Consent Form: Development Phase: Focus Group for Students	2	06 January 2011
Participant Consent Form: Development Phase: Focus Group for Pharmacists	2	06 January 2011
Participant Consent Form: Intervention Phase: On behalf of Medical Practices	2	06 January 2011
Participant Consent Form: Intervention Phase: Patients	2	06 January 2011
Participant Consent Form: Review Phase: Focus Group for Pharmacists	2	06 January 2011
Participant Consent Form: Review Phase: Focus Group for Patients	2	06 January 2011
Participant Consent Form: Review Phase: Focus Group for Students	2	06 January 2011
Participant Consent Form: Review Phase: Focus Group for GPs	2	06 January 2011
Questionnaire: Intervention Phase: Patient Questionnaire	2	06 January 2011
Letter of invitation to participant: Development Phase, GPs	2	06 January 2011
Letter of invitation to participant: Development Phase, Patients	2	06 January 2011
Letter of invitation to participant: Development Phase, Students	2	06 January 2011
Letter of invitation to participant: Development Phase, Pharmacists	2	06 January 2011
Letter of invitation to participant: Intervention Phase, Medical Practices	2	06 January 2011
Letter of invitation to participant: Intervention Phase, Patients	2	06 January 2011
Letter of invitation to participant: Intervention Phase, Students	2	06 January 2011
Letter of invitation to participant: Review Phase, GPs	2	06 January 2011
Letter of invitation to participant: Review Phase, Patients	2	06 January 2011
Letter of invitation to participant: Review Phase, Students	2	06 January 2011
Letter of invitation to participant: Review Phase, Pharmacists	2	06 January 2011

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

#### After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

This Research Ethics Committee is an advisory committee to East of England Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within  
the National Patient Safety Agency and Research Ethics Committees in England

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

10/H0306/77

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely



**Mr John Richardson**  
Chair

Email: [lynda.mccormack@eoe.nhs.uk](mailto:lynda.mccormack@eoe.nhs.uk)

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Clare Symms,  
Research Governance Manager  
NHS Norfolk  
Lakeside 400, Chapel Way  
Broadland Business Park  
Thorpe St. Andrew  
Norwich  
NR7 0WG

**NOTICE OF SUBSTANTIAL AMENDMENT**

*For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) at <http://eudract.emea.eu.int/document.htm#guidance>.*

*To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.*

*Further guidance is available at <http://www.nres.npsa.nhs.uk/applicants/review/after/amendments.htm>.*

<b>Details of Chief Investigator:</b>	
<i>Name:</i>	Professor David Wright
<i>Address:</i>	School of Pharmacy University of East Anglia Norwich NR4 7TQ
<i>Telephone:</i>	01603 592042
<i>Email:</i>	d.j.wright@uea.ac.uk
<i>Fax:</i>	

<b>Full title of study:</b>	Supervised Pharmacy Student-led Medication Review of Diabetic Patients in Primary Care: A pilot study to ascertain the potential costs and effects
<b>Name of main REC:</b>	Cambridgeshire 3 Research Ethics Committee
<b>REC reference number:</b>	10/H0306/77
<b>Date study commenced:</b>	1.2.11
<b>Protocol reference (if applicable), current version and date:</b>	Version 2 5.1.11
<b>Amendment number and date:</b>	No 1 7.1.11

**Type of amendment (indicate all that apply in bold)**

(a) Amendment to information previously given on the NRES Application Form

Yes

If yes, please refer to relevant sections of the REC application in the "summary of changes" below.

(b) Amendment to the protocol

No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes          No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

**Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?**

Yes

**Summary of changes**

Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study. In the case of a modified amendment, highlight the modifications that have been made.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

We aim to change the name slightly from :

Supervised Pharmacy Student-led Medication Review of Diabetic Patients in Primary Care:  
A pilot study to ascertain the potential costs and effects

By changing 'Diabetic Patients' to 'Patients with Diabetes' to give:  
Supervised Pharmacy Student-led Medication Review of Patients with Diabetes in Primary Care:  
A pilot study to ascertain the potential costs and effects

**Any other relevant information**

*Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.*


The phraseology requested is the preferred wording in the East of England as it is more respectful to patients by not labelling them as a disease state.

**List of enclosed documents**

<i>Document</i>	<i>Version</i>	<i>Date</i>

**Declaration**

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator: 

Print name: D. DICKINSON

Date of submission: 30/3/11



Dr David Wright  
Professor in Pharmacy Practice  
School of Pharmacy  
University of East Anglia  
Norwich Research Park  
Norwich  
Norfolk  
NR4 7TJ

10.8.11

Lynda McCormack  
Coordinator  
Norfolk Research Ethics Committee  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

10<sup>th</sup> August 2011

**REC Reference number: 10/H0306/77**

Dear Lynda

Whilst discussing the study with patients with diabetes at a recent focus group we have received some useful suggestions. Following this I am writing to seek permission to make minor amendments.

It has been suggested by our patient focus group that some patients may be more likely to read the full Patient Information Leaflet and therefore participate if there is a very short resume of the study near the beginning of the introductory letter. The following paragraph has been added to the letter.

*This project will provide an opportunity for some of our patients to have their medication reviewed by a final year pharmacy student from the University of East Anglia. As part of this project, patients will be able to talk to the student about their medicines, find out how they work and why they are prescribed. As you know you are already regularly reviewed, however, we would like to know if student pharmacists can contribute any more to this process. If you agree to this, the medication review would be between November and January.*

I am therefore asking that the letter Annex 3.2 from the GP be amended to reflect this.

Enclosed:  
Annex 3.2



Study name: Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care

REC reference: **10/H0306/77**

Request for a minor amendment.

I have attached a copy of the questionnaire (previously approved by REC) for which we wish to request approval for minor amendments.

The amendments are shown (highlighted in yellow) on the other copies attached.

The changes requested are:

- The addition of the words Follow up
- The addition of the words Control or Intervention
- The use of the 3L instead of 5L version of EQ5D as recommended by the health economist working with the study
- The addition of questions related to the use of Pharmacies by the patients on the back page
- Addition of reference number boxes to facilitate accurate data handling

The rationale for this is to :

- Ensure that the correct document is used for each group and that no possible confusion is made between base line and post intervention.
- To ensure that reference numbers are used to prevent duplicate questionnaires being sent out.
- The questions on the last page relate to information which was stated as requiring collection in the approved protocol post intervention. This relates to the use of pharmacies by patients in each group (control or intervention) and the only way to collect it is to ask the patients as the data is currently not recorded by pharmacies.

This questionnaire has been revised with the help of the Management Group and the Steering Groups for this study. In particular the patients on the Steering Group requested a number of changes which have been included.

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

**Please enter a short title for this project** (maximum 70 characters)  
Supervised pharmacy student led medication review in primary care.

**1. Is your project research?**

Yes  No

**2. Select one category from the list below:**

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

**If your work does not fit any of these categories, select the option below:**

Other study

**2a. Please answer the following question(s):**

- a) Does the study involve the use of any ionising radiation?  Yes  No
- b) Will you be taking new human tissue samples (or other human biological samples)?  Yes  No
- c) Will you be using existing human tissue samples (or other human biological samples)?  Yes  No

**3. In which countries of the UK will the research sites be located?(Tick all that apply)**

- England
- Scotland
- Wales
- Northern Ireland

**3a. In which country of the UK will the lead NHS R&D office be located:**

England  
 Scotland  
 Wales  
 Northern Ireland  
 This study does not involve the NHS

**4. Which review bodies are you applying to?**

NHS/HSC Research and Development offices  
 Social Care Research Ethics Committee  
 Research Ethics Committee  
 National Information Governance Board for Health and Social Care (NIGB)  
 Ministry of Justice (MoJ)  
 National Offender Management Service (NOMS) (Prisons & Probation)

*For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.*

**5. Will any research sites in this study be NHS organisations?**

Yes    No

**5a. Do you want your NHS R&D application(s) to be processed through the NIHR Coordinated System for gaining NHS Permission?**

Yes    No

*If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.*

**6. Do you plan to include any participants who are children?**

Yes    No

**7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?**

Yes    No

*Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.*

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?**

Yes    No

**9. Is the study or any part of it being undertaken as an educational project?**

Yes    No

Please describe briefly the involvement of the student(s):

---

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

Yes  No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

Yes  No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

Yes  No

## NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).  
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

## Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	David	Wright
Work Address	School of Pharmacy		
	UEA		
	Norwich		
PostCode	NR4 7TJ		
Email	d.j.wright@uea.ac.uk		
Telephone	01603592042		
Fax			

Full title of study:	Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects
Lead sponsor:	NHS Norfolk
Name of REC:	Cambridgeshire 3
REC reference number:	10/H0306/77
Name of lead R&D office:	NHS Norfolk
Date study commenced:	31.1.11
Protocol reference (if applicable), current version and date:	
Amendment number and date:	2: 14.3.13

## Type of amendment

(a) Amendment to information previously given in IRAS

Yes  No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

Yes  No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting

documentation for the study

Yes  No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

Yes  No

#### Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

With the changes to NHS structure NHS Norfolk and Waveney will cease to exist on 31st March. The Sponsor will therefore change to NHS South Norfolk Clinical Commissioning Group on 1st April at the same address.

The R&D office contact will remain the same, however the primary care R&D office is also now hosted by NHS South Norfolk CCG.

#### Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

#### List of enclosed documents

Document	Version	Date
----------	---------	------

#### Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

This section was signed electronically by Dr David Wright on 19/03/2013 16:46.

Job Title/Post: Professor of Pharmacy Practice  
 Organisation: UEA  
 Email: d.j.wright@uea.ac.uk

#### Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Miss Clare Symms on 15/03/2013 09:12.

Job Title/Post:	Research Governance Manager
Organisation:	NHS Norfolk & Waveney / NHS South Norfolk CCG
Email:	clare.symms@nhs.net

## NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs). For CTIMPs, please use the European Commission notice of substantial amendment form at <http://eudract.emea.europa.eu/document.html>. The form should be completed by the Chief Investigator using language comprehensible to a lay person. Support in principle should be sought from the study sponsor before the amendment is submitted.

## Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	David	Wright
Work Address	School of Pharmacy		
	UEA		
	Norwich		
PostCode	NR4 7TJ		
Email	d.j.wright@uea.ac.uk		
Telephone	01603592042		
Fax			

Full title of study:	Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects
Lead sponsor:	NHS Norfolk
Name of REC:	Cambridgeshire 3
REC reference number:	10/H0306/77
Name of lead R&D office:	NHS Norfolk
Date study commenced:	1.1.11
Protocol reference (if applicable), current version and date:	
Amendment number and date:	1 28.9.11

## Type of amendment

(a) Amendment to information previously given in IRAS

 Yes  No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

 Yes  NoIf yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.



(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes  No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

Yes  No

#### Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Following a literature search it became apparent that a number of studies in related areas in USA and Australia use questionnaires at the end of student consultations with patients to give a measure of the student's performance in terms of clinical knowledge and consultation skills. These were used as the basis for one of our questionnaires and the general ideas were incorporated into the others. No one questionnaire found in the literature was suitable for use in our study in the original format due to differences in the delivery of student training and healthcare in those countries.

Students currently recruited to the study have stated that they would like feedback about their performance after the consultation, both from supervising pharmacists and patients. We feel that a questionnaire is the best way for patients to provide feedback if they want to, as meeting the student face to face could be difficult for them and will take more of their time.

In stakeholder focus groups (part of the development phase of the study as approved by REC) Pharmacists, Last year's 4th year Pharmacy Students and Patients with Diabetes all requested feedback after the consultation.

The Steering Group for the study which includes two students who graduated from the pharmacy degree this summer and two patients all agreed that the use of the questionnaires was sensible and desirable. At a meeting on 22.9.11 they inspected a version of the questionnaires and the current version incorporates their recommended changes. The content of the questionnaires is the result of the above.

We feel that not only will these questionnaires give students feedback, but that they will allow us to assess the value and effectiveness of the process in addition to the measures approved previously.

The patient questionnaire will allow us to evaluate the acceptance to patients and the value to patients of the consultation.

The student version of the same questionnaire allows us to evaluate the student's perception of their own performance compared to that given by the patient. This has provided useful data in studies in the USA.

The student's questionnaire will enable student participants in the study to give feedback to the researchers on the process in the study. It will, we hope, inform us if the students found the process to be of value and if they would want changes made before the study, if successful, proceeds further.

If any person decides to not complete a form there will be no pressure to complete.

#### Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

#### List of enclosed documents

Document	Version	Date
Protocol	4	22/09/2011
Questionnaire for patients	1	22/09/2011
Questionnaire for students comparing patient's score	1	22/09/2011

**Declaration by Chief Investigator**

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I confirm that the study sponsor has been notified of the proposed amendment.*
3. *I consider that it would be reasonable for the proposed amendment to be implemented.*

**Date:**.....

DRAFT

Mr Stuart Kent  
Vice-Chair  
Cambridgeshire 3 Research Ethics Committee  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

7<sup>th</sup> January 2011

**REC Reference number: 10/H0306/77**

Dear Mr Kent

Thanks very much for your letter dated 8<sup>th</sup> December 2010. In particular thank you for including the clarifications which we provided at the meeting, all of which I believe accurately reflect our responses.

In response to your request for further clarification:

i) We will include the additional cholesterol test and have updated the protocol, patient information leaflet and consent form accordingly. New versions included are:

Protocol ??  
Patient Information Leaflet ??  
Patient Consent Form ??

ii) We have changed the title to 'Supervised pharmacy student led medication review of patients with diabetes in primary care: A pilot study to ascertain the costs and effects'

Protocol ??

iii) We have included a sentence in the background of the introduction earlier on to reflect the focus of the study on patients with diabetes.

RICK – leave this to you

Protocol ??

iv) We have amended the on-line application to reflect the fact that participants who lose capacity to consent during the study will be withdrawn.

v) We have confirmation that suitable indemnity is in place for the GP practices

E.mail confirmation

*Rick please include this – sent to you on Dec 28th*

vi) The questionnaire to measure adherence which we are intending to use is a validated tool and therefore we are reticent to alter this as it stands. If a multi-compartment compliance aid is being used by the patient they are less likely to report forgetting to take dosages. It should not affect the other domains within the questionnaire.

We are however willing to add the following two questions to the questionnaire to address your concerns:

I occasionally take extra doses of my medicines

Strongly Agree  Agree  Unsure  Disagree  Strongly Disagree

I am currently using a pill dispenser to help me to remember to take doses

Yes  No

*Rick, what do you think? If you agree then please add to questionnaire.*

vii) The letters have all been amended to remove the 'on'

Letter ??

viii) The invitation letters have been amended according to your direction

Letter??

ix) Information sheets have been amended to differentiate between the main study as part of this project and a future study which may result from this pilot.

We have also included a statement to confirm to potential participants that appropriate indemnity is in place.

All information sheets now have the correct name of the ethics committee included.

Information sheets??

x) The 'will' has been deleted as suggested and confirmation of indemnity provided

Information leaflet – Invitation for a GP to join a focus group ??

xi) We have included information regarding the extra blood test and have removed the suggested part of the sentence.

Information leaflet – Invitation for a patient to join a research project – Intervention phase ??

Xii) We have included the following sentence within the information for students:

'The project is in addition to the current course and non-participation is not expected to adversely affect your studies or assessment performance.'

All amendments have been highlighted as requested.

Whilst reviewing the documents we have also identified a number of minor typos and grammatical errors and have taken the liberty of correcting these as well. These are also highlighted for your information.

Please contact me if you require any further clarifications.

Thanks in advance for your consideration.

Yours sincerely

A handwritten signature in black ink, appearing to read 'David Wright', with a large, stylized initial 'D'.

David Wright

Mr Stuart Kent  
Vice-Chair  
Cambridgeshire 3 Research Ethics Committee  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

7<sup>th</sup> January 2011

**REC Reference number: 10/H0306/77**

Dear Mr Kent

Thanks very much for your letter dated 8<sup>th</sup> December 2010. In particular thank you for including the clarifications which we provided at the meeting, all of which I believe accurately reflect our responses.

In response to your request for further clarification:

i) We will include the additional cholesterol test and have updated the protocol and the patient information leaflet accordingly. New versions included are:

Protocol	V2 section 2.3 and 2.7
Patient Information Leaflet	Annex 3.2
Medical Practice Information Leaflet	Annex 3.1

ii) We have changed the title to 'Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the costs and effects'

Protocol V2 and all Annexes

iii) We have included a sentence in the background of the introduction earlier on to reflect the focus of the study on patients with diabetes.

Protocol V2. Summary (before Background)

iv) We have amended the on-line application to reflect the fact that participants who lose capacity to consent during the study will be withdrawn.

A35 Screen copy of the relevant IRAS form page attached.

v) We have confirmation that suitable indemnity is in place for the GP practices.

E.mail confirmation:

*Copy of e mail dated 5.1.11 from Dr Paul Mills R&D at NHS Norfolk attached*

*Copy of e mail from Sue Steel Research Contracts Manager at University of East Anglia*

vi) The questionnaire, Annex 3.4, to measure adherence which we are intending to use is a validated tool and therefore we are reticent to alter this. After discussion with researchers who have used this tool, they advise that the use of a multi-compartment compliance aid such as a dosette box will not affect the results.

We are, however, willing to add the following question to the questionnaire to address your concerns:

I am currently using a multi-compartment plastic box to hold my tablets or capsules (e.g. dosette) and this helps me to remember to take my doses

Yes  No

In addition we are advised that the question dealing with occasionally taking extra doses is dealt with by question 25 "I alter the dose of it". Accordingly we have not amended the questionnaire to reflect this. Hopefully this meets with your approval.

vii) The letters have all been amended to remove the 'on' in:

Letters: Annex 2.1, 2.2, 2.3, 2.4, 3.1, 4.1, 4.2, 4.3, 4.4.

viii) The invitation letters have been amended according to your direction:

Letter: Annex 2.2

Also Patient Information Leaflet Annex 2.2

ix) Information sheets have been amended to differentiate between the main study as part of this project and a future study which may result from this pilot.

Information Leaflets: Annex 2.1, 2.2, 2.3, 4.1, 4.2., 4.3, 4.4

We have also included a statement to confirm to potential participants that appropriate indemnity is in place.

Information Leaflets: Annex 2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3, 4.1, 4.2, 4.3, 4.4

All information sheets now have the correct name of the ethics committee included.

Information leaflets: Annex 2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 3.3, 4.1, 4.2, 4.3, 4.4.

x) The 'will' has been deleted as suggested.

Changed to : "You may not benefit directly as the aim of the study....."

Confirmation of indemnity has been received. This has been added:

Information leaflet – Annex 2.1 and 3.1

xi) We have included information regarding the extra blood test and have removed the suggested part of the sentence.

Information leaflet – Invitation for a patient to join a research project –  
Intervention phase Annex 3.2

Xii) We have included the following sentence within the information for students:

'The project is in addition to the current course and non-participation is not expected to adversely affect your studies or assessment performance.'

Annex 2.3, 3.3, 4.3

All amendments have been highlighted as requested.

Whilst reviewing the documents we have also identified a number of minor typos and grammatical errors and have taken the liberty of correcting these as well.

Please contact me if you require any further clarifications.

Thanks in advance for your consideration.

Yours sincerely

David Wright  
Professor in Pharmacy Practice  
Primary Investigator





Dr David Wright  
Professor in Pharmacy Practice  
School of Pharmacy  
University of East Anglia  
Norwich  
Norfolk  
NR4 7TJ

Mr Stuart Kent  
Vice-Chair  
Cambridgeshire 3 Research Ethics Committee  
Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

3<sup>rd</sup> February 2011

**REC Reference number: 10/H0306/77**

Dear Mr Kent

Whilst reviewing the documents for this study we have identified a number of minor errors and are writing to inform you of these and seek your permission for the very minor amendments. These relate to the information leaflets (numbers listed below) whereby the version number was correctly updated for submission to yourself but unfortunately the date was not updated from the original. These have all now been updated to 7.1.11 in order to reflect the correct amendments.

Please see Appendix for the list of documents..

Please accept our apologies for this oversight.

Additionally we would like to see your opinion on two further amendments. The committee requested that the title of the project should be changed to "Supervised Pharmacy Student-led Medication Review of Diabetic Patients in Primary Care". The policy within the Eastern Region SHA vision document (Towards the best together) is to use the phrase "patients with diabetes" instead of "diabetic patients" and we therefore seek your approval to amend the title to "Supervised Pharmacy Student-led Medication Review of Patients with Diabetes in Primary Care" and to change all use of the word 'diabetic' to 'patients with diabetes'.

Secondly Professor Amanda Howe, who in addition to her academic role represents G.P.s within the trial, has suggested that within the GP invitation letter (Annex 3.1) the word "employed" in the sentence "We are writing to invite you to take part in the above research study because you are a medical practice in Norfolk NHS which *employs* a practice pharmacist" is technically incorrect. She

recommends that we amend the sentence to read "We are writing to invite you to take part in the above research study because you are a medical practice in Norfolk NHS which has a practice pharmacist working with it." This mirrors the wording used in the information leaflet Annex 3.1.

Please contact me if you require any further clarifications.

Thanks in advance for your consideration.

Yours sincerely

A handwritten signature in black ink, appearing to read 'David Wright', with a large, stylized initial 'D'.

David Wright

## Appendix

### Documents updated to 7.1.11

#### Development Phase

- Annex 2.1. Invitation for a General Practitioner to join a Focus Group
- Annex 2.2 Invitation for a Patient to join a Focus Group
- Annex 2.3 Invitation for a Student to join a Focus Group
- Annex 2.4 Invitation for a Pharmacist to join a Focus Group

#### Intervention Phase

- Annex 3.1 Invitation for a Medical Practice to join a Research Project
- Annex 3.2 Invitation for a Patient to join a Research Project
- Annex 3.3 Invitation for a Student to join a Research Project

#### Review Phase

- Annex 4.1 Invitation for a General Practitioner to join a Focus Group
- Annex 4.2 Invitation for a Patient to join a Focus Group
- Annex 4.3 Invitation for a Student to join a Focus Group
- Annex 4.4 Invitation for a Pharmacist to join a Focus Group

**NOTICE OF SUBSTANTIAL AMENDMENT**

*For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) at <http://eudract.emea.eu.int/document.html#guidance>.*

*To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.*

*Further guidance is available at <http://www.nres.npsa.nhs.uk/applicants/review/after/amendments.htm>.*

<b>Details of Chief Investigator:</b>	
<i>Name:</i>	Professor David Wright
<i>Address:</i>	School of Pharmacy University of East Anglia Norwich NR4 7TQ
<i>Telephone:</i>	01603 592042
<i>Email:</i>	d.j.wright@uea.ac.uk
<i>Fax:</i>	

<b>Full title of study:</b>	Supervised Pharmacy Student-led Medication Review of Diabetic Patients in Primary Care: A pilot study to ascertain the potential costs and effects
<b>Name of main REC:</b>	Cambridgeshire 3 Research Ethics Committee
<b>REC reference number:</b>	10/H0306/77
<b>Date study commenced:</b>	1.2.11
<b>Protocol reference (if applicable), current version and date:</b>	Version 2 5.1.11
<b>Amendment number and date:</b>	No 1 7.1.11

**Type of amendment (indicate all that apply in bold)**

(a) *Amendment to information previously given on the NRES Application Form*

Yes

*If yes, please refer to relevant sections of the REC application in the "summary of changes" below.*

(b) *Amendment to the protocol*

No

*If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.*

(c) *Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study*

Yes          No

*If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.*

**Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?**

Yes

**Summary of changes**

*Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study. In the case of a modified amendment, highlight the modifications that have been made.*

*If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.*

We aim to change the name slightly from :

Supervised Pharmacy Student-led Medication Review of Diabetic Patients in Primary Care:  
A pilot study to ascertain the potential costs and effects

By changing 'Diabetic Patients' to 'Patients with Diabetes' to give;

Supervised Pharmacy Student-led Medication Review of Patients with Diabetes in Primary Care:  
A pilot study to ascertain the potential costs and effects

**Any other relevant information**

*Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.*

The phraseology requested is the preferred wording in the East of England as it is more respectful to patients by not labelling them as a disease state.

**List of enclosed documents**

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol	2	5.1.11
Protocol	3	30.3.11

**Declaration**

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

*Signature of Chief Investigator:* .....

*Print name:* .....

*Date of submission:* .....



**Health Research Authority**  
NRES Committee East of England - Norfolk

Victoria House  
Capital Park  
Fulbourn  
Cambridge  
CB21 5XB

22 May 2012

Professor David Wright  
d.j.wright@uea.ac.uk

Professor of Pharmacy Practice  
School of Pharmacy, UEA  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

<b>Study title:</b>	Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects
<b>REC reference:</b>	10/H0306/77
<b>Amendment number:</b>	Email from David Wright
<b>Amendment date:</b>	03 April 2012
<b>Amendment detail:</b>	Minor amendments to the questionnaire including (1) Ensure the correct documentation is used for each group and there is no confusion between base line and post intervention, by adding the word 'control' or 'intervention' (2) The addition of questions related to the pharmacies(3)The use of 3L instead of 5L version of EQ5D

Thank you for your letter of 03 April 2012, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

**Documents received**

The documents received were as follows:


Document	Version	Date
Sponsor authority	Email from Clare Symms	30 April 2012
Questionnaire: Follow up Control group	3	14 March 2012
Questionnaire: Follow up Intervention group	3	14 March 2012
Notification of a Minor Amendment	Email from David Wright	03 April 2012

#### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**10/H0306/77: Please quote this number on all correspondence**

Yours sincerely



**Sarah Clark**  
Committee Co-ordinator

E-mail:

Copy to: **Ms Clare Symms, NHS Norfolk**  
[clare.symms@norfolk.nhs.uk](mailto:clare.symms@norfolk.nhs.uk)



**Mr Richard Adams**  
School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ

**Research & Development**  
NHS Norfolk  
Lakeside 400  
Old Chapel Way  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG

Tel: 01603 257283  
Fax: 01603 257292  
E-mail: [paul.mills@norfolk.nhs.uk](mailto:paul.mills@norfolk.nhs.uk)  
[www.norfolk.nhs.uk/research](http://www.norfolk.nhs.uk/research)

9 January 2014

**Re: 2010IC02 (CSP 63837). Supervised pharmacy student led medication review in primary care: A pilot study to ascertain the potential costs and effects**

STANDARD TERMS & CONDITIONS ATTACHED TO NHS PERMISSION FOR RESEARCH IN  
NHS NORFOLK, NHS SUFFOLK, NHS GREAT YARMOUTH & WAVENEY AND NORFOLK  
COMMUNITY HEALTH & CARE NHS TRUST

NHS Permission from NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust is conditional upon acceptance of these standard terms and conditions. It is the investigators responsibility to ensure that these are disseminated to all parties involved in the study.

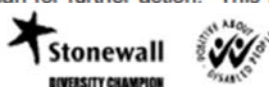
#### 1. Validity of permission

NHS Permission is only valid if the research commences within one year of the date NHS permission was granted. NHS Permission is only granted for those sites listed on the NHS Permission letter(s) for the above study.

#### 2. Safety and conduct of research

The Investigator will notify the R&D Office at NHS Norfolk immediately if they are or become aware of any information which would cast doubts upon, or alter in any material way, any information contained in the original application, or a later amendment application, such as to raise questions about the safety and/or continued conduct of the research.

The investigator or Sponsor may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health & safety, however the R&D office must be notified that such measures have been taken, detailing the reasons why such measures were taken and the plan for further action. This notification should take place at the



Chair: Sheila Childerhouse  
Chief Executive: Andrew Morgan

Visit our website: [www.norfolk.nhs.uk](http://www.norfolk.nhs.uk)

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NHS Norfolk represents the Norfolk Primary Care Trust  
NHS Norfolk hosts the Research Management and Governance Services for NHS Norfolk, NHS Suffolk,  
NHS Great Yarmouth & Waveney and Norfolk Community Health & Care NHS Trust  
ST&C of approval NHSNorfolk Jan2011  
Review date – April 2012

same time as required notification to the Research Ethics Committee and any regulatory authorities.

### **3. Confidentiality**

The investigator and all members of his/her team are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. The investigator is responsible for ensuring that all members of his/her team understand and comply with the requirements of the NHS Confidentiality Code of Practice (<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>) and the Data Protection Act 1998, and to be made aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution. The investigator is also required to adhere to the NHS Norfolk guidance "Access to Patient Notes for Research Purposes – Guidance Notes for Primary Care" November 2009 which are available on the R&D website (<http://www.norfolk.nhs.uk/node/1480#confidentiality>).

### **4. Interventional Studies**

The granting of NHS permission for this study does not commit the PCT to ongoing financial support for any intervention trialled. Where excess treatment costs are to be incurred on a study, written agreement must be obtained from the Trust in advance of the study starting.

### **5. Observational or Non-Interventional Studies**

If the research is classified as an observational or non-interventional study, NHS permission is contingent on the following:

- (a) the assignment of any patient involved in the research to a particular therapeutic strategy is not to be decided in advance by reference to the study protocol;
- (b) the clinical care, management, investigation and supervision of any patient involved in the study must be determined by the clinical judgement of the treating clinicians and in accordance with the normal practice of the treating institution; it must not be influenced by or contingent upon the patient's involvement in the study.

### **6. Documentation to be supplied to NHS Sites**

It is the investigator's responsibility to provide all participating sites or participant identification centres with all relevant study information to enable them to fulfil their role within the research. This will include as a minimum:

- (a) Final approved protocol
- (b) Copies of REC favourable opinion (including list of approved documentation), NHS Permission letter covering that site, any other approvals necessary (e.g. MHRA)
- (c) Participant information sheets, consent forms, invitation letters, posters/adverts and any other documentation given to the participant

It is the investigator's responsibility to update the information held at each site with any amendments made to this documentation and all approval letters applicable to those amendments.

### **7. Protocol and Protocol amendments**

The Investigator must conduct the research in accordance with the Protocol. All amendments made during the study should be notified to and discussed with the R&D office at NHS Norfolk prior to implementation (except in cases of emergency where the welfare of the subject is paramount – see clause 2) and in parallel with any necessary regulatory or ethical review. This applies both to substantial and non-substantial amendments.

### **8. Serious Adverse Events**

The Investigator will inform the R&D Office at NHS Norfolk of any serious adverse events relevant to any local participants in the research within 24 hours of such events happening or of the investigator learning about them if later. This requirement is in addition to any duties the

Investigator has to the Ethics Committee or the Sponsors of the research. The Investigator must also comply with relevant Trust incident reporting mechanisms.

#### **9. Ethical favourable opinion**

The Investigator will adhere to any applicable Research Ethics Committee terms and conditions of favourable opinion.

#### **10. Monitoring**

The Investigator will provide the R&D Office at NHS Norfolk with details of the progress of the research. This should be submitted on the Annual/Final Monitoring Report Form (available on request), at intervals of one year unless otherwise specified in the letter of NHS Permission, and on conclusion of the research. This will include details of numbers of patients screened and recruited from all NHS Norfolk, NHS Suffolk and NHS Great Yarmouth & Waveney sites.

If a research project is discontinued, the R&D Office at NHS Norfolk must be informed and an Annual/Final Monitoring Report Form submitted. This is in addition to any requirements from the Research Ethics Committee.

#### **11. Payments to Practices / Directorates**

The investigator will co-operate with the R&D office to facilitate payments of support funding to practices / Directorates for work incurred in the conduct of this study. This may include, but is not limited to, provision of screening and recruitment figures, numbers of bloods etc on an ongoing basis.

#### **12. Smartcards**

Where an investigator or a member of his/her team has been issued with a Smartcard for the project allowing access to SystemOne clinical databases each individual is required to notify the R&D office at NHS Norfolk when their involvement in the project is complete on a site by site basis to allow deactivation of the smartcard at that particular site.

#### **13. Research Audit**

NHS organisations are required to monitor research projects to ensure adherence to the Research Governance Framework and other legal and regulatory requirements. This is achieved through routine audits. The Investigator agrees that the research project may be subject to audit, either as part of routine or 'for cause' audit activity. The Investigator agrees to cooperate with any audits or investigations undertaken by the host institution or regulatory authorities as required.

The investigator is required to contact the R&D office at NHS Norfolk if they receive notification of any research audit or inspection to be conducted at any NHS Norfolk, NHS Suffolk, NHS Great Yarmouth & Waveney or Norfolk Community Health & Care NHS Trust site.

#### **14. Dissemination**

The investigator is responsible for disseminating information on study progress and any findings/issues etc to all sites on an ongoing basis throughout the study and at study conclusion.

#### **15. Roles and responsibilities**

The Investigator will comply with the roles and responsibilities of the researcher, as described in the DH Research Governance Framework for Health & Social Care. In particular they will ensure that all members of the study team are able by knowledge, experience, training and supervision to undertake the roles assigned to them and are made aware of these standard terms and conditions of approval.

Where the research is being conducted in full or in part within general practice the principles outlined in NHS Norfolk "Good Practice Guidelines for researchers working with General Practice" must be followed. These are available from the R&D website (<http://www.norfolk.nhs.uk/node/1427>).

#### **16. Intellectual property rights**

ST&C of approval NHSNorfolk Jan2011  
Review date – April 2012

NHS responsibilities for intellectual property are defined in the NHS Executive's Policy Framework for the Management of Intellectual Property (HSC 1998/106). Copies of this document, are available from the Research and Development office and the investigator is referred to the Intellectual Property Policy of their relevant Trust(s).

Intellectual property (patents, copyright, design rights, trade-marks, know-how) which arise in, or during, the course of an employee's employment, belong to their employer, unless an existing contract overrules. By agreement to these terms and conditions the Investigator confirms his/her agreement to the allocation, treatment, management, handling and assignment of any intellectual property arising from the research in accordance with the intellectual property policies of the relevant host Trust.

In particular, where a research agreement relevant to the research requires that a relevant Trust should assign the rights to intellectual property arising from the research to the Sponsor of that research, the Investigator will cooperate to make that assignment effective in accordance with the terms of that agreement.

**17. Publications**

The investigator will inform the R&D office of any publications or publicity arising from the study and, at the request of the R&D office will use his/her best endeavours to ensure that the role of the host NHS organisation is acknowledged in any such publication or publicity.

**18. Health and safety**

It is the responsibility of the Investigator to be familiar with and comply with the Health and Safety Policies of the relevant Trust(s) copies of which may be accessed via the R&D office.

**19. Research outside the NHS**

The Investigator recognises that agreements and 'permission' granted by NHS Norfolk and/or on behalf of NHS Suffolk and NHS Great Yarmouth & Waveney apply to research activity on NHS premises involving patients and their tissues or records, clients, staff and NHS services. They do not apply to patients who are being treated privately nor does it extend, for example, to social services (except those working within Norfolk Learning Difficulties Service) or local education services. Separate agreements and approval for research access to these sectors will be required.

I confirm that I accept the above terms and conditions of approval.

Signed:.....

Name:.....

Date:.....

Please copy this document returning the original to the R&D office at NHS Norfolk and retain the copy for your files.

**NRES Committee East of England - Norfolk**

Nottingham REC Centre  
The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0115 8839436

01 May 2013

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy , UEA  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

**Amendment number:** 2: 14/03/2013

**Amendment date:** 14 March 2013

**IRAS project ID:** 63837

Thank you for submitting the above amendment, which was received on 01 May 2013. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

**Documents received**

The documents to be reviewed are as follows:

Document	Version	Date
Covering Letter	Email from Rick Adams	01 May 2013
Notice of Substantial Amendment (non-CTIMPs)	2: 14/03/2013	14 March 2013

**Notification of the Committee's decision**

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

**10/H0306/77:**

**Please quote this number on all correspondence**

Yours sincerely

**Miss Zoe Birtwistle**  
**Assistant Committee Co-ordinator**

E-mail: NRESCommittee.EastMidlands-Derby@nhs.net

Copy to: *Ms Clare Symms, NHS Norfolk*  
*Ms Clare Symms, NHS Norfolk*

**NRES Committee East of England - Norfolk**

Nottingham REC Centre  
The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0115 8839436

01 May 2013

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy , UEA  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77

**Amendment number:** 2: 14/03/2013

**Amendment date:** 14 March 2013

**IRAS project ID:** 63837

Thank you for submitting the above amendment, which was received on 01 May 2013. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

**Documents received**

The documents to be reviewed are as follows:

Document	Version	Date
Covering Letter	Email from Rick Adams	01 May 2013
Notice of Substantial Amendment (non-CTIMPs)	2: 14/03/2013	14 March 2013

**Notification of the Committee's decision**

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

**10/H0306/77:**

**Please quote this number on all correspondence**

Yours sincerely

**Miss Zoe Birtwistle**  
**Assistant Committee Co-ordinator**

E-mail: NRESCommittee.EastMidlands-Derby@nhs.net

*Copy to: Ms Clare Symms, NHS Norfolk*  
*Ms Clare Symms, NHS Norfolk*



**NRES Committee East of England - Norfolk**

Nottingham REC Centre  
The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0115 8839436

14 May 2013

Professor David Wright  
Professor of Pharmacy Practice  
School of Pharmacy, UEA  
School of Pharmacy  
UEA  
Norwich  
NR4 7TJ

Dear Professor Wright

**Study title:** Supervised pharmacy student led medication review of diabetic patients in primary care: A pilot study to ascertain the potential costs and effects

**REC reference:** 10/H0306/77  
**Amendment number:** 2: 14/03/2013  
**Amendment date:** 14 March 2013  
**IRAS project ID:** 63837

The above amendment was reviewed at the meeting of the Sub-Committee held on 13 May 2013.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter	Email from Rick Adams	01 May 2013
Notice of Substantial Amendment (non-CTIMPs)	2: 14/03/2013	14 March 2013

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

**10/H0306/77:****Please quote this number on all correspondence**

Yours sincerely



**Dr Michael Sheldon**  
Chair

E-mail: [NRESCommittee.EastofEngland-Norfolk@nhs.net](mailto:NRESCommittee.EastofEngland-Norfolk@nhs.net)

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Ms Clare Symms, NHS Norfolk  
Ms Clare Symms, NHS Norfolk*

**NRES Committee East of England - Norfolk**

**Attendance at Sub-Committee of the REC meeting on 13 May 2013**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Michael Sheldon	Retired Clinical Psychologist	Lay
Dr Robert Stone	General Practitioner	Expert

## **Appendix D2: Ethics Approved Documents – Development**

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Development Phase

### Invitation for a General Practitioner/Specialist Nurse to Join a Focus Group

## Participant Information Leaflet



GP/SN  
Trial  
Information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

You are invited to take part in a research study. This leaflet provides information about the study. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

#### **What is the purpose of the study?**

The purpose of our study is to find out what the benefits are to patients of allowing final year students to review the medicines of patients with diabetes and to provide a medicines centred consultation. The purpose of this focus group is to present the project to general practitioners and obtain their views on how best to run the project so that it maximises patient benefit whilst causing minimal disruption to the medical practice.

#### **Why have I been invited?**

You have been chosen because you work in a GP Practice which has agreed to take part in the study. We need to obtain your views about the practical aspects of this before we undertake the research.

#### **Do I have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. After you have read this information, we will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form you are free to withdraw from the study at any time.

#### **What happens to me if I agree to take part in this study?**

You will be invited to attend a focus group at a suitable location agreed between us. There will be approximately six to eight people in this group plus two members of the research team. In the unlikely event of too many people offering to take part we will randomly select eight and inform you of the outcome. A researcher will ask the group questions to do with the trial. These could be anything from the way in which you were asked to join the study and layout and design of questionnaires to the service and information that we hope to provide via the final year pharmacy students.

#### **What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion.

#### **Will I benefit from participation in this study?**

You may not benefit directly as the aim of the study is to ensure that prescribing for patients with type 2 diabetes is maximised and that patients fully understand why they are prescribed their medicines. Your participation in the focus group will help to ensure that the project runs smoothly and causes you minimal disruption.

### **How much time will I need to spend on the study?**

The focus group will take approximately one hour. We will pay for reasonable travel costs to and from the meeting and will provide a meal.

### **Confidentiality: Will the information be kept confidential?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. Information will be used to improve the design and structure of the main study. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.

### **What if there is a problem?**

In the unlikely event of a problem occurring, indemnity will be provided by NHS Norfolk.

### **Who has reviewed the study?**

This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

### **What will happen to the results of the study?**

The results of the study will be used to decide if we need to make any changes to the way that we plan to undertake the main study. In addition these results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

### **How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact either Professor David Wright at the UEA on 01603 592042 or email [d.i.wright@uea.ac.uk](mailto:d.i.wright@uea.ac.uk) or Clare Symms, Research Governance Manager at NHS Norfolk on 01603 257020 or email [clare.symms@norfolk.nhs.uk](mailto:clare.symms@norfolk.nhs.uk). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

**Thank you for taking the time to read this information sheet.  
You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
Lakeside 400  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG  
01603 257125



School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Phone: 01603 593144

## Consent Form

### Focus Group for General Practitioner/Specialist Nurse Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Development Phase

Researcher: Rick Adams, tel: 01603 591996  
[richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

Please initial boxes

- 1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- 3. I agree for the focus group to be audio taped.
- 4. I agree to take part in the above study.

Name (please print)                      Signature                      Date

Address (please print): .....  
.....  
.....  
.....

Please tick the box if you would like to receive details of the results of the study

Focus group consent form. GP/Specialist Nurse V3 14.6.11



## UEA LETTER-HEADED PAPER

{DATE}

{Study Practice}  
{Study Practice address}

Dear {study GP Practice},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the development phase of the above research study because you are a GP/Specialist Nurse working in a medical practice which has agreed to participate in the main study. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Study Information Sheet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Study Information Sheet", you decide that you would like to take part, please read and sign the enclosed "GP/Specialist Nurse Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996) or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by email at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Development Phase

### Invitation for a Student to Join a Focus Group

### Participant Information Leaflet



Patient  
Trial  
information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

This leaflet provides information about the study. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

#### **What is the purpose of the study?**

The purpose of our study is to find out what the benefits are to patients of final year pharmacy students providing a review of medicines and a face to face consultation to help patients with diabetes better understand how their medicines work. Before we do this we would, however, like to obtain student opinions on how best to prepare them for the project and to ensure that students get the most from the experience. Therefore we are inviting you to join a focus group to help us to try to get the process right from the start.

#### **Why have I been invited?**

You have been chosen because you expressed an interest in taking part on the original consent form that you signed.

#### **Do I have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. After you have read this information, we will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form, you are free to withdraw from the study at any time. The standard of education you receive as part of your set course will not be affected by whether or not you take part in the study.

#### **What happens to me if I agree to take part in this study?**

You will be invited to the School of Pharmacy at the UEA to attend a focus group. There will be approximately six to eight people in this group plus two researchers. In the unlikely event of too many people offering to take part we will randomly select eight and inform you of the outcome. You will receive a brief presentation on the proposed study and then you will be asked for your opinions on the different elements.

#### **What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion.

#### **Will I benefit from participation in this study?**

You will not benefit directly, although your participation will help to make sure that, if students continue to undertake education this way in the future, that it is better for patients with type 2 diabetes and hopefully a better education for the students.

#### **How much time will I need to spend on the study?**

The focus group will take approximately one hour. We will pay for reasonable travel costs to and from the UEA and will provide a meal.

**Confidentiality: Will the information be kept confidential?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. Information will be used to improve the design and structure of the main study. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.

**What if there is a problem?**

In the unlikely event of a problem occurring, indemnity (a form of insurance cover) will be provided by NHS Norfolk.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

**What will happen to the results of the study?**

The results of the study will be used to decide if we need to make any changes to the way that we plan to undertake the main study. In addition these results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact Professor Duncan Craig, Head of the School of Pharmacy.

Thank you for taking the time to read this information sheet.

You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason. The project is in addition to the current course and non-participation is not expected to adversely affect your studies or assessment performance.

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
Lakeside 400  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG  
01603 257125



School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Phone: 01603 593144

## Consent Form

### Focus Group for Students

### Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Development Phase

Researcher: Rick Adams, tel: 01603 591996  
[richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

Please initial boxes

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
3. I agree for the focus group to be audio taped.
4. I agree to take part in the above study.

Name (please print)                      Signature                      Date

Address (please print): .....  
.....  
.....  
.....

Please tick the box if you would like to receive details of the results of the study

Focus group consent form. Students. V3 14.6.11

## **UEA LETTER-HEADED PAPER**

{DATE}

{Student address}

Dear {study Student},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the development phase of the above research study because you are a Student who has agreed to take part in the above study. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Study Information Sheet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Study Information Sheet", you decide that you would like to take part, please read and sign the enclosed "Student Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996) or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by e mail at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Development Phase

### Invitation for a Pharmacist to Join a Focus Group

### Participant Information Leaflet



Patient  
Trial  
information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

You are invited to take part in a research project. This leaflet provides information about the study. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

#### **What is the purpose of the study?**

The purpose of this study is to find out what the benefits are to patients of final year pharmacy students providing a medication review and a medicines related consultation to patients with diabetes. At this developmental stage of the study we are undertaking focus groups to obtain the views of pharmacists who work within medical practices about the best way to conduct the project.

#### **Why have I been invited?**

You have been chosen because you work as a pharmacist for the PCT with a medical practice in NHS Norfolk. We will need to ask for assistance from such pharmacists and therefore need to obtain your views about the practical aspects of this before we undertake the research.

#### **Do I have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. After you have read this information we will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form, you are free to withdraw from the study at any time.

#### **What happens to me if I agree to take part in this study?**

You will be invited to the School of Pharmacy at the UEA to attend a focus group. There will be approximately six to eight people in this group plus two researchers. In the unlikely event of too many people offering to take part we will randomly select eight and inform you of the outcome. You will receive a short presentation on the project and then will be asked your views on the different elements within it. This should take no longer than one hour.

#### **What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion.

#### **Will I benefit from participation in this study?**

You will not benefit directly, although your participation will help to make sure that, if students continue to undertake education in this way in the future, that it is better for patients with type 2 diabetes and hopefully a better education for the students.

#### **How much time will I need to spend on the study?**

The focus group will take approximately one hour. We will pay for reasonable travel costs to and from the UEA and will provide a meal.

#### **Confidentiality: Will the information be kept confidential?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. Information will be used to improve the design and structure of the main study. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.



**What if there is a problem?**

In the unlikely event of a problem occurring, indemnity will be provided by NHS Norfolk.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

**What will happen to the results of the study?**

The results of the study will be used to decide if we need to make any changes to the way that we plan to undertake the main study. In addition these results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact the Patient Advice and Liaison Service on freephone 0800 587 4132 or via email at [pals@norfolk.nhs.net](mailto:pals@norfolk.nhs.net). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

**Thank you for taking the time to read this information sheet.  
You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
 Lakeside 400  
 Broadland Business Park  
 Thorpe St Andrew  
 Norwich  
 NR7 0WG  
 01603 257125



School of Pharmacy  
 University of East Anglia  
 Norwich  
 NR4 7TJ  
 Phone: 01603 593144

## Consent Form

### Focus Group for Pharmacists

### Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Development Phase

Researcher: Rick Adams, tel: 01603 591996  
[richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

Please initial boxes

- 1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
- 3. I agree for the focus group to be audio taped.
- 4. I agree to take part in the above study.

Name (please print)                      Signature                      Date

Address (please print): .....

.....

.....

.....

Please tick the box if you would like to receive details of the results of the study

Focus group consent form. Pharmacists. V3 14.6.11

## **UEA LETTER-HEADED PAPER**

{DATE}

{Pharmacist address at NHS Norfolk}

Dear {Pharmacist},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the development phase of the above research study because you are a Pharmacist working with one of the Practices that has agreed to participate. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Study Information Sheet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Study Information Sheet", you decide that you would like to take part, please read and sign the enclosed "Pharmacist Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996) or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by e mail at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Development Phase

### Invitation for a Patient to Join a Focus Group

### Participant Information Leaflet



Patient  
Trial  
information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

You are invited to take part in a research project. This leaflet provides information about the study. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

### **What is the purpose of the study?**

The purpose of our study is to find out what the benefits are to patients of final year pharmacy students providing a review of medicines and a face to face consultation to help patients with diabetes better understand how their medicines work. Before we do this we would, however, like to obtain patient opinions on how best to run the project and to ensure that patients get the most from the experience. Therefore we are inviting you to join a focus group to help us to try to get the process right from the start.

### **Why have I been invited?**

You have been chosen because you are a patient with type 2 diabetes within Norfolk who is a member of Diabetes UK and have shown an interest in participating in research studies.

### **Do I have to take part?**

No. It is entirely up to you whether you decide to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive in any way.

### **What happens to me if I agree to take part in this study?**

You will be invited to the School of Pharmacy at the UEA to attend a focus group. There will be approximately six to eight people in this group plus two researchers. In the unlikely event of too many people offering to take part we will randomly select eight and inform you of the outcome. A researcher will provide a brief overview of the project and then ask the group for their opinions. We will pay for any travel expenses incurred and a meal will be provided.

### **What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion. We will pay your travel expenses so that it will not cost you any money.

### **Will I benefit from participation in this study?**

You will not benefit directly, although your participation will help to make sure that the study is carried out in a way which hopefully achieves the best results and is best for those taking part.

### **How much time will I need to spend on the study?**

The focus group will take approximately one hour.

**Confidentiality: Will the information be kept confidential?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. Information will be used to improve the design and structure of the main study. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.

**What if there is a problem?**

In the unlikely event of a problem occurring, indemnity (a form of insurance cover) will be provided by NHS Norfolk.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

**What will happen to the results of the study?**

The results of the study will be used to decide if we need to make any changes to the way that we plan to undertake the main study. In addition these results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact the Patient Advice and Liaison Service on freephone 0800 587 4132 or via email at [pals@norfolk.nhs.net](mailto:pals@norfolk.nhs.net). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

**Thank you for taking the time to read this information sheet.  
You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason. Your medical care will not be affected in any way whether you decide to participate in the study or not.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
Lakeside 400  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG  
01603 257125



School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Phone: 01603 593144

## Consent Form

### Focus Group for Patients

### Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Development Phase

Researcher: Rick Adams, tel: 01603 591996  
[richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

Please initial boxes

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
3. I agree for the focus group to be audio taped.
4. I agree to take part in the above study.

Name (please print)                      Signature                      Date

Address (please print): .....

.....

.....

.....

Please tick the box if you would like to receive details of the results of the study

## **UEA LETTER-HEADED PAPER**

{DATE}

{Patient address}

Dear {study Patient},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the development phase of the above research study because you are a Patient with type 2 diabetes within the Norfolk who is a member of Diabetes UK and has shown an interest in participating in research studies. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Study Information Sheet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Study Information Sheet", you decide that you would like to take part, please read and sign the enclosed "Patient Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996) or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by e mail at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA



## **Appendix D3: Ethics Approved Documents – Intervention**

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Intervention Phase

### Invitation for a Medical Practice to Join a Research Project

### Participant Information Leaflet



Patient  
Trial  
information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

## Annex 3.1

Your medical practice is invited to take part in a research study. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

### **What is the purpose of the study?**

The purpose of this study is to determine the effects of final year pharmacy students providing a medication review and face to face consultation with patients with type 2 diabetes. When the patient's medicines are reviewed they will be compared with current national guidance. The aim of the student consultation is to help the patient understand why they are prescribed their medicines and why it is important that they take them. This model of involving pharmacy students within patient services is novel for pharmacy and therefore there is a need to determine how best to deliver this and what benefits, if any, there are.

### **What does this mean for the medical practice?**

Your practice pharmacist would invite patients with type 2 diabetes to be involved in the study on behalf of the researchers. Only those who provide consent will be included.

Rick Adams (an experienced pharmacist who holds a PCT contract) will access the medical records of participating patients in order to obtain baseline data before intervention and then final data after the intervention. This data will include BP, HbA1C, cholesterol and the number of times the patient has used the practice.

Final year pharmacy students, with appropriate preparation, will then attend the medical practice with the practice pharmacist or the researcher, Rick Adams, present, to review the medicines of the patients they have been allocated. As part of the preparation they will require access to a room for two afternoons with either Rick Adams or a PCT pharmacist in order to learn how to use the IT system.

The students will undertake a medication review, discuss their findings with the practice pharmacist or Rick Adams and then with either a GP or specialist nurse prescriber (as you see appropriate) at the end of the session. Due to the numbers of patients and students required we believe that this will be needed on two separate occasions.

If the practice requests it, they will be given a copy of the medication review care plans at the end of the session.

At least four weeks after this the patient will then be invited to the clinical trials unit at the University of East Anglia to discuss their medicines with the student who undertook the original medication review. The student will ensure that the patient understands what their medicines are for and why they need to take them.

We will require a BP, HbA1c and cholesterol level six months after the end of the study for each participating patient unless a recent one is recorded.

GP study invitation V3 14.6.11

### **Why has this practice been invited?**

Your practice has a PCT pharmacist working with it, so you will already be aware of the range of services that pharmacists can perform. In addition we will require assistance from a PCT pharmacist at stages in the research and logistically it will be better to employ the services of a pharmacist who knows the practice.

### **Does my practice have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. We will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form, you are free to withdraw from the study at any time.

### **Will the practice be paid for participation in this study?**

The practice will receive support funding from Norfolk & Suffolk CLRN to cover the costs of participating in this study.

### **Who will see the patients' medical records?**

In addition to your practice staff, two student pharmacists will look at the medical records of patients in the student review group to help decide if their medication needs to be changed.

A trained university researcher (Rick Adams), who also holds a contract with NHS Norfolk, will also have access to patients' medical records. This is necessary to allow him to collect information about any changes that happen during the study period, such as the medicines prescribed or the number of times the patient visits the surgery about their health.

Authorised monitors from NHS Norfolk may also look at participants' medical records to check that the research is being carried out according to the approved protocol.

### **How many patients will be involved?**

There will be approximately 160 patients involved in this study, from four different medical practices. This will allow 80 in the review group and 80 controls.

### **Will the information remain confidential?**

Yes. Any information provided will remain confidential within the university research team and will not be disclosed to anyone other than yourself or nominated colleagues.

Anyone who has access to the records will be bound by a signed contract of confidentiality. Information will be securely stored by researchers according to university policy in a way that means patients cannot be identified from the information provided.

### **What if there is a problem?**

The students will be covered by university insurance (UEA) for involvement in research work such as this study. This includes the time that they are in the GP practice. Rick Adams and the other PCT pharmacists involved in the study are employed by NHS Norfolk and hence will be covered by NHS indemnity for their work on the study.

**Has the research been reviewed?**

The research has been reviewed and funded by Research for Patient Benefit which is part of the National Institute for Health Research (part of the NHS) which supports medical research throughout the United Kingdom. In addition, a steering committee comprising senior researchers at the School of Pharmacy, School of Medicine, Health Policy & Practice and the School of Education & Lifelong Learning as well as a patient with type 2 diabetes collaboratively produced and reviewed the research.

It has also been approved by Cambridgeshire 3 Research Ethics Committee.

**What will happen to the results of the study?**

The results of the study will be used to find out whether pharmacy students providing medication reviews is beneficial to patients with type 2 diabetes. It will also give us information about whether this new teaching method is beneficial to the training of pharmacy students. These results may be published in scientific journals or presented at meetings. The results will also be used to form part of an educational qualification undertaken by Rick Adams at the University of East Anglia. Information gathered during the study or published afterwards will not include any names or personal details that would allow individual patients to be identified. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact either Professor David Wright at the UEA on 01603 592042 or email [d.i.wright@uea.ac.uk](mailto:d.i.wright@uea.ac.uk) or Clare Symms, Research Governance Manager at NHS Norfolk on 01603 257020 or email [clare.symms@norfolk.nhs.uk](mailto:clare.symms@norfolk.nhs.uk). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

Thank you for taking the time to read this information sheet.

You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason.

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413. Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
Lakeside 400  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG  
01603 257020



School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Phone: 01603 593144

**Consent Form**

**On Behalf of Medical Practitioners**

**Study title: Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Intervention Phase**

**Name of Researcher:** Richard Adams

**Please initial boxes**

1. I confirm that I have read and understand the information sheet dated XXXXXXXX for the above study and have had the opportunity to ask questions.
  
2. I understand that the medical practice participation is voluntary and that I am free to withdraw at any time, without giving any reason.
  
3. I agree to take part in this study.

\_\_\_\_\_  
Name (please print)  
(on behalf of the Practice)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Address (please print): .....  
.....  
.....

Please tick the box if you would like to receive details of the results of the study

## UEA LETTER-HEADED PAPER

{DATE}

{Study Practice}  
{Study Practice address}

Dear {study GP Practice},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the above research study because you are a medical practice in Norfolk NHS which employs a practice pharmacist. Before you decide whether or not to take part in the study, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Study Information Sheet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Study Information Sheet", you decide that your Practice would like to take part, please read and sign the enclosed "GP Practice Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996 or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by email at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Intervention Phase

### Invitation for a Student to Join a Research Project

### Participant Information Leaflet



Patient  
Trial  
information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)



### Annex 3.3

You are invited to take part in a research study. This study is designed to find out the effects of pharmacy students being given more opportunity to work with patients during their training. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

#### **What is the purpose of the study?**

The purpose of this study is to find out what the benefits are to patients and final year pharmacy students of final year pharmacy students providing a medication review in a medical practice and patient consultation to patients with type 2 diabetes.

#### **Why have I been invited?**

You will be a final year pharmacy student when we are undertaking the medication reviews, which is when we would hope to undertake this new way of teaching, as by then students such as yourself will have developed sufficient knowledge and skills to take part in this study.

#### **What happens to me if I agree to take part in this study?**

If you agree to take part, you will post your consent form to the research team at the University of East Anglia.

As well as additional training that we have developed for all third year pharmacy students, those students consenting to be part of the research project will undertake the following training which will not be offered to other students. This will be in your own time and will not form part of the set course:

- A medication review skills workshop utilising dummy patient records (two hours) in order to gain more practice with the IT package.
- Two medicines related consultations with pre-prepared and scripted 'actor' patients (two hours).
- A training session at the PCT or in a GP practice on the use of the practice information system (two hours).

You will need to apply for an honorary contract at NHS Norfolk (although we will assist with the paperwork):

- You will then undertake a session at a GP practice when you will, in a pair with another student, access the medical records on the computer of four patients. Data will be recorded by you onto a laptop using a pharmaceutical care package. Recommendations that you are able to identify for changes in relation to the patient's medication will be assessed by a practice pharmacist or Rick Adams and any that are suitable will be forwarded to the GP/nurse specialist for a meeting with yourself when changes can be implemented if the GP/nurse agrees. You will receive feedback on your performance.
- At a second session at the UEA you will be randomly assigned to two of the four patients and undertake a medication related consultation with the patient using the computer record that you made at the previous session. The sessions will be filmed (as communication skills workshops currently are at the UEA). Any recommendations that you make will be assessed by Rick Adams and if suitable will be forwarded to the GP/nurse specialist for possible action. At a later date you will receive feedback on your performance from Rick Adams and Paul Grassby.

**Will I benefit from participation in this study?**

We cannot guarantee that you will benefit from participation in this study. However, we hope that the additional training as well as the contact with GPs, nurse, patients' records and patients will be a useful experience which improves your consultation skills and confidence when working alongside healthcare professionals.

**Do I have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. After you have read this information, we will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form, you are free to withdraw from the study at any time. The standard of education you receive as part of your set course will not be affected by whether or not you take part in the study.

**How much time will I need to spend on the study?**

We estimate that you will need approximately six hours preparation in the third year and eight hours during your fourth year on the pharmacy course. In addition there will be travel time to practices which will vary depending on location. All practices are in Norfolk and we will pay your travel expenses.

**Confidentiality: Will anybody be able to gain information about myself from this study?**

No, you will not be identified. Your performance within the project will be kept within the project team and will not be communicated to anyone outside of the team.

**What if there is a problem?**

Students, such as yourself, involved in the study will be covered by university insurance for involvement in research work such as this study. This includes the time that you are in the GP practice. Rick Adams and the other PCT pharmacists involved in this study are employed by NHS Norfolk and hence will be covered by NHS indemnity for their work on this study.

**What will happen to the results of the study?**

The results of the study will be used to find out whether pharmacy students providing medication reviews is beneficial to patients with type 2 diabetes. It will also give us information about whether this new teaching method is beneficial to pharmacy students. These results may be published in scientific journals or presented at meetings. The results will also be used to form part of an educational qualification undertaken by Rick Adams at the University of East Anglia. Information gathered during the study or published afterwards will not include any names or personal details that would allow individuals to be identified. If you wish, a summary of the study results will be sent to you after the research has been completed.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact Professor Duncan Craig, Head of the School of Pharmacy.

Annex 3.3

Thank you for taking the time to read this information sheet.  
You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason. The project is in addition to the current course and non-participation is not expected to adversely affect your studies or assessment performance.

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
Lakeside 400  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG  
01603 257020



School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Phone: 01603 593144

**Consent Form**

**Students**

**Study title: Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Intervention Phase**

**Name of Researcher:** Richard Adams

**Please initial boxes**

1. I confirm that I have read and understand the information sheet dated XXXXXXXX for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my education being affected.
3. I understand that data collected about my performance during the study may be looked at by responsible individuals from the University of East Anglia, and that I will be filmed during a session. I give permission for this information to be collected for use in the study.
4. I agree to take part in this study.

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Address (please print): .....  
.....  
.....

Please tick the box if you would like to receive details of the results of the study

## **PRACTICE LETTER-HEADED PAPER**

{DATE}

{Study student}  
{Study student address}

Dear {student},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the above research project. Before you decide whether or not to take part in the study, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Participant Information Leaflet" carefully. Talk to others about the study if you wish before making up your mind. As the information sheet explains, you do not need to take part in the study if you do not want to.

If, after reading the "Participant Information Leaflet", you decide that you would like to take part, please read and sign the enclosed "Student Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 or by email at Richard.Adams@uea.ac.uk.

Thank you for considering taking part in this research.

Yours sincerely,

Professor David Wright  
Chief Investigator

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Intervention Phase

### Invitation for a Patient to Join a Research Project

#### Participant Information Leaflet



Patient  
Trial  
information  
V4  
10.8.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

### Annex 3.2

You are invited to take part in a research study. This study is designed to find out the effects of pharmacy students working more closely with patients with type 2 diabetes during their training. This leaflet provides information about the study, which we want you to understand before you agree to take part. Please read this leaflet carefully; it is designed to provide answers to some of the questions that you may have about the study.

#### **What is the purpose of the study?**

The purpose of the study is to find out the patient benefits and patient acceptability of final year pharmacy students reviewing the medicines of patients with type 2 diabetes and providing a face to face consultation to help them better understand their medicines.

#### **Why have I been invited?**

Your doctor's records show that you are receiving medicine(s) used to treat type 2 diabetes and registered with one of the four medical practices in Norfolk which has agreed to take part in this study.

#### **Do I have to take part?**

No. It is entirely up to you whether you decide to take part or not. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive in any way.

#### **What happens to me if I agree to take part in this study?**

You will need to complete the enclosed consent form. Once we have received this, you will be allocated to one of two groups: 'standard-care' or 'medication review'. We do not know yet which will be the best way of helping patients. To find out we need to compare treatments. We put patients into groups ('standard-care' or 'medication review') and compare the results to see if one is better. The decision as to which group you will join is random (like the tossing of a coin). This is why we do not yet know which group you would be in.

You will be asked to complete a postal questionnaire at the beginning of the study and again after six months. The questionnaire will ask for some details about your health, medicines and experience of using medicines and should take no longer than 20 minutes to complete.

#### **Standard care**

If you are allocated to 'standard care' you will not be asked to do anything else. You will receive the standard care that your medical practice has always provided. We need a group like this to be able to compare the benefits of the student review with the usual care provided to patients like yourself.

#### **Medication review**

If you are allocated to 'medication review' two final year pharmacy students will go to your medical practice, together with a Primary Care Trust (PCT) pharmacist who already works with the GP practice accessing patients' medical records or Rick Adams who is a registered pharmacist currently working for NHS Norfolk (the local PCT) and the University of East Anglia(UEA). Rick is experienced in conducting medication reviews and so will closely supervise the students. The students will then access your medical records and review your medication to check that your prescribed medicines are in line with current best prescribing practice. If any changes that may further enhance your care are identified, the student will pass on this information to the person that usually manages your diabetes. This may be your doctor or nurse who will then take appropriate action which may mean no changes at all.

### Annex 3.2

At least four weeks after this has been done you will be invited to your GP Practice for a consultation with one final year pharmacy student. This consultation should take between 20 to 30 minutes. It is an opportunity to discuss the medicines that you are prescribed and/or buy in pharmacies and you can ask questions about your medicines that you perhaps have not had the time to ask your doctor or nurse. During this consultation, an experienced pharmacist will be present to ensure that all information provided to you is correct. The student's performance will also be filmed so that we can provide them with detailed feedback about their performance. The camera will be positioned so that you will not be visible in this recording. At the end of the consultation you can make any comments that you think are relevant to Rick Adams.

After six months Rick Adams will check your medical records at your GP practice. If you have not had a blood test to check HbA1c (to show glucose control) or cholesterol in the previous three months we will ask your GP to organise a blood test for you.

#### **What are the possible risks and disadvantages of taking part?**

There are no risks in taking part. All actions by the students will be supervised by a qualified pharmacist and any recommendations will be reviewed by a doctor or nurse at your GP practice. The time taken to fill in the two questionnaires could be considered a disadvantage. We will pay your travel expenses so the consultation will not cost you any money.

#### **Will I benefit from participation in this study?**

There is no guarantee that you will be allocated to the medication review group. However, if you are in the group receiving a medication review, we cannot promise that the study will help you but we hope that it may be helpful to you in your personal management of your diabetes. Also we hope that the results of the study will help patients like you with type 2 diabetes in the future.

#### **What will happen if I don't want to carry on with the study?**

You are free to withdraw from the study at any time. If you withdraw we will use the information collected up to the time of your withdrawal. Withdrawal from the study will not affect the usual care that you receive from your medical practice.

#### **Who will see my medical records?**

If you are allocated to 'standard care', Rick Adams will access your records at your medical practice to obtain details about the management of your conditions. This will include information such as the medicines that you are prescribed and your recent blood test results.

If you are allocated to 'medication review', the two final year pharmacy students that will do your medication review will also look at your medical records in addition to Rick.

Authorised monitors from NHS Norfolk may also look at the records of some people participating in the study to check that the research is being carried out according to the approved protocol.

#### **What if there is a problem?**

In the unlikely event of you suffering any adverse effects from taking part in this study you would retain the same legal rights as any other patient treated in the NHS.

The students will be covered by university insurance (UEA) for involvement in research work such as this study. This includes the time that they are in the GP practice. Rick Adams and the other pharmacists involved in the study are employed by NHS Norfolk and hence will be covered by NHS indemnity for their work on the study.

#### **Confidentiality: Will anybody be able to gain information about me from this study?**

Patient study invitation V4 10.8.11



### Annex 3.2

No. Any information that you provide in questionnaires or that we obtain from your medical records will remain confidential within the university research team and will not be disclosed to anyone, other than the person that normally manages your medicines at your medical practice. Anyone who has access to your records will be bound by a signed contract of confidentiality. Students will receive supervised training in confidentiality. All information stored for the project will have names and contact details removed so that you cannot be identified. At all times we will follow ethical and legal practice.

#### **How many patients will be involved?**

There will be approximately 160 patients involved in this study from four different medical practices.

#### **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

#### **What will happen to the results of the study?**

The results of the study will be used to find out whether pharmacy students providing medication reviews is beneficial to patients with type 2 diabetes. It will also give us information about whether this new teaching method is beneficial to pharmacy students. These results may be published in scientific journals or presented at meetings. The results will also be used to form part of an educational qualification undertaken by Rick at the University of East Anglia. Information gathered during the study or published afterwards will not include any names or personal details that would allow individual patients to be identified. If you wish, a summary of the study results will be sent to you after the research has been completed.

#### **How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact the Patient Advice and Liaison Service on freephone 0800 587 4132 or via email at [pals@norfolk.nhs.net](mailto:pals@norfolk.nhs.net). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

**Thank you for taking the time to read this information sheet.**

**You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason. Your medical care will not be affected in any way whether you decide to participate in the study or not.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413. Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.

**Consent Form**

**Patients**

**Study title: Supervised Pharmacy Student-led Medication Review of Patients with Diabetes in Primary Care: Intervention Phase**

**Name of Researcher:** Richard Adams

**Please initial boxes**

1. I confirm that I have read and understand the information sheet dated XXXXX for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by responsible individuals from the University of East Anglia, from regulatory authorities or from the NHS. I give permission for these individuals to have access to my records.
4. I understand that when I meet the student the consultation will be filmed but I will not be visible in the film although my voice may be heard.
5. I agree to take part in this study.

\_\_\_\_\_  
Name (please print)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Address (please print): .....  
.....  
.....

Please tick the box if you would like to receive details of the results of the study

## PRACTICE LETTER-HEADED PAPER

{DATE}

{Study patient}  
{Study patient address}

Dear {study patient},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing on behalf of our research colleagues to invite you to take part in the above research study. I have identified you from my practice records as someone who has long-term Type 2 Diabetes - at the moment the research team has no information about you. Before you decide whether or not to take part in the study, we wanted to provide you with information about why the research is being done and what it would involve for you.

This study will provide an opportunity for some of our patients to have their medication reviewed by a final year pharmacy student from the University of East Anglia. If you are willing to take part in the study you may be given the opportunity to talk to a pharmacy student about your medicines, find out how they work and why they have been prescribed. As you know you are already regularly reviewed, however, we would like to know if student pharmacists can contribute any more to this process. If you agree to this, the medication review would be between November and January.

Please take time to read the enclosed "Study Information Sheet" carefully to find more information. Talk to others about the study if you wish before making up your mind. As the information sheet explains, you do not need to take part in the study if you do not want to.

If, after reading the "Study Information Sheet", you decide that you would like to take part, please read and sign the enclosed "Patient Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk).

A member of staff at this Practice might contact you by telephone at a later date to check that you have received all the information that you need to make a decision. Thank you for considering taking part in this research.

Yours sincerely,

Dr {Senior Partner}  
on behalf of NAME1 Practice

V5 1.9.11

Date

Address  
Address  
Address  
Address  
Address

Dear (Patient Name)

**Re: Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

Thank you for returning the signed consent form to indicate that you are willing to take part in this study.

As soon as we have received enough replies from other patients we will be writing to you to let you know which of the two groups mentioned in the information leaflet sent to you by your GP practice that you will be allocated to. This will be organised by chance, like the tossing of a coin, which is the usual method in research to make sure that we cannot influence the result.

Thank you.

Yours sincerely

Rick Adams  
Research Pharmacist  
School of Pharmacy

Date

Address  
Address  
Address  
Address  
Address

Dear (Patient name)

**Re: Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

I am writing to thank you for agreeing to take part in this research study. Using the usual random method, which is similar to tossing a coin so that we cannot influence the result, you have been allocated to usual care (what we call the control group). This means that nothing different will happen to you other than asking you to complete a questionnaire at the beginning of the study and again at the end of the study.

The first questionnaire will be sent soon and we would be very grateful if you would complete it and return in the stamped addressed envelope provided. The second questionnaire will be sent to you approximately three months after the first questionnaire.

I can assure you that that your role in the research is important and that it was worth offering to join the study and to complete the questionnaire. What happens to the control group tells us what would have happened to patients if they had not received the consultation with a student. This is the only way that we will know for sure if the new system works for patients or not, so your role is just as important as the other patients and your answers on the questionnaire are essential to ensure a correct result.

Once again, thank you for participating and I will be posting the questionnaires to you very soon.

Yours sincerely

Rick Adams  
Research Pharmacist  
School of Pharmacy

Date

Address  
Address  
Address  
Address  
Address

Dear (Patient name)

**Re: Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

I am writing to thank you for agreeing to take part in this research study. It is only by patients such as yourself volunteering to help with research like this that we can be sure if a new way of treating patients is of any benefit.

Using the usual random method, which is similar to tossing a coin so that we cannot influence the result, you have been allocated to the intervention group.

This means that, as stated, in the information leaflet sent to you by your GP practice, we will ask you to complete a questionnaire on two occasions. The first questionnaire will be sent to you soon and we would be very grateful if you would complete it and return it in the stamped addressed envelope provided. In addition, whilst supervised by a pharmacist, a pair of students will look at your medical record at the GP practice. We will then invite you to your GP practice to meet one of the students for a medication review.

The second questionnaire will be sent to you to complete approximately three months after having your medication review with the student.

Thank you.

Yours sincerely

Rick Adams  
Research Pharmacist  
School of Pharmacy

Date

Address  
Address  
Address  
Address  
Address

Dear (Patient name)

**Re: Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

I am writing to thank you for agreeing to take part in this research study. It is only by patients such as yourself taking part in research that we can find the true answer to questions like the current one about patient care. On this occasion we were very fortunate to find that so many patients volunteered to join the study resulting in more patients than we can accommodate. I therefore have to advise you that we are unable to include you at this time, but hope that this will not stop you from volunteering to participate in such studies in the future.

Thank you very much for your help.

Yours sincerely

Rick Adams  
Research Pharmacist  
School of Pharmacy

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Intervention Phase Patient Questionnaire

### Guidance on completing this questionnaire:

- This questionnaire is designed to take about 20 minutes to complete.
- Please tick or circle one box **only** in response to each question unless requested to do otherwise.
- The questionnaire consists of five sections.
- Please complete **all** sections in the questionnaire to the best of your knowledge.
- Full instructions for completion are included at the start of each section.
- Once completed, please return questionnaire in the stamped addressed envelope provided.



### Contact details:

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎:01603 591996

Email: [richard\\_adams@uea.ac.uk](mailto:richard_adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎:01603 592042

Email: [d.l.wright@uea.ac.uk](mailto:d.l.wright@uea.ac.uk)



## Section A Quality of life

Under each heading, please tick ONE box that best describes your health TODAY.

### 1 MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

### 2 SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

### 3 USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

### 4 PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

### 5 ANXIETY / DEPRESSION

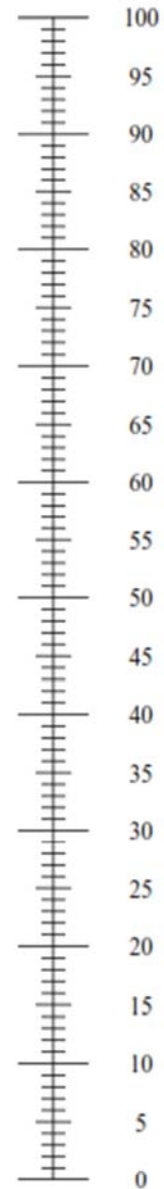
- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

6 We would like to know how good or bad your health is TODAY.

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.  
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health  
you can imagine



The worst health  
you can imagine

## Section B Information about medicines

We would like to ask you about the *information you have received about your medicines*.

- Please rate the information you have received about each of the following aspects of your medicines.
- Although the questions only talk about one medicine, if you have to take more than one please give your overall feeling about information you have received **about all of your medicines**.

	Have you received enough information about:	Amount of information received				
		TOO MUCH	ABOUT RIGHT	TOO LITTLE	NONE RECEIVED	NONE NEEDED
7	What the medicines are called					
8	What these medicines for					
9	What they do					
10	How they work					
11	How long they take to act					
12	How you can tell if they are working					
13	How long you need to be on the medicine					
14	How to use them					
15	How to get a further supply					
16	What you should do if you forget to take a dose					
17	Whether the medicines will have any unwanted effects (side effects)					
18	What are the risks of you getting side effects					
19	What you should do if you experience unwanted side effects					
20	Whether you can drink alcohol whilst taking this medicine					
21	Whether the medicine will interfere with other medicines					
22	Whether the medication will make you feel drowsy					
23	Whether the medication will affect your sex life					

## Section C Questions about using your medicines

- Many people find a way of using their medicines which suits them.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you use your medicines.

Here are some ways in which people have said that they use their medicines.

For each of the statements, please tick the box which best applies to you for all of the medicines that you have been prescribed.

	Your own way of using your medicines	Always	Often	Sometimes	Rarely	Never
24	I forget to take them					
25	I alter the dose					
26	I stop taking them for a while					
27	I decide to miss out a dose					
28	I take less than instructed					

## Sub-section C Additional information about using your medicines

Please tick **one** box:

- 29 I am currently using a multi-compartment plastic box to hold my tablets or capsules (e.g. dosette) and this helps me to remember to take my doses

Yes  No

## Section D Your views about medicines prescribed for you

- We would like to ask you about your personal views about medicines prescribed for you.
- These are statements other people have made about their medicines.
- Please show how much you agree or disagree with them by ticking the appropriate box.

**There are no right or wrong answers.  
We are interested in your personal views.**

	Views about MEDICINES PRESCRIBED FOR YOU	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
30	My health, at present, depends on my medicines					
31	Having to take medicines worries me					
32	My life would be impossible without my medicines					
33	I sometimes worry about long term effects of my medicines					
34	Without my medicines I would be very ill					
35	My medicines are a mystery to me					
36	My health in the future will depend on my medicines					
37	My medicines disrupt my life					
38	I sometimes worry about becoming too dependent on my medicines					
39	My medicines protect me from becoming worse					
40	These medicines give me unpleasant side effects					

## Section E View on diabetes treatment

The following questions are concerned with the treatment for your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks.

- Please answer each question by **circling a number** on each of the scales.

41. How satisfied are you with your current treatment?

very satisfied      6    5    4    3    2    1    0      very dissatisfied

42. How often have you felt that your blood sugars have been unacceptably high recently?

most of the time    6    5    4    3    2    1    0      none of the time

43. How often have you felt that your blood sugars have been unacceptably low recently?

most of the time    6    5    4    3    2    1    0      none of the time

44. How convenient have you been finding your treatment to be recently?

very convenient    6    5    4    3    2    1    0      very inconvenient

45. How flexible have you been finding your treatment to be recently?

very flexible      6    5    4    3    2    1    0      very inflexible

46. How satisfied are you with your understanding of your diabetes?

very satisfied      6    5    4    3    2    1    0      very dissatisfied

47. Would you recommend this form of treatment to someone else with your kind of diabetes?

Yes, I would definitely recommend the treatment    6    5    4    3    2    1    0      No, I would definitely not recommend the treatment

48. How satisfied would you be to continue with your present form of treatment?

very satisfied      6    5    4    3    2    1    0      very dissatisfied

**Please make sure that you have circled one number on each of the scales.**

## Section F Use of Pharmacy Services

Over the last 3 months has you visited a Pharmacy more/ less

Over the last 3 months have you spoken to a Pharmacist (other than during the study) More Less

If you have spoken to a Pharmacist more did you discuss your medicines yes No

**Thank you for finding the time to complete this questionnaire.**

Please use the space provided below to make any comments about your responses to individual questions, the questionnaire and study then return the questionnaire in the stamped addressed envelope provided.

### References:

- Q1-Q6: UK (English) v.2 © 2009 EuroQol Group. EQ-5D™ is a trade mark of the EuroQol Group  
Q7-Q23: Satisfaction with Information about Medicines Scale (SIMS) ©RHorne University of Brighton Horne, R., Hankins, M., & Jenkins, R. (2001). The Satisfaction with Information about Medicines Scale (SIMS): A new measurement tool for audit and research. *Quality in Health Care*, 10, 135-140  
Q24-Q28: MARS\_5 RH2\_06.doc Medication Adherence Report Scale (MARS\_5) ©Robert Horne 1991, 2006)  
Q30-Q40: Horne, R., Weinman, J., & Hankins, M. 1999, "The Beliefs about Medicines Questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication", *Psychology and Health*, vol. 14, pp. 1-24  
Q41-Q48: DTSQs © Prof Clare Bradley 9/93 Standard UK English (rev. 7/4) Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK

## **UEA LETTER-HEADED PAPER**

{DATE}

{Study patient}  
{Study patient address}

Dear {study patient},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing following your decision to participate in the above study. In the information leaflet that we provided you were informed that we would need you to complete a questionnaire if you joined the study.

A copy of the questionnaire is enclosed and we would be grateful if you would complete it. This should take no more than 20 minutes. Instructions are included on page one of the questionnaire. A stamped addressed envelope is enclosed to return the completed questionnaire.

The information that you provide will remain confidential to the research team and is essential to enable us to decide if the new method of teaching final year pharmacy students with patients can benefit patients.

If you have any questions about completing the questionnaire, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 593144 or by email at [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk).

Thank you for your assistance.

Yours sincerely,

Professor David Wright and Rick Adams

V3 14.6.11



# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Intervention Phase Follow up Patient Questionnaire (Intervention Group)

### Guidance on completing this questionnaire:

- This questionnaire is designed to take about 20 minutes to complete.
- Please tick or circle one box **only** in response to each question unless requested to do otherwise.
- The questionnaire consists of five sections.
- Please complete **all** sections in the questionnaire to the best of your knowledge.
- Full instructions for completion are included at the start of each section.
- Once completed, please return the questionnaire in the stamped addressed envelope provided.



Reference No.



### Contact details:

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎:01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎:01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

## Section A Quality of life

Under each heading, please tick ONE box that best describes your health TODAY.

### 1 MOBILITY

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

### 2 SELF-CARE

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

### 3 USUAL ACTIVITIES (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

### 4 PAIN / DISCOMFORT

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

### 5 ANXIETY / DEPRESSION

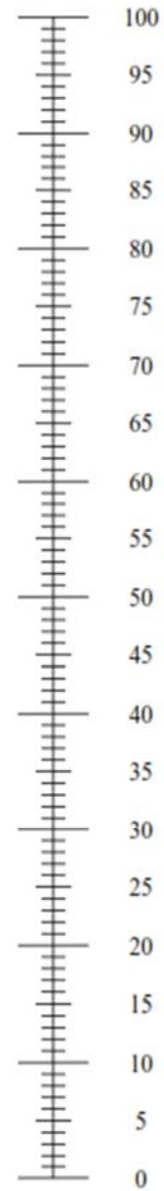
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

**6 We would like to know how good or bad your health is TODAY.**

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.  
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health  
you can imagine



The worst health  
you can imagine

## Section B Information about medicines

We would like to ask you about the *information you have received about your medicines*.

- Please rate the information you have received about each of the following aspects of your medicines.
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Have you received enough information about:		Amount of information received				
		TOO MUCH	ABOUT RIGHT	TOO LITTLE	NONE RECEIVED	NONE NEEDED
7	What the medicines are called					
8	What these medicines for					
9	What they do					
10	How they work					
11	How long they take to act					
12	How you can tell if they are working					
13	How long you need to be on the medicine					
14	How to use them					
15	How to get a further supply					
16	What you should do if you forget to take a dose					
17	Whether the medicines will have any unwanted effects (side effects)					
18	What are the risks of you getting side effects					
19	What you should do if you experience unwanted side effects					
20	Whether you can drink alcohol whilst taking this medicine					
21	Whether the medicine will interfere with other medicines					
22	Whether the medication will make you feel drowsy					
23	Whether the medication will affect your sex life					



**Section C Questions about using your medicines**

- Many people find a way of using their medicines which suits them.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you use your medicines.

Here are some ways in which people have said that they use their medicines.

For each of the statements, please tick the box which best applies to you for all of the medicines that you have been prescribed.

	Your own way of using your medicines	Always	Often	Sometimes	Rarely	Never
24	I forget to take them					
25	I alter the dose					
26	I stop taking them for a while					
27	I decide to miss out a dose					
28	I take less than instructed					

**Sub-section C Additional information about using your medicines**

Please tick **one box**:

29 I am currently using a multi-compartment plastic box to hold my tablets or capsules (e.g. dosette) and this helps me to remember to take my doses

Yes  No

## Section D Your views about medicines prescribed for you

- We would like to ask you about your personal views about medicines prescribed for you.
- These are statements other people have made about their medicines.
- Please show how much you agree or disagree with them by ticking the appropriate box.

**There are no right or wrong answers.  
We are interested in your personal views.**

	Views about MEDICINES PRESCRIBED FOR YOU	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
30	My health, at present, depends on my medicines					
31	Having to take medicines worries me					
32	My life would be impossible without my medicines					
33	I sometimes worry about long term effects of my medicines					
34	Without my medicines I would be very ill					
35	My medicines are a mystery to me					
36	My health in the future will depend on my medicines					
37	My medicines disrupt my life					
38	I sometimes worry about becoming too dependent on my medicines					
39	My medicines protect me from becoming worse					
40	These medicines give me unpleasant side effects					



## Section E Your views about your diabetes treatment

The following questions are concerned with the treatment for your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks.

- Please answer each question by **circling a number** on each of the scales.

41. How satisfied are you with your current treatment?  
very satisfied      6    5    4    3    2    1    0      very dissatisfied
42. How often have you felt that your blood sugars have been unacceptably high recently?  
most of the time    6    5    4    3    2    1    0      none of the time
43. How often have you felt that your blood sugars have been unacceptably low recently?  
most of the time    6    5    4    3    2    1    0      none of the time
44. How convenient have you been finding your treatment to be recently?  
very convenient    6    5    4    3    2    1    0      very inconvenient
45. How flexible have you been finding your treatment to be recently?  
very flexible      6    5    4    3    2    1    0      very inflexible
46. How satisfied are you with your understanding of your diabetes?  
very satisfied      6    5    4    3    2    1    0      very dissatisfied
47. Would you recommend this form of treatment to someone else with your kind of diabetes?  
Yes, I would definitely recommend the treatment    6    5    4    3    2    1    0      No, I would definitely not recommend the treatment
48. How satisfied would you be to continue with your present form of treatment?  
very satisfied      6    5    4    3    2    1    0      very dissatisfied

**Please make sure that you have circled one number on each of the scales.**

## Section F Use of Pharmacy Services

Over the last 3 months approximately how many times have you spoken to a pharmacist in a pharmacy shop (chemist)?

If you answered more than zero, how many times have you spoken to a pharmacist in the last 3 months for each of the following reasons:

- Extra information about your medicines.....
- To discuss how you use your medicines (Medicines Use Review of your medicines) .....
- Advice on a minor condition.....
- Advice on whether to go to your doctor or nurse.....
- Other .(please specify).....

Please tick the box which most closely reflects your opinion about the following statement – “As a result of the consultation when I met a student as part of this study I am far more likely to speak to a pharmacist about my medicines or health”.

Strongly agree	Agree	Unsure	Disagree	Strongly disagree

**Thank you for finding the time to complete this questionnaire.**

Please use the space provided below if you wish to make any comments about the study or your responses to individual questions in the questionnaire. **Then return the questionnaire in the stamped addressed envelope provided**

References:

Q1-Q6: UK (English) v.2 © 2009 EuroQol Group. EQ-5D™ is a trade mark of the EuroQol Group  
 Q7-Q23: Satisfaction with Information about Medicines Scale (SIMS) ©RHome University of Brighton Horne, R., Hankins, M., & Jenkins, R. (2001). The Satisfaction with Information about Medicines Scale (SIMS): A new measurement tool for audit and research. *Quality in Health Care*, 10, 135-140  
 Q24-Q28: MARS\_5 RH2\_06.doc Medication Adherence Report Scale (MARS\_5) ©Robert Horne 1991, 2006)  
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 Q41-Q48: DTSQs © Prof Clare Bradley 9/93 Standard UK English (rev. 7/4) Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK



# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Intervention Phase Follow up Patient Questionnaire (Control Group)

### Guidance on completing this questionnaire:

- This questionnaire is designed to take about 20 minutes to complete.
- Please tick or circle one box **only** in response to each question unless requested to do otherwise.
- The questionnaire consists of five sections.
- Please complete **all** sections in the questionnaire to the best of your knowledge.
- Full instructions for completion are included at the start of each section.
- Once completed, please return the questionnaire in the stamped addressed envelope provided.



Reference  
No.



### Contact details:

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎:01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎:01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

## Section A Quality of life

Under each heading, please tick ONE box that best describes your health TODAY.

### 1 MOBILITY

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

### 2 SELF-CARE

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

### 3 USUAL ACTIVITIES (*e.g. work, study, housework, family or leisure activities*)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

### 4 PAIN / DISCOMFORT

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

### 5 ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

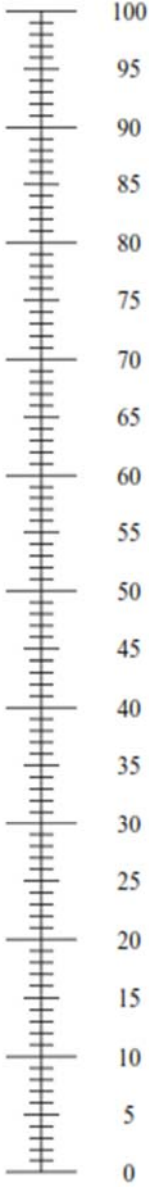
Ref No

**6 We would like to know how good or bad your health is TODAY.**

- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.  
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health  
you can imagine



The worst health  
you can imagine

## Section B Information about medicines

We would like to ask you about the *information you have received about your medicines*.

- Please rate the information you have received about each of the following aspects of your medicines.
- Although the questions only talk about one medicine, if you have to take more than one please give your overall feeling about information you have received **about all of your medicines**.

Have you received enough information about:		Amount of information received				
		TOO MUCH	ABOUT RIGHT	TOO LITTLE	NONE RECEIVED	NONE NEEDED
7	What the medicines are called					
8	What these medicines for					
9	What they do					
10	How they work					
11	How long they take to act					
12	How you can tell if they are working					
13	How long you need to be on the medicine					
14	How to use them					
15	How to get a further supply					
16	What you should do if you forget to take a dose					
17	Whether the medicines will have any unwanted effects (side effects)					
18	What are the risks of you getting side effects					
19	What you should do if you experience unwanted side effects					
20	Whether you can drink alcohol whilst taking this medicine					
21	Whether the medicine will interfere with other medicines					
22	Whether the medication will make you feel drowsy					
23	Whether the medication will affect your sex life					

## Section C1 Questions about using your medicines

- Many people find a way of using their medicines which suits them.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you use your medicines.

Here are some ways in which people have said that they use their medicines.

For each of the statements, please tick the box which best applies to you for all of the medicines that you have been prescribed.

	Your own way of using your medicines	Always	Often	Sometimes	Rarely	Never
24	I forget to take them					
25	I alter the dose					
26	I stop taking them for a while					
27	I decide to miss out a dose					
28	I take less than instructed					

## Section C2 Additional information about using your medicines

Please tick **one** box:

- 29 I am currently using a multi-compartment plastic box to hold my tablets or capsules (e.g. dosette) and this helps me to remember to take my doses

Yes

No

## Section D Your views about medicines prescribed for you

- We would like to ask you about your personal views about medicines prescribed for you.
- These are statements other people have made about their medicines.
- Please show how much you agree or disagree with them by ticking the appropriate box.

**There are no right or wrong answers.  
We are interested in your personal views.**

	Views about MEDICINES PRESCRIBED FOR YOU	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
30	My health, at present, depends on my medicines					
31	Having to take medicines worries me					
32	My life would be impossible without my medicines					
33	I sometimes worry about long term effects of my medicines					
34	Without my medicines I would be very ill					
35	My medicines are a mystery to me					
36	My health in the future will depend on my medicines					
37	My medicines disrupt my life					
38	I sometimes worry about becoming too dependent on my medicines					
39	My medicines protect me from becoming worse					
40	These medicines give me unpleasant side effects					

## Section E Your views about your diabetes treatment

The following questions are concerned with the treatment for your diabetes (including insulin, tablets and/or diet) and your experience over the past few weeks.

- Please answer each question by **circling a number** on each of the scales.

41. How satisfied are you with your current treatment?

very satisfied      6    5    4    3    2    1    0      very dissatisfied

42. How often have you felt that your blood sugars have been unacceptably high recently?

most of the time    6    5    4    3    2    1    0      none of the time

43. How often have you felt that your blood sugars have been unacceptably low recently?

most of the time    6    5    4    3    2    1    0      none of the time

44. How convenient have you been finding your treatment to be recently?

very convenient    6    5    4    3    2    1    0      very inconvenient

45. How flexible have you been finding your treatment to be recently?

very flexible      6    5    4    3    2    1    0      very inflexible

46. How satisfied are you with your understanding of your diabetes?

very satisfied      6    5    4    3    2    1    0      very dissatisfied

47. Would you recommend this form of treatment to someone else with your kind of diabetes?

Yes, I would definitely recommend the treatment    6    5    4    3    2    1    0      No, I would definitely not recommend the treatment

48. How satisfied would you be to continue with your present form of treatment?

very satisfied      6    5    4    3    2    1    0      very dissatisfied

**Please make sure that you have circled one number on each of the scales.**

**Section F    Use of Pharmacy Services**

Over the last 3 months approximately how many times have you spoken to a pharmacist in a pharmacy shop (chemist) about your medicines or health?

If you answered more than zero, how many times have you spoken to a pharmacist in the last 3 months for each of the following reasons:

- Extra information about your medicines.....
- To discuss how you use your medicines (Medicines Use Review ) .....
- Advice on a minor condition.....
- Advice on whether to go to your doctor or nurse.....
- Other (please specify).....

**Thank you for finding the time to complete this questionnaire.**

Please use the space provided below if you wish to make any comments about the study or your responses to individual questions in the questionnaire. **Then return the questionnaire in the stamped addressed envelope provided**

References:

Q1-Q6: UK (English) v.2 © 2009 EuroQol Group. EQ-5D™ is a trade mark of the EuroQol Group

Q7-Q23: Satisfaction with Information about Medicines Scale (SIMS) ©RHorne University of Brighton Horne, R., Hankins, M., & Jenkins, R. (2001). The Satisfaction with Information about Medicines Scale (SIMS): A new measurement tool for audit and research. *Quality in Health Care, 10*, 135-140

Q24-Q28: MARS\_5 RH2\_06.doc Medication Adherence Report Scale (MARS\_5) ©Robert Horne 1991, 2006)

Q30-Q40: Horne, R., Weinman, J., & Hankins, M. 1999, "The Beliefs about Medicines Questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication", *Psychology and Health*, vol. 14, pp. 1-24

Q41-Q48: DTSQs © Prof Clare Bradley 9/93 Standard UK English (rev. 7/4) Health Psychology Research, Dept of Psychology, Royal Holloway, University of London, Egham, Surrey, TW20 0EX, UK



## **Appendix D4: Ethics Approved Documents – Review**

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Review Phase

### Invitation for a General Practitioner to Join a Focus Group

### Participant Information Leaflet



Patient  
Trial  
Information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

#### Annex 4.1

You are invited to take part in a research study.. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

#### **What is the purpose of the study?**

We would like to seek your opinions on the pharmacy student project which has taken place within your medical practice. The purpose of this part of the study is to determine what worked well and what could be improved if the process was repeated.

#### **Why have I been invited?**

You have been chosen because you were a participant in the study previously.

#### **Do I have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. After you have read this information, we will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form, you are free to withdraw from the study at any time.

#### **What happens to me if I agree to take part in this study?**

You will be invited to attend a focus group at a suitable location agreed between us. There will be approximately six to eight people in this group plus two researchers. In the unlikely event of too many people offering to take part we will randomly select eight and inform you of the outcome. One of the researchers will ask the group for their opinions on the different parts of the student project.

#### **What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion.

#### **Will I benefit from participation in this study?**

You will not benefit directly, although your participation will help to make sure that if students continue to undertake education in this way in the future that it is better for patients with type 2 diabetes and for the medical practices within which the students are located.

#### **How much time will I need to spend on the study?**

The focus group will take approximately one hour. We will pay for reasonable travel costs to and from the meeting and will provide a meal.

#### **Confidentiality: Will the information be kept confidential?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.

Focus Group GP invitation V3 14.6.11

**What if there is a problem?**

In the unlikely event of a problem occurring, indemnity will be provided by NHS Norfolk.

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

**What will happen to the results of the study?**

The results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact either Professor David Wright at the UEA on 01603 592042 or email [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk) or Clare Symms, Research Governance Manager at NHS Norfolk on 01603 257020 or email [clare.symms@norfolk.nhs.uk](mailto:clare.symms@norfolk.nhs.uk). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

**Thank you for taking the time to read this information sheet.**

**You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



## UEA LETTER-HEADED PAPER

{DATE}

{Study Practice}  
{Study Practice address}

Dear {study GP Practice},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the review phase of the above research study because you are a GP who was involved in the main study. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Participant Information Sheet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Participant Information Sheet", you decide that you would like to take part, please read and sign the enclosed "GP Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996) or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by email at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Review Phase

### Invitation for a Student to Join a Focus Group

### Participant Information Leaflet



Patient  
Trial  
Information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

You are invited to take part in a focus group. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

**What is the purpose of the study?**

We would like to obtain your views on the experience in order to determine what went well and what could be improved if it was to be repeated.

**Why have I been invited?**

You have been chosen because you took part in the study previously.

**Do I have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. After you have read this information, we will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form, you are free to withdraw from the study at any time. The standard of education you receive as part of your set course will not be affected by whether or not you take part in the study.

**What happens to me if I agree to take part in this study?**

You will be invited to the UEA to attend a focus group. There will be approximately six to eight people in this group plus two researchers. In the unlikely event of too many people offering to take part we will randomly select participants and inform you of the outcome. A researcher will ask the group for their opinions on the trial. This could range from your opinions on the preparation for the clinics, experiences within the medical practice and experiences with the patients.

**What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the focus group.

**Will I benefit from participation in this study?**

You will not benefit directly, although your participation will help to make sure that if future students undertake such roles the experience is maximised both for themselves and for the patients.

**How much time will I need to spend on the study?**

The focus group will take approximately one hour. We will pay for reasonable travel costs to and from the UEA and will provide a meal.

**Confidentiality: Will the information be kept confidential?**

The focus group discussion will be audio recorded and listened to by the research team at the UEA. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.



**What if there is a problem?**

In the unlikely event of a problem occurring, indemnity (a form of insurance cover) will be provided by NHS Norfolk.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

**What will happen to the results of the study?**

The results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact Professor Mark Searcy, Head of the School of Pharmacy.

**Thank you for taking the time to read this information sheet.**

**You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason. The project is in addition to the current course and non-participation is not expected to adversely affect your studies or assessment performance.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
Lakeside 400  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG  
01603 257125



School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Phone: 01603 593144

## Consent Form

### Focus Group for Students

### Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Review Phase

Researcher: Rick Adams, tel: 01603 593144  
[richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

Please initial boxes

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
3. I agree for the focus group to be audio recorded.
4. I agree to take part in the above study.

Name (please print)                      Signature                      Date

Address (please print): .....  
.....  
.....  
.....

Please tick the box if you would like to receive details of the results of the study

## **UEA LETTER-HEADED PAPER**

{DATE}

{Student address}

Dear {study student},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the review phase of the above research study because you are a student who has taken part in the above study. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Participant Information Leaflet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Participant Information Leaflet", you decide that you would like to take part, please read and sign the enclosed "Student Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 593144 (ext 3144) or by email at [richard.Adams@uea.ac.uk](mailto:richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by email at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA

# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Review Phase

### Invitation for a Pharmacist to Join a Focus Group

### Participant Information Leaflet



Patient  
Trial  
information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎ 01603 591996

Email: [richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎ 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

#### Annex 4.4

You are invited to take part in a focus group. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

#### **What is the purpose of the study?**

The purpose of this focus group is to review the student project and determine what went well and what could be improved from your perspective.

#### **Why have I been invited?**

You have been chosen because you helped us with the study previously.

#### **Do I have to take part?**

No, taking part in the study is voluntary - it is up to you to decide. After you have read this information, we will ask you to sign a consent form showing that you agree to take part. Even if you sign the consent form, you are free to withdraw from the study at any time.

#### **What happens to me if I agree to take part in this study?**

You will be invited to the School of Pharmacy at the UEA to attend a focus group. There will be four people in this group plus two researchers. A researcher will ask the group questions to do with the trial. These could be anything from the way in which you were asked to join the study, layout and design of questionnaires to the service and information that we hope to provide via the final year pharmacy students.

#### **What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion.

#### **Will I benefit from participation in this study?**

You will not benefit directly, although your participation will help to make sure that, if students continue to undertake education in this way in the future, that the intervention benefits the practice whilst causing minimal disruption.

#### **How much time will I need to spend on the study?**

The focus group will take approximately one hour. We will pay for reasonable travel costs to and from the UEA and will provide a meal.

#### **Confidentiality: Will the information be kept confidential?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.

#### **What if there is a problem?**

In the unlikely event of a problem occurring, indemnity will be provided by NHS Norfolk.

#### **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

Focus group pharmacist invitation V3 14.6.11

**What will happen to the results of the study?**

The results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact the Patient Advice and Liaison Service on freephone 0800 587 4132 or via email at [pals@norfolk.nhs.net](mailto:pals@norfolk.nhs.net). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

**Thank you for taking the time to read this information sheet.**

**You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413. Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



## UEA LETTER-HEADED PAPER

{DATE}

{Pharmacist address at NHS Norfolk}

Dear {Pharmacist},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the development phase of the above research study because you were involved in the main study. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Participant Information Leaflet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Participant Information Leaflet", you decide that you would like to take part, please read and sign the enclosed "Pharmacist Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996) or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by email at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA  
On behalf of research team at UEA



# Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care:

## Review Phase

### Invitation for a Patient to Join a Focus Group

### Participant Information Leaflet



Patient  
Trial  
Information  
V3  
14.6.11

**Contact details:**

Rick Adams research pharmacist (NHS Norfolk / University of East Anglia)

☎: 01603 591996

Email: [rcharl.adams@uea.ac.uk](mailto:rcharl.adams@uea.ac.uk)

David Wright professor in Pharmacy Practice (University of East Anglia)

☎: 01603 592042

Email: [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk)

## Annex 4.2

You are invited to take part in a focus group. We want to make sure that you understand the study before you agree to take part so please read this leaflet; it provides answers to some of the questions that you may have about the study.

### **What is the purpose of the study?**

The purpose of this part of the study is to find out your opinions on the student project in which you were involved. We would like to know what went well and what could be improved if we were to repeat the process.

### **Why have I been invited?**

You have been chosen because you took part in the study previously.

### **Do I have to take part?**

No. It is entirely up to you whether you decide to take part or not. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive in any way.

### **What happens to me if I agree to take part in this study?**

You will be invited to a meeting room at a local hotel to attend a focus group. There will be approximately six to eight people in this group plus two researchers. In the unlikely event of too many people offering to take part we will randomly select eight and inform you of the outcome. A researcher will ask the group questions to do with the trial. These could be anything from the way in which you were asked to join the study and layout and design of questionnaires to the service and information that we hope to provide via the final year pharmacy students.

### **What are the possible risks and disadvantages of taking part?**

We do not anticipate any disadvantages to you participating in this focus group, apart from the time taken to complete the discussion. We will pay your travel expenses so that it will not cost you any money.

### **Will I benefit from participation in this study?**

You will not benefit directly, although your participation will help to make sure that if future students undertake such roles the experience is maximised for patients and students.

### **How much time will I need to spend on the study?**

The focus group will take approximately one hour.

### **Confidentiality: Will the information be kept confidential?**

The focus group discussion will be tape-recorded and listened to by the research team at the UEA. The research team will maintain confidentiality when referring to the findings of the focus group. Any data that can identify you will **not** be published and nobody outside the research team will be able to access any information you give us. Audio recordings will be stored in a secure location at the UEA and destroyed no later than two years after the completion of the study.

### **What if there is a problem?**

In the unlikely event of a problem occurring, indemnity (a form of insurance cover) will be provided by NHS Norfolk.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by Cambridgeshire 3 Research Ethics Committee.

**What will happen to the results of the study?**

The results may be published in scientific journals or presented at meetings. If you wish, a summary of the study results will be sent to you after the research has been completed.

**How to comment or complain:**

If you wish to complain or have any concerns about any aspect of this research then please contact the Patient Advice and Liaison Service on free phone 0800 587 4132 or via email at [pals@norfolk.nhs.net](mailto:pals@norfolk.nhs.net). Alternatively, the usual National Health Service complaints mechanisms are available (NHS Complaints Team 01603 257093 or 257017).

**Thank you for taking the time to read this information sheet.  
You are free not to participate and if you decide to take part you may withdraw from the study at any time without reason. Your medical care will not be affected in any way whether you decide to participate in the study or not.**

If you would like any further information about this project, please contact the UEA Medicines Management Team on 01603 593413.  
Alternatively, you can obtain independent advice from the Patient Advice and Liaison Service on freephone 0800 587 4132.



NHS Norfolk  
Lakeside 400  
Broadland Business Park  
Thorpe St Andrew  
Norwich  
NR7 0WG  
01603 257125



School of Pharmacy  
University of East Anglia  
Norwich  
NR4 7TJ  
Phone: 01603 593144

## Consent Form

### Focus Group for Patients

### Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care: Review Phase

Researcher: Rick Adams, tel: 01603 591996  
[richard.adams@uea.ac.uk](mailto:richard.adams@uea.ac.uk)

Please initial boxes

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
3. I agree for the focus group to be audio taped.
4. I agree to take part in the above study.

Name (please print)                      Signature                      Date

Address (please print): .....  
.....  
.....  
.....

Please tick the box if you would like to receive details of the results of the study

## UEA LETTER-HEADED PAPER

{DATE}

{Patient address}

Dear {study Patient},

### **Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care**

We are writing to invite you to take part in the review phase of the above research study because you were involved in the main study. Before you decide whether or not to take part in this part of the study which involves attendance at a focus group, we wanted to provide you with information about why the research is being done and what it would involve for you.

Please take time to read the enclosed "Participant Information Sheet" carefully. If you require further information please contact one of us (see below) and we can arrange a meeting and/or send a full protocol.

If, after reading the "Participant Information Sheet", you decide that you would like to take part, please read and sign the enclosed "Patient Consent Form". This should be posted to the research team at the University of East Anglia using the reply-paid envelope provided. The research team will contact you directly after they receive your consent form.

If you have any questions about taking part, please contact Rick Adams from the research team at the University of East Anglia. You can contact him by telephone on 01603 591996 (ext 1996) or by email at [Richard.Adams@uea.ac.uk](mailto:Richard.Adams@uea.ac.uk). Alternatively you can contact Prof David Wright by telephone on 01603 592042 (ext 2042) or by email at [d.j.wright@uea.ac.uk](mailto:d.j.wright@uea.ac.uk).

Thank you for considering taking part in this research.

Yours sincerely,

RA

On behalf of research team at UEA

**Appendix D5 : Ethics Approved Documents – UEA**

Richard Adams  
School of Pharmacy  
UEA  
Norwich Research Park  
NR4 7TJ

Research & Enterprise Services  
West Office (Science Building)  
University of East Anglia  
Norwich Research Park  
Norwich, NR4 7TJ

Telephone: +44 (0) 1603 591574  
Fax: 01603 591550  
Email: [fmh.ethics@uea.ac.uk](mailto:fmh.ethics@uea.ac.uk)

Web: [www.uea.ac.uk/researchandenterprise](http://www.uea.ac.uk/researchandenterprise)

12<sup>th</sup> June 2012

Dear Richard

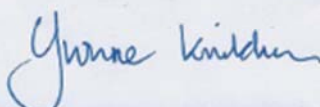
**Supervised Pharmacy Student-led Medication Review of Patients with Diabetes in Primary Care: A pilot study to ascertain the potential costs and benefits. Reference: 2011/2012-44**

The submission of your above proposal has been considered by the Faculty Research Ethics Committee at their meeting on 31<sup>st</sup> May 2012 and we can confirm that your proposal has been approved.

Please could you ensure that any further amendments to either the protocol or documents submitted are notified to us in advance and also that any adverse events which occur during your project are reported to the Committee. Please could you also arrange to send us a report once your project is completed.

The Committee would like to wish you good luck with your project

Yours sincerely



Yvonne Kirkham  
Project Officer



**Faculty of Health  
Researcher Safety Checklist**

**Project Title:** Supervised Pharmacy Student-Led Medication Review of Patients with Diabetes in Primary Care

**Principle Investigator:** Professor David Wright

ACTION	Notes on project-specific arrangements & guidelines	Whose responsibility?	Done?
<b>Organisational</b>			
Take general risk assessment into account when designing project	Only requesting anonymised data after approval of results by the teaching committee, so low risk.	Rick Adams	Yes
Take general risk assessment into account when costing project proposal	Low risk as no additional funding required.	Rick Adams	Yes
Confirm professional indemnity insurance for researchers	The main project is covered by indemnity. This section is low risk.	Rick Adams	Yes
Take researcher's experience / personality / background into account when recruiting	No additional recruiting will be required for this element of the research.	Rick Adams	Yes
Obtain UEA ID, and any honorary contract IDs	In place	Rick Adams	Yes
Teams attends training course on safety issues and management	N/A as only transfer of anonymised data	Rick Adams	Yes
Confirm adequate business-use insurance for researchers' own transport	N/A	Rick Adams	Yes
Clarify circumstances in which home visit is necessary (vs. more neutral environment)	N/A	Rick Adams	Yes
Attend cultural awareness training course	N/A	Rick Adams	Yes
Attend course (or use other means) to raise awareness of risks concerning specific groups (e.g. drug users) and topics (e.g. mental health, poverty, discrimination, social exclusion)	N/A	Rick Adams	Yes
Organise team meeting to agree on general level of risk, systems and responsibilities	Discussed with the Management group for the project.	Rick Adams	Yes



Attend training course on interpersonal behaviour and handling aggression / difficult situations	N/A	Rick Adams	Yes
Attend first-aid training course	N/A	Rick Adams	Yes
Set up incident reporting and debriefing system	N/A	Rick Adams	Yes
Review potential for clash between researcher safety and informant confidentiality	Safety is not an issue. The research design ensures confidentiality as all data will be anonymised by Head of Teaching (PHA) before transfer to the researcher.	Rick Adams	Yes
<b>Operational (Site visit for interview)</b>			
Review informant notes beforehand, to identify potential risk	Not applicable as no home visits		N/A
Phone other health/social workers in contact with informant, for relevant information and suggestions			N/A
Phone informant on the day, to identify potential risk			N/A
Visit site beforehand to assess risk (or make enquiries about the neighbourhood with other colleagues / sources)			N/A
Determine presence of any potentially dangerous animals, and decide what approach to take			N/A
Take minimum valuables			N/A
Note emergency phone number cancelling credit cards etc			N/A
Take mobile phone			N/A
Take personal alarm			N/A
Dress appropriately			N/A
Go with colleague / work in pairs			N/A
If taking laptop, delete personal info on it			N/A
Decide on appropriate transport (car / taxi / bicycle / foot), bearing in mind location of parking place / drop-off point, journey between there and informant's home, time of day arriving and departing			N/A
Set up location-monitoring arrangements (e.g. group whiteboard, pre-arranged pick-up by colleague / taxi, prearranged phone-calls to/from a specific colleague at 'base')			
Agree telephone code-word(s) for danger, and response(s)			N/A

**Signature:**

**Date:**

**UNIVERSITY OF EAST ANGLIA  
FACULTY OF MEDICINE AND HEALTH SCIENCES  
RESEARCH ETHICS COMMITTEE**  
**Application Form for Ethical Approval of a Research Project**

Please refer to the guidelines when completing this form.  
This document should help members of the FMH Ethics Committee understand the objectives of your project/research and the procedures to be conducted.  
It is **ESSENTIAL** that you use non-technical language that can easily be understood by non-specialists and lay members of the Committee, and all applications need to include all relevant documents.  
It is not acceptable to refer the committee to a protocol, and the information on the application, together with the attachments, should be sufficient to allow the Committee to form an opinion.  
Forms may be reviewed by the Chair and will be returned to you if you do not meet these requirements. This will delay approval of your application as applications cannot be accepted after the deadline.

Does the project involve the use of **drugs, or testing of new equipment, or research on NHS patients**? ~~YES~~/NO  
(If YES, it **MUST** be referred to an NHS Research Ethics Committee for approval)

Does the project involve NHS staff or premises? ~~YES~~/NO  
(If YES, it must be referred to the Faculty of Medicine and Health Sciences Research Ethics Committee)

Does the project involve the use of Human Tissue? ~~YES~~/NO  
(If YES, it must be referred to the Faculty of Medicine and Health Sciences Research Ethics Committee)

Is the project a Service Evaluation? ~~YES~~/NO  
(If YES, it must be referred to the Faculty of Medicine and Health Sciences Research Ethics Committee with evidence of acceptance by the relevant NHS Trust)

Is the project an Audit? ~~YES~~/NO  
(If YES, it must be referred to the Faculty of Medicine and Health Sciences Research Ethics Committee with evidence of acceptance by the relevant NHS Trust)

1. Name of applicant: ...RICHARD ADAMS.....  
(Block letters)
2. Academic address for correspondence: School of Pharmacy.....  
...UEA, Norwich Research Park.....  
...Norwich.....Post code: NR4 7TJ
3. Tel No: ...01603 593144..... Fax No: .....
4. E-mail address: ...richard.adams@uea.ac.uk.....
5. School (AHP, MED, NAM): .....PHA.....

6. Status of applicant (Staff, UG or PG student - and year of course): .PG year 2

7. If Student:  
Is this study being carried out to fulfil a required part of your course? Yes/~~No~~  
Part of the research project  
If No:  
Please confirm contact details of supervisor

.....  
Name of supervisor: .....Professor David Wright.....

8. Has this application gone to an Ethics Committee elsewhere? ~~Yes~~/No

If YES, please indicate where and include copies of correspondence:

.....  
Please send 16 copies of the proposal and application form (stapled together in the top left-hand corner) to: Andrea Walker, *Research & Enterprise Office, SCI Building, Room 0.03*, University of East Anglia, Norwich NR4 7TJ; plus an e-mail copy to [fmh.ethics@uea.ac.uk](mailto:fmh.ethics@uea.ac.uk) on or before the deadline shown on the website. (<http://www.uea.ac.uk/foh/research/ethics-committee>).

For any queries telephone: 01603 591566

**Project details** (please could sections 9, 10 and 11 be limited to a maximum of 3000 words.

9. Full title: Supervised Pharmacy Student-led Medication Review of Patients with Diabetes in Primary Care: A pilot study to ascertain the potential costs and benefits
10. Purpose of project: To identify the presence or otherwise of academic dominance in either participating students or non participating students before or after the main study intervention.
11. Methodology, Procedure and Analysis: Data required will be collected by Prof David Wright (as head of teaching on this course) and after anonymisation will be passed to Richard Adams for data analysis.
12. Resources required: None
13. Source of Funding N/A
14. Has this project been peer reviewed? Please could you include details of who the project has been peer reviewed by.  
The main project was peer reviewed and funded by RfPB. This component has not been discussed by the Management Group for this study which includes 4 Professors (PHA, MED and EDU) and 3 Senior Lecturers at the UEA

15. Ethical issues (Please also complete research safety checklist even if no risks are identified)

This is a low risk element of the project. No results will be viewed until after the exam board has ratified results so this data collection can have no influence on students' results. In addition Richard Adams will not know the identity (other than which group they belong to) of the students.

16. Proposed start and finish dates:

Start date: ...June 2012..... Finish date: ...Jan 2014 is final date for completion of the whole research

17. Where will the research be carried out?  
School of Pharmacy, UEA

18. Do you need to survey UEA students or staff outside the Faculty of Medicine and Health Sciences? If so, you need to get approval in principle from the Dean of Students prior to applying to the FMH Ethics Committee. Please attach a copy of approval in principle to this application form.

NO

[https://www.uea.ac.uk/popolpoly\\_fs/1.151266!survey\\_form.pdf](https://www.uea.ac.uk/popolpoly_fs/1.151266!survey_form.pdf)

19. Information sheets and consent forms must be appended (c.f. NRES site for models, [www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk) Please ensure that participants are requested to initial the boxes on the consent forms.

None produced.

20. **Checklist (double click on each box and select 'checked' once done)**

Have you completed all sections of the application in language which will be understood by lay people?

Has your supervisor signed the form?

Have you included your academic address (not your home address)?

Have you numbered all the pages in your protocol/attachments? (If the pages are not numbered the Committee may return your application)

Have you included the following documents, if applicable?

Protocol

Gatekeeper consent  N/A

Consent forms  N/A

Participant information sheets (using NRES format)  N/A

Letters to participants  N/A

Copies of questionnaires  N/A

Copies of correspondence from other ethic committees  N/A

- Copies of all recruitment letters, emails, posters and adverts  N/A
- Research Safety Checklist
- Dean of Student Office approval in principle for survey
- Verbal approval from Annie Grant DoS
- Have you proof-read your application to check for typographical and grammatical errors?
- Have you included a header and footer on each page with your name, date of submission and page number?
- Have you included 16 photocopies? No
- . 10 copies as instructed by the office
- Have you e-mailed a copy to the Research & Enterprise Office?

<b>Supervisory arrangements for STUDENT PROJECTS ONLY</b>	
Degree/Course	.....
School	.....
Academic Supervisor	.....
I have read this application and can confirm that I am taking supervisory responsibility for this project.	
In the case of a student research outside the normal course requirements I confirm that I am happy to take responsibility for the quality of protocol design, the provision of necessary resources, statistical support and usual supervision and governance of the student.	
Project Supervisor's signature	Date
.....	.....
Post Held	.....

# Appendix E: Student Preparative Training

Full Preparative Training Schedule

Workshop Information

Role Play

## Student-led medication reviews for patients with diabetes

### Draft Training Program 2011

#### Section A Clinical knowledge and I.T skills

Date: Summer	Pre-course reading	Duration: 2 hours
<ul style="list-style-type: none"> <li>• To update knowledge of therapeutics for patients with diabetes</li> </ul> <p>Including:</p> <ul style="list-style-type: none"> <li>• Relevant guidelines</li> <li>• Drug regimes</li> <li>• Place in therapy of interventions (drug and non drug)</li> <li>• Side effects</li> <li>• Cardiovascular significance</li> <li>• Patient Decision Aids</li> </ul>		<p>Facilitated by: Paul Grassby</p> <p><i>Self directed</i></p> <p><i>These will continue to be sent during the first weeks of semester 1</i></p>
Date: Mon 3 <sup>rd</sup> and 10 <sup>th</sup> October	Medical Practice I.T. system	Duration: 3 hours
<p>N.B. There will be 4 half day sessions over the 2 days in order that we can have groups of only 10 students to enable better training. Each student will only attend <b>one half day session</b>.</p> <p>At the session you will be issued with a smartcard which will enable you to gain access to patient records at GP Practices. Please keep this safe.</p> <ul style="list-style-type: none"> <li>• Instruction will be given by the trainer from the PCT.</li> <li>• You will then practice to gain competence in the use of the electronic system used to store medical records at GP Practices (access, navigation and data collection)</li> <li>• A 'Dummy' electronic patient record will be provided to enable a realistic practice session.</li> <li>• N.B. a template will be provided to guide data collection. Please bring this with you to the next session when it will be used to create care plans.</li> </ul>		<p>Facilitated by: I.T. Trainer from NHS Norfolk Rick Adams Paul Grassby</p> <p>Location: PCT computer training room (Dereham)</p> <p>Minibus booked- <b>see schedule</b> to see which group you are in. Buses leave from behind Congregation Hall (at back of LCR) 0845 or 1245</p>
Date: Wed 19th October	I.T. care planning package	Duration: 2 hours
<ul style="list-style-type: none"> <li>• Instruction and then practice to gain competence in the use of the care planning template utilising the information collected in the previous session</li> <li>• Produce files detailing medical history, medicine history, demographics, adherence attitudes , and possible drug therapy problems</li> </ul> <p>The care plan produced will be used to practice consultations during the next session</p>		<p>Facilitated by: Paul Grassby Rick Adams</p> <p>Location: ITCS 0.17 1400-1600</p>

## Section B Consultation and feedback skills

Date: <i>Mon 31<sup>st</sup> October</i>	Consultation and feedback	Duration: 2 hours
	<p>This session will be run as a workshop: but prior to the day a podcast giving guidance on how to carry out a good consultation with a patient will be posted on the blackboard site for the trial.</p> <ul style="list-style-type: none"> <li>Paul Grassby and Rick Adams will demonstrate good and bad consultation skills in practice sessions. Followed by group discussion</li> <li>Debi Bhattacharya will discuss Motivational Interviewing with practical examples</li> <li>Students will, in pairs, undertake consultations using the care plan produced during the last session</li> <li>Students will in pairs undertake practice of Motivational Interviewing</li> </ul>	<p>Facilitated by: Paul Grassby Debi Bhattacharya Rick Adams</p> <p>Location: TPSC 1.1 1400 - 1600</p>
Date: <i>Mon 14<sup>th</sup> November</i>	Consultation and feedback practice	Duration: 3 hours
	<ul style="list-style-type: none"> <li>Short scripts detailing information for 2 patients similar to that which you will obtain for patients when you visit GP Practices will be sent to you in advance. We will ask you to use the care plan to decide on issues for discussion.</li> <li>Using the documentation produced above you will each meet 2 patients (professional actors) to undertake a consultation. The actor script will be detailed to allow discussion</li> <li>The sessions will be filmed to allow for reflection. In addition, members of staff (see right) will observe sessions and provide feedback to groups of 6 students to allow identification of issues.</li> <li>The actors will be asked to use a questionnaire to provide feedback to students on performance from the perspective of a patient. This will be confidential to the student but you are welcome to ask for advice from a member of staff.</li> <li>Groups of 6 students will then have 25 mins to discuss the case and agree issues for feedback to a local GP. Working in groups will enable you to share ideas and learn from each other.</li> <li>Feedback to a real GP (time allowed 25mins) will provide experience and feedback prior to you working in GP Practices.</li> <li>Following the session students will be able to post comments on a discussion board (on the blackboard site for the study). In addition individual feedback will be available from Rick Adams (email richard.adams@uea.ac.uk)</li> </ul>	<p>Facilitated by: Rick Adams Paul Grassby Debi Bhattacharya David Wright Local GPs</p> <p>Location : Clinical Trials Unit situated on ground floor of Med School</p> <p>Each student will be allocated a 2hr session</p>

Any student experiencing problems with the course may email Rick Adams (rich



# Patient focussed consultations



## Outline

Activity	Time approx.
○ Presentation: <ul style="list-style-type: none"><li>● Sources of non-adherence</li><li>● Predictors of behaviour</li></ul>	45 mins
Break	15 mins
Reflection and summarising	30 mins
Break	10 mins
Decisional balance and key question	30 mins
Break	10 mins
Self efficacy and outcome expectancy	30 mins
Break	20 minutes
Educational role play	1 hour

### Notes for Students

You will be working in an area where patients are attending the clinical trials unit so please think about your behaviour and any comments that you might make to colleagues.

This exercise will involve you on a one to one basis undertaking a medication review with a 'patient'. It is not an exam, but an opportunity to practice prior to meeting a real patient.

You will be provided with some data, similar to that which you will later use at a GP practice.

Aim to finish in 20 minutes.

Remember that you need to agree an agenda. The word agree is important as it is a two way exercise. You need to find out if there is anything that the patient particularly wants to discuss, but also you need to agree that you have 20mins available. Is that OK with the patient? They will be used to less but a few patients, given the opportunity would like to chat all day. In real life you have other patients waiting.

You need to obtain sufficient information from the patient to complete the care plan, thus allowing you to produce issues for action.

We will expect you to collect the patient from the waiting room, as you might in a GP Practice

Advice given to us by patients about what they like and dislike during medication reviews:

- Engage them in a dialogue.
- Greet your patient, explain what will happen and ensure that they are comfortable.
- Do not appear timid – you need to be confident.
- You need to be competent.
- Do not simply read a list of questions as they find it annoying, eg asking the name, dose, etc of each, one after the other. See if the patient responds to a general open question and then check details.
- It may help to learn what you need to ask as a script so that you appear more confident.
- Entering details on a computer can come between you and the patient. Many excellent doctors conduct the consultation and write up the notes after the patient leaves.
- Do not forget to check issues with open questions.

At the end of the consultation sum up quickly and ask the patient if you have got it right. Then ask if there is anything else that you should have asked or that they want to tell you.

Complete. Thank them. Say goodbye.

At the end of the session you will discuss the issues with other students and then feedback to a GP. This is a real GP so use appropriate language.

Anything that you identify as a problem or issue, feed it back.

If anything is uncertain or the patient is unclear, feed it back.

### **Notes for Patient Actors**

This exercise is aimed at training the students rather than as an exam. Therefore any 'errors' on your part will not 'fail' them.

The script is designed to provide you with answers to questions that you may be asked.

Please try to answer in a natural way. There is no need to be difficult. If the student asks a question and in real life you would give the answer then do so. If, however, you would not normally give all the information without additional questions then wait for them.

At some point a student may ask a question to which the script does not provide the answer. If there is an obvious answer then give it based on your own experience or simply say that you do not know.

If possible, endeavour to carry out the scenario without reading. We want the students to experience a consultation with a 'patient' before they do the same with a real patient.

In a medication review the aim is to identify actual or potential problems for resolution and to additionally ensure that the patient takes their medicines correctly. It also gives the patient an opportunity to ask questions to understand their treatment.

## Notes on Consultation

Much of this is common sense but do not treat this as an interrogation of a patient to obtain information. You are not there to hear the sound of your own voice.

Guidance ( based on the Calgary- Cambridge guide)

- A. Establish an initial rapport
  1. Greet the patient and check their name
  2. Introduce yourself –name, role nature of the interview
  3. Demonstrate respect. And interest. Ensure the patient is comfortable
- B. A GP would need to identify the reason for the consultation but you still need to gather information
  1. Identify problems. Use open questions such as Do you have any problems with your medicine or Do you have any problems with your health lately
  2. Listen to the response. Do not interrupt this opening statement and let them have space to think (do not start talking at the first gap). You want to find out what they think
  3. Confirm the problems and screen for further. You may find a problem that the patient has not told other health care professionals. E.g " so you say that you have a side effect with drug A. Do you have problems with other drugs and if so what is the problem"

#### Instructions for Supervisors

The aim of this session is to give the students a chance to practice their consultation skills and to gain feedback in order improve. It is not an exam.

The students will be given basic details (similar to that which can be taken from the medical records) about their patient in advance. This mirrors the situation when they access real patients' records and then consult the patient later.

The consultation will take place in a consultation room in the clinical trials unit.

The consultations will be filmed and I would like you to control the camera.

Your role is to observe and to evaluate the consultation rather than to intervene.

The student should, when ready, go to the waiting room and collect their patient, bring him/her back to the room and commence. They have 20mins for the consultation.

The actors have been asked to complete an assessment of the student's consultation, using the form which will be used by the real patients. Please collect this form, ensure that the student's name is written on it and retain it. I will then copy these and send one copy to the student for reflection.

I will also ask you to complete an MRCF which I ask you to write the student's name on and retain. Like the form above I will copy it and send a copy to the student for reflection.

When the students have undertaken 2 consultations each we (students & supervisors) will need to assemble in the allocated room for a group feedback. Please be prepared to pass on issues identified during the consultation, both good and bad so that the students can all learn from each others experience.

The students will then have approx 20 mins to discuss together and agree on issues for feedback to the GP.

They will then feedback to the GP for upto 20 mins

#### General note.

You will be given fire instructions on arrival. In the event of a fire please instruct the students where to go.

The other rooms in the unit are being used by the trials unit so real patients will also be in the area. I have informed the students of this as they may need to check their behaviour or comments.

Supervisor Time	Paul Room 3	Sarah Room 4	Debi Room 5
0900-0950	(1) Alice Gombakomba Beverley Watson Scenario A Steven Atkins Scenario C	(2) Amy Cox Steven Atkins Scenario C Beverley Watson Scenario A	(3) Carlene Acolaste Karen Watson Scenario A Burtie Atkins Scenario C
0950-1000	Students 1 - 6 receive 10 mins feedback from supervisors		
1000-1050	(7) Lok Yi Samantha Po Beverley Watson Scenario A Steven Atkins Scenario C	(8) Nicola De-La-Mare Steven Atkins Scenario C Beverley Watson Scenario A	(9) Olivia Kanka Karen Watson Scenario A Burtie Atkins Scenario C
1050-1100	Students 7 - 12 receive 10 mins feedback from supervisors		
1100-1150	(13) Alice Hill Beverley Watson Scenario A Steven Atkins Scenario C	(14) Anthony Hunter Steven Atkins Scenario C Beverley Watson Scenario A	(15) Donna Constantine Karen Watson Scenario A Burtie Atkins Scenario C
1150-1200	Students 13 - 18 receive 10 mins feedback from supervisors		
1200-1250	(19) Mary Jane Aungon Beverley Watson Scenario A Steven Atkins Scenario C	(20) Saagar Gohil Steven Atkins Scenario C Beverley Watson Scenario A	(21) Sidra Awan Karen Watson Scenario A Burtie Atkins Scenario C
1250-1300	Students 19 - 24 receive 10 mins feedback from supervisors		
1300-1330	<b>STAFF LUNCH</b>		
1330-1420	(25) Connie Pringle Beverley Watson Scenario A Steven Atkins Scenario C	(26) Ell Bojungs Steven Atkins Scenario C Beverley Watson Scenario A	(27) Emma Stuart Karen Watson Scenario A Burtie Atkins Scenario C
1420- 1430	Students 25 - 30 receive 10 mins feedback from supervisors		
1430-1520	(31) Jane Thayaparan Beverley Watson Scenario A Steven Atkins Scenario C	(32) Mariam Souza-Ainembabazi Steven Atkins Scenario C Beverley Watson Scenario A	(33) Obed Amoah Karen Watson Scenario A Burtie Atkins Scenario C
1520-1530	Students 31-35 receive 10 mins feedback from supervisors		
1530-1620	(36) Victoria Nelson Beverley Watson Scenario A Steven Atkins Scenario C	(37) Rowena Dudeney Steven Atkins Scenario C Beverley Watson Scenario A	(38) Katie Friend Karen Watson Scenario A Burtie Atkins Scenario C
1620-1630	Students 36-39 receive 10 mins feedback from supervisors		
1630-1730			

Claire Room 6	Jenny Room 7	Dave Room 8
(4) Emma O'Keefe Burtie Atkins Scenario C Karen Watson Scenario A	(5) Hannah Wicks Shereen Watson Scenario A Paul Atkins Scenario C	(6) Jaime Valentim Paul Atkins Scenario C Shereen Watson Scenario A
(10) Sam Tran Burtie Atkins Scenario C Karen Watson Scenario A	(11) Sola Olawore Shereen Watson Scenario A Paul Atkins Scenario C	(12) Thandazani Ncube Paul Atkins Scenario C Shereen Watson Scenario A
(16) Jade Barrett Burtie Atkins Scenario C Karen Watson Scenario A	(17) Holly McDonnell Shereen Watson Scenario A Paul Atkins Scenario C	(18) Stephanie Abdel Kodos Paul Atkins Scenario C Shereen Watson Scenario A
(22) Tasha Moore Burtie Atkins Scenario C Karen Watson Scenario A	23) Angela Businge Shereen Watson Scenario A Paul Atkins Scenario C	(24) Benjamin Leung Paul Atkins Scenario C Shereen Watson Scenario A
(28) Hannah Larter Burtie Atkins Scenario C Karen Watson Scenario A	(29) Helen Bollans Shereen Watson Scenario A Paul Atkins Scenario C	(30) Ivy Ng Paul Atkins Scenario C Shereen Watson Scenario A
(34) Shirley Mills Burtie Atkins Scenario C Karen Watson Scenario A	(35) Jenna Ng Shereen Watson Scenario A Paul Atkins Scenario C	Spare spaces to allow for problems Supervisors might be changed to allow for other commitments
(39) Florine Squirrel Burtie Atkins Scenario C Karen Watson Scenario A	Spare spaces to allow for problems Supervisors might be changed to allow for other commitments	Spare spaces to allow for problems Supervisors might be changed to allow for other commitments

Feedback
Students 1 - 6 30 mins discussion to decide care issues 30 mins feedback to GP (Amanda Howe)
Students 7 - 12 30 mins discussion to decide care issues 30 mins feedback to GP (Amanda Howe or Chris Barclay)
Students 13 - 18 30 mins discussion to decide care issues 30 mins feedback to GP (Chris Barclay)
Whilst actors/supervisors having lunch, students 19 - 24 will be having their 30 mins discussion (in a consultation room). 1330-1400
Students 19 - 24 30 mins feedback to GP (Chris Barclay)
Students 25 - 30 30 mins discussion to decide care issues 30 mins feedback to GP (Chris Barclay)
Students 31 - 35 30 mins discussion to decide care issues 30 mins feedback to GP (Chris Barclay)
Students 36-39 30 mins discussion to decide care issues 30 mins feedback to GP (Chris Barclay)



**Patient A 1**  
**Beverley Watson**  
**23 Brighton Rd**  
**Norwich**  
 NR29 2TU

Age: 59  
 BMI: 32.5  
 Last BP: 150/90  
 Wt 88Kg  
 Ht 5ft 6"

May 2011  
 May 2011

PMH:  
 Chest infection Jan 1997  
 Back pain Aug 2001  
 Constipation Oct 2001  
 Diabetes type 2 Oct 2007  
 Hyperlipidaemia Feb 2009  
 Hypertension Sept 2009

Allergies:  
 Penicillin Jan 2007

Drug history:	Issues	Stop
Amoxicillin 250mg tabs	12 Jan 2007	15 Jan 2007
Clarithromycin 500mg bd	15 Jan 2007	20 Jan 2007
Diclofenac 50mg tabs	20 Aug 2001	15 Sept 2001
Co-dydramol .....	30 Sept 2001	25 Oct 2001
Senna 7.5mg .....	15 Oct 2001 (one issue)	
Metformin 500mg bd	26 Oct 2007	Repeated monthly since
Simvastatin 40mg on	27 Feb 2009	10 May 2009
Pravastatin 40mg on	15 July 2009	Repeated since
Bendroflumethiazide 25mg od	4 Sept 2009	Repeated since
Lercanidipine 10mg od	14 April 2010	Repeated since

Results (recent):  
 HbA1c – 8.75% Oct 2011  
 Renal )  
 Electrolytes ) All Normal  
 LFT )

BP:  
 150/90 1 May 2011  
 160/90 7 Sept 2010  
 170/95 12 Apr 2010  
 160/90 10 Oct 2010  
 180/95 2 Sept 2009

### **Patient A**

#### **Possible issues for feedback:**

Allergy – Penicillin – describe.

Back pain – is it still a problem?

Constipation – was it caused by Co-dydramol? Did it resolve?

Why did Diclofenac stop! – stomach pain?

#### **Adherence:**

Metformin – with food.

Pravastatin

Bendroflumethiazide – do you ever miss out due to excess wine? Misses due to early meetings.

Lercanidipine – before food. Avoid large amounts of Grapefruit juice

Any side effects – give examples.

Counsel – Pravastatin report pain, Bendroflumethiazide, Lercanidipine will not feel benefit but prevents cardiovascular events.

#### **Lifestyle:**

Exercise – recommend extra gentle exercise even taking the stairs at work.

Diet poor. Not five fruit and veg and cannot include potato.

Reduce fat – biscuits, chips, etc. Include fruit and veg. Try to cut out sugary biscuits. Substitute some fruit for biscuits if possible or try taking sandwiches to work. If made at home will save money as well

Bendroflumethiazide – Tell patient-if you cannot take I will talk to doctor about a change if you agree.

Try Paracetamol 2 qds for back pain. If no good see doctor. Tell doctor that back pain still there and what

suggested. Stop the Ibuprofen as it is potentially bad for your stomach and renal

Need to cut alcohol. Depending on glass size and type of wine could be 35-40 units/week. Can cause liver

problems, cardiovascular problems and increase triglycerides (blood fat) and therefore increase cardiovascular risk

Increase Lercanidipine or add ACE: take before food.

Add Simvastatin intolerance to allergy list.

Check Penicillin.

Penicillin – add penicillin allergy details.

### **Patient A 1**

Name: Beverley Watson  
23 Brighton Rd  
Norwich  
NR29 2TU  
01603 409001  
Mobile 07788543876 but you prefer that it is not used as you do not want calls at work

Age: 59 DOB 19<sup>th</sup> May 1952  
Weight: 88kg  
Height 5ft 6". Not sure what that is in Kg

### **Social**

You work as an office manager for a large insurance company. It is a high powered job and stressful.  
You live with your husband in a detached 4 bedroom house in Eaton. It is a nice quiet area where professionals live.  
You have 2 daughters of 25 and 23.

### **If asked about Allergies**

Penicillin gave you a slight rash on your arm.  
Simvastatin gave you muscle pain which lasted about 2 weeks. If asked about the fact that you are on Pravastatin the doctor put you on that as a replacement for the Simvastatin.  
No other allergies (food, dust etc all OK)  
If asked about problems with any medicines or any medicines that you had to stop you had a tablet for your back pain that gave you stomach pains so the doctor stopped it.  
If asked your mobility is fine but you get a bit out of breath when exerting yourself. I will get around to more exercise at some point but I am too busy with work  
You wear glasses to read but can see very well with them.  
Hearing, dexterity, all OK. No swallowing difficulties or problems getting down the medication.  
If asked if you can read alright be offended as you are an office manager  
If asked if you use a compliance aid (medidose, dosette etc) you can remember very well thank you!

Alcohol – you state that you only drink a couple –well maybe 3-glasses of white wine at the pub.  
Also a glass of wine at home each evening. It helps you to relax so it is a good thing. If asked the glass is a large wine glass but you are never drunk – not like those jobs in town at the weekend..  
Have never smoked as it is a filthy habit and you are glad that they banned smoking in buildings. It also helps as your staff do not disappear for a quick smoke.

### **Diet**

You follow the diet that the nurse gave you but when you are very busy at work or at meetings you eat biscuits, chocolate etc. (a few times a week) because there just is not time to get out to the shop for a sandwich! There are meetings and paperwork to finish first

Now that you are on a Statin at least you do not have to worry about the fat in your diet as much and often eat chips, etc. Especially at the pub on Saturday and enjoy eggs, creamy food, etc. This means that you probably do not eat five portions of fruit and veg a day and anyway you feel that is just another thing that the government tell people to do when they should be solving the money crisis. If asked the veg you eat are mainly potatoes, plus peas or carrots. You eat an apple each day (to keep the doctor away). So juice at breakfast, potatoes, peas or carrots and an apple make 4. If asked the juice at breakfast is a small glass of orange or grapefruit. If they tell you not to drink grapefruit ask why.

### **Exercise**

There is just not time to fit in exercise but at the weekend you get a good amount of exercise as you walk via the park to the pub with your husband for lunch (maybe 20 mins each way). When you were younger you used to play tennis in summer and squash in winter. You were quite good at it, but it was mainly a social thing as it was a good club and a good place to meet people for a drink afterwards. You intend to take up golf when there

is time as it is a good place to meet the right people and get exercise. On the other hand you are not sure about your back pain as it will not help the swing.  
If asked you drive to work on the other side of the city. You need your car for meetings

#### Information needs

"Why do I need 2 tablets to cure my high blood pressure"? Can't the doctor find one that does the job properly on its own. I do not like that Bendroflu...methozode (it is really Bendroflumethiazide) as it causes problems with going to the loo too often in the morning

#### Your medical history

##### PMH:

Chest infection Jan 1997 It was a bad winter and everyone had bad chests. You had a bad cough and went to the doctor for antibiotics. He gave you one antibiotic which gave you a rash on your arm but then gave you another one. That with a few days off work made you better. If asked the second antibiotic did not give you any diarrhoea

Back pain Aug 2001 It was your fault. You were gardening and lifted a big pot (containing a bougainvillea) and felt your lower back just go. You put up with it for several weeks taking ibuprofen (not sure of the strength but took it as it said on the label – 2 tablets three times daily) When you went to the doctor he gave you some tablets (Co something but cannot remember the name) but they gave you terrible constipation so after a couple of months you stopped. The back is better than it was but still hurts especially if you try to lift anything. You still have back pain. Not too bad but annoying. Dull ache lower back. No pain in leg. No shooting stabbing electric type pains. Yes you would like help with it but you did not like the constipation or stomach pain caused by the previous tablets.

Constipation Oct 2001 The doctor gave you some tablets which helped. It was embarrassing to have to ask him and it was too uncomfortable

Diabetes type 2 Oct 2007 You went to the doctor in 2007 due to tiredness and thirst. You had noticed a frequent need to pass urine. The nurse tested your urine and they took blood test The doctor started you on Metformin because he said you had diabetes.

Hyperlipidaemia Feb 2009 "You know what it is like when they get you in their grip. They test you for everything and treat things that you did not know you had". You did not feel ill from it

Hypertension Sept 2009 Same as the above

#### Your current medication:

Lercanidipine 10mg each morning.

Bendroflumethiazide 2.5mg each morning.

Pravastatin 40mg each night (you prefer to call it Lipitor).

Metformin 500mg three times daily – if asked you take it when you remember so not always with or after food.

If asked you do not use inhalers, eyedrops etc but use E45 sometimes for dry skin

You can remember all the names and doses.

You take all the tablets as your doctor told you although (if asked) you often miss out the Bendroflumethiazide as it causes problems at work. You cannot afford to keep going to the toilet as you often have early meetings and it can get embarrassing.

You still get the Bendroflumethiazide from the doctor as he tries to help and you do not want to upset him.

Pravastatin the Doctor changed you to that after a gap of 2 months after stopping Simvastatin (due to muscle pain) and you have experienced no problems since.

#### Drugs that you buy

If asked if you buy medicines from a Pharmacy you sometimes buy ibuprofen. If they ask about OTC you do not understand. If asked the ibuprofen is for your back. It does help a bit. You use two tablets sometimes three times daily daily. Not sure of the strength. It does not really relieve it totally.

If asked you do get stomach pain but you put it down to the stress of the job.

You do not believe in herbal or homeopathic preparations. Waste of money

You collect your own prescriptions from the Pharmacy in Sainsbury's off Thunder Lane as it is on your way home

Nobody in your family ever had diabetes

Both parents died in their 70's of old age as far as you know

**General ideas – if asked**

You are a bit pompous.

You are unhappy that you are not as well as you wanted to be but now that you are under the care of the doctor it is his job to keep me well. The tablets should do the job shouldn't they?

"I would like to make sure that I keep well as I have heard that diabetes can cause problems such as bad circulation and you do not want to finish up as a cripple". You can admit that you have put the diabetes to the back of your mind as you do not want it to rule you. Maybe that means that you have not been as good at controlling it with drugs and lifestyle as you should have been.

**Patient C1**

Steven Atkins

Age: 65

BMI: 28

Last BP: 120/60

1 Nov 2011

**PMH:**

Hypertension

May 2000.

Diabetes type 2

Jan 2001

MI (STEM1)

Aug 2003

Chest infection

Apr 2004

Flu-like illness

Oct 2011

**Allergies:**

None known.

**Drug history:**

Bendroflumethiazide 2.5mg od

Start

Stop

May 2000

Aug 2003

Glipizide 5mg om

Jan 2001

Feb 2001

Glipizide 10mg om

Feb 2001

Mar 2002

Gliclazide .....

Mar 2002

Oct 2010

Ramipril 2.5mg om

Aug 2003

Oct 2003

Atenolol 25mg od

Aug 2003

Simvastatin 40mg on

Aug 2003

Aspirin 75mg om

Aug 2003

Clopidogrel 75mg om

Aug 2003

Aug 2004

Ramipril 5mg om

Oct 2003

Aug 2011

Atenolol 50mg od

Jan 2004

Amoxicillin 500mg ...

12 Apr 2004

17 Apr 2004

Metformin 500mg bd

Oct 2010

Oct 2011

Metformin 850mg bd

Oct 2011

Pavacol D linctus prn

2 Nov 2110

Ramipril .10 mg on

Aug 2011

**Results (recent):**

Creatinine

Oct 2011

100micromol/l

Potassium

Oct 2011

4.0 mmol/l

Sodium

Oct 2011

140mmol/l

Urea

Oct 2011

6.0 mmol/l

Total cholesterol

Oct 2011

4.9 mmol/l

HDL

Oct 2011

0.90 mmol/l

LDL

Oct 2011

4.4 mmol/l

HbA1c

Oct 2011

8.0%

### Patient C 1

Name: Steven Atkins  
Age: 65  
DOB 15.3.46  
12 Gladstone Close  
Nelson  
Norwich  
NR40 5XR  
Tel 01603 654987

Weight: 65Kg  
Ht 5ft 7"

#### **Social**

Retired estate agent. Retired after heart attack as it was just too much, That job was good until the recession hit and then it was hard to sell houses so the stress went up.

Live with wife

Live in a bungalow

If asked you have one son who has been in the Army since leaving school. You are proud of him – he has just come back from Afghanistan. Thank goodness and he will be able to leave soon on a pension.

#### **Allergies:**

Do not know of any drug allergies. No drugs stopped due to problems.

You get a bit of a runny nose in summer probably from grass pollen. If asked you buy Zirtek (you do not know the drug name) and take one tablet daily if the problem is bad.

You wear glasses and can see OK.

Your fingers are a bit stiff these days and you can get into the medicines but sometimes it hurts a bit.

Reading Ok

Swallowing not a problem. " I enjoy my food so it is not a problem"

Patient notes:

If asked you take all your tablets as prescribed as you really want to keep well.

You collect your own medicines from Lloyds on Ipswich Road.

You have no problem swallowing or getting your medicines down

**You find it hard to hear these days if someone talks quietly** and also it is really hard to hear a conversation in a noisy room

If the student talks very quietly please ask him/her to speak up. If they do not please ad lib and decide if it is appropriate to feign non comprehension due to not hearing. No hearing aid used

You have heard of the boxes to put tablets in but do not use one. You write down all your medicines to try to remember.

#### **"Smoking, alcohol, diet**

You have smoked 20 cigarettes a day for years. Since school. Have tried to give up several times over the years but it has never worked. Your wife also smokes which makes it harder

If offered help to give up smoking say that you have tried several times. You bought nicotine patches from the Chemist but after a week or two just started again. You have never tried a supported programme at the GP Practice but would give it a try

You like wine and probably share three bottles a week with your wife whilst you watch 'telly'. If asked you drink equal amounts.

Few cups of tea and coffee a day.

Generally good **diet.**" If questioned then think and say maybe about 4 fruit and veg/day. Not much salt. Do not like fatty food so if they tell you to cut out fat ask how they expect you to do so. You eat very little cheese as you do not like it much.

You think that your diet is Ok but to be honest you do not remember what the nurse told you as you were too worried about your general health. If you are convinced that diet will help then you are happy to change, at least a bit. You are worried that the 'better' food might cost a lot as you are retired now.

#### **General ideas on diet and exercise**

Your wife worries about your health and that means that sometimes you do not do things like exercise which might help in case she thinks that you have done too much. If the student explains that you will be healthier if you try some of the things (exercise, diet, taking your medication properly) and your wife will have less need to worry then respond positively.

You are worried about your heart and that is why you do very little exercise as you do not want to stress it too much. You can respond well to advice if the student offers any.

### Medical history

Hypertension May 2000 You had no signs of high blood pressure (query what they mean if they use hypertension) but the doctor said that it was high when I had a routine test. The useless tablet did not stop my heart attack though.

Diabetes type 2 Jan 2001 I did not know about diabetes. The nurse found that I had it at a clinic. It has not been too bad since but over the years the dose has changed and you do not know why they keep changing the drug. Sometimes you have felt quite bad (sugar high) over the years.

Heart attack Aug 2003 The heart attack was a big shock. You had terrible chest pain in Sainsbury's and they called an ambulance. "The hospital were wonderful but they put me on lots of new tablets and then kept changing them." Why so many?

Chest infection Apr 2004 If asked you had a bad chest infection (? a few years ago – not sure of date or year). Everyone had it that winter. Cough, sputum (yellow-green), temperature and just felt awful, but the antibiotics worked.

Flu-like illness Oct 2011 If asked you recently had a bout of what you thought was flu. The doctor advised bed rest and pain killers. It lasted about a week. If asked you had a dry, tickly cough since. You have read about this in the leaflet with Ramipril and are worried that it might be the side effect that. They mention

### Pharmacy

You get all your medicines from Boots on Cambridge Rd. You phone the surgery and they send your repeat prescription to Boots and you collect. They are always so busy that I do not like to ask questions

### Current medicines:

If asked what they for are then information is below

heart: Ramipril 10mg each morning.

Diabetes: Metformin 850mg twice daily. (If asked with breakfast and tea.)

Cough: Pavacol D linctus (If asked you started it recently due to a tickly cough and take 10ml twice daily. It does help. If asked the cough started after the flu)

Heart: Atenolol 50mg at night. (The doctor told you to split the doses of the Ramipril and Atenolol – one morning and one evening.)

Heart: Aspirin 75mg each morning.

Heart (is it blood fat?): Simvastatin 40mg at night.

If asked you do not use inhalers, creams, eyedrops etc

If asked you know that Metformin is for diabetes but not really sure what the others are for. They all started after the heart attack and are obviously something to do with my heart Yes I would like to know what they all do please, if asked. Why do I have so many just for the heart? Why can't I just have one good one to do the job?

If asked about problems you have noticed that :-

you get cold fingers and feet and now that winter is coming it is getting worse again. Could it be one of my tablets?

You have felt a bit lightheaded lately.

You have had stomach pain and 'upset' over the last few weeks. Feeling sick and a bit of a 'runny' tum.

N.B. you will need to judge the way that student asks the question. If you feel that they only ask about a problem or specifically ask about a symptom give them that. If they ask in an open manner and you would normally have given all the information yourself then do so. If they ask a closed question like do you have a pain then just say yes.

You would like to know about your medicines. What are they for and are there any major problems or side effects

You take all your medicines as prescribed as you want to keep as well as you can, but it is a real nuisance taking so many tablets as it feels as if it rules your life

### Drugs bought from the Pharmacy

If the student asks about OTC you do not understand.

If asked you by the occasional bottle of senna tablets

You get a bit of a runny nose in summer probably from grass pollen, so you buy Zirtek (you do not know the drug name) and take one tablet daily if the problem is bad.

If asked about herbal – you buy Valerian tablets from Holland and Barrett as it is supposed to be calming and that is good for your heart

No homeopathic. Where would I buy that anyway?



**Patient C**

**Feedback:**

The lightheadedness is probably low BP but might be sugars! Suggest testing both. If BP low reduce dose of Ramipril and retest in one to two weeks. If sugars high or low consider change to Metformin and retest.

Dry cough – probably due to the flu. Check in two weeks. If still there consider change to Ramipril.

GI upset probably due to higher dose of Metformin. If continues, consider SR. Pain in stomach could be Statin so monitor.

Counsel patient re smoking. Suggest smoking cessation programme to include NRT.

Wine = 30 units/week shared so 15 units/person/week. Okay for men.

Possibly consider having a flu jab this winter.

## **The Calgary Cambridge Consultation Guide**

### **A Initiating the session**

### **B. Gathering information**

### **C. Providing structure**

### **D. Building the relationship**

### **E. Explanation and planning**

### **F. Closing the session**

### **A Initiating the session**

#### *a. Establishing initial rapport*

1. Greet patient and obtain patient's name
2. Introduce self and clarify role
3. Demonstrate interest and respect, attend to patient's physical comfort

#### *b. Identifying the reason(s) for the consultation*

4. Identify the patient's problems or the issues that the patient wishes to address with appropriate opening question (e.g. "What problems brought you to the hospital?" or "What would you like to discuss today?" or "What questions did you hope to get answered today?") Agenda
5. Listen attentively to the patient's opening statement, without interrupting or directing patient's response
6. Confirm list and screens for further problems (e.g. "so that's headaches and tiredness; anything else.....?")
7. Negotiate agenda taking both patient's and pharmacist's needs into account

### **B. Gathering information**

#### *a. Exploration of problems*

8. Encourage patient to tell the story of the problem(s) from when first started to the present in own words (clarifying reason for presenting now)
9. Use open and closed questioning techniques, appropriately moving from open to closed
10. Listening: listen attentively, allowing patient to complete statements without interruption and leaving space for patient to think before answering or go on after pausing
11. Facilitate patient's responses verbally and non verbally e.g. use of encouragement, silence, repetition, paraphrasing, interpretation
12. Pick up verbal and non-verbal cues (body language, speech, facial expression, affect); check out and acknowledges as appropriate
13. Clarify patient's statements that are unclear or need amplification (e.g. "Could you explain what you mean by light headed")

14. Periodically summarise to verify own understanding of what the patient has said; invite patient to correct interpretation or provide further information.
15. Uses concise, easily understood questions and comments, avoid or adequately explain jargon
16. Establish dates and sequence of events

*b. Additional skills for understanding the patient's perspective*

17. Actively determine and appropriately explore:

- patient's ideas (i.e. beliefs re cause)
- patient's concerns (i.e. worries) regarding each problem
- patient's expectations (i.e., goals, what help the patient had expected for each problem)
- effect: how each problem affects the patient's life

18. Encourage patient to express feelings

**C. Providing structure**

*a. Making organisation overt*

19. Summarise at the end of a specific line of inquiry to confirm understanding before moving on to the next section
20. Progress from one section to another using signposting, transitional statements; includes rationale for next section

*b. Attending to flow*

21. Structure interview in logical sequence
22. Attend to timing and keeping interview on task

**D. Building the relationship**

*a. Using appropriate non-verbal behaviour*

23. Demonstrates appropriate non verbal behaviour
  - eye contact, facial expression
  - posture, position & movement
  - vocal cues e.g. rate, volume, tone
24. If read, write notes or use computer, do it in a manner that does not interfere with dialogue or rapport
25. Demonstrate appropriate confidence

*b. Developing rapport*

26. Accept legitimacy of patient's views and feelings; not judgmental
27. Use empathy to communicate understanding and appreciation of the patient's feelings or predicament; overtly acknowledge patient's views and feelings
28. Provide support: express concern, understanding, willingness to help; acknowledge coping efforts and appropriate self care; offer partnership

29. Deals sensitively with embarrassing and disturbing topics and physical pain, including when associated with physical examination

*c. Involving the patient*

30. Shares thinking with patient to encourage patient's involvement (e.g. "What I'm thinking now is....")

31. Explains rationale for questions or parts of physical examination that could appear to be non-sequiturs

32. During physical examination, explains process, asks permission

**Not part of Calgary Cambridge**

**Bring patient back on to track**

**E. Explanation and planning**

*a. Providing the correct amount and type of information*

33. Chunk and check: give information in assimilable chunks; check for understanding, use patient's response as a guide to how to proceed

34. Assess patient's starting point: ask for patient's prior knowledge early on when giving information; discover extent of patient's wish for information

35. Ask patients what other information would be helpful e.g. aetiology, prognosis

36. Give explanation at appropriate times: avoid giving advice, information or reassurance prematurely

*b. Aiding accurate recall and understanding*

37. Organize explanation: divide into discrete sections; develop a logical sequence

38. Use explicit categorization or signposting (e.g. 'There are three important things that I would like to discuss. First ...'; 'Now, shall we move on to ...')

39. Uses repetition and summarizing to reinforce information

40. Language: use concise, easily understood statements; avoid or explains jargon

41. Uses visual methods of conveying information: diagrams, models, written information and instructions

42. Check patient's understanding of information given (or plans made), e.g. by asking patient to restate in own words; clarify as necessary

*c. Achieving a shared understanding: incorporating the patient's perspective*

43. Relate explanations to patient's illness framework: to previously elicited ideas, concerns and expectations

44. Provide opportunities and encourage patient to contribute: to ask questions, seek clarification or express doubts; respond appropriately

45. Pick up verbal and non-verbal cues, e.g. patient's need to contribute information or ask questions; information overload; distress

46. Elicit patient's beliefs, reactions and feelings re information given, terms used; acknowledges and addresses where necessary

*d. Planning: shared decision making*

47. Share own thinking as appropriate: ideas, thought processes, dilemmas

48. Involve patient by making suggestions rather than directives
49. Encourage patient to contribute their thoughts: ideas, suggestions and preferences
50. Negotiate a mutually acceptable plan
51. Offer choices: encourage patient to make choices and decisions to the level that they wish
52. Check with patient: if plans accepted; if concerns have been addressed

## **F. Closing the session**

### *a. Forward planning*

53. Contract with patient re next steps for patient and physician
54. Safety net, explaining possible unexpected outcomes, what to do if plan is not working, when and how to seek help

### *b. Ensuring appropriate point of closure*

55. Summarise session briefly and clarifies plan of care This is a good way of signalling the end
56. Final check that patient agrees and is comfortable with plan and ask if any corrections, questions or other items to discuss
57. Relate procedures to treatment plan: value, purpose
58. Encourage questions about and discussion of potential anxieties or negative outcomes

### *If discussing opinion and significance of problem*

60. Offer opinion of what is going on and names if possible
61. Reveal rationale for opinion
62. Explain causation, seriousness, expected outcome, short and long term consequences
63. Elicit patient's beliefs, reactions, concerns re opinion

### *If negotiating mutual plan of action*

64. Discuss options eg, no action, investigation, medication or surgery, non-drug treatments (physiotherapy, walking aides, fluids, counselling, preventive measures)
65. Provide information on action or treatment offered
  - o name
  - o steps involved, how it works
  - o benefits and advantages
  - o possible side effects
66. Obtain patient's view of need for action, perceived benefits, barriers, motivation
67. Accept patient's views, advocates alternative viewpoint as necessary
68. Elicit patient's reactions and concerns about plans and treatments including acceptability
69. Take patient's lifestyle, beliefs, cultural background and abilities into consideration
70. Encourage patient to be involved in implementing plans, to take responsibility and be self-reliant
71. Ask about patient support systems, discuss other support available

# Appendix F: Intervention Medication Reviews

[Examples of Interventions at Level 2 and Level 3 Medication Reviews](#)

[Full List of Interventions at Level 2 and Level 3 Medication Reviews](#)

<b>Action and Outcome</b>	<b>Example</b>
<b>Allergy status</b> including side-effects. Issue raised by student and confirmed by pharmacist.	No allergy status recorded
Issue raised by student and accepted but with pharmacist input. Side effects due to atenolol?	
Issue raised by pharmacist.	Terbinafine - side effects?
<b>Special needs</b> include insight, dexterity, ability, swallowing etc. Issue raised by student and confirmed by pharmacist.	Check dexterity with opening packaging due to RA.
<b>Compliance aids</b> used or needed. Issue raised by student and confirmed by pharmacist.	Need for compliance aids?
<b>Lifestyle</b> - obtaining information. Issue raised by student and confirmed by pharmacist.	Smoking status queried with pt
<b>Medical history.</b> Issue raised by student and confirmed by pharmacist.	Check if patient still has IBS
Issue raised by student and accepted but with pharmacist input. Check patient's pain control	
<b>Medication history.</b> Issue raised by student and confirmed by pharmacist.	Check amitriptyline indication
Issue raised by student and accepted but with pharmacist input. Check amitriptyline indication.	
Issue raised by student but rejected by pharmacist.	Dose of metformin is too high
<b>Compliance issues.</b> Issue raised by student and confirmed by pharmacist.	Check compliance and inhaler technique
Issue raised by pharmacist.	Aspirin collected but not taken
<b>Over the counter medicines and herbal.</b> Issue raised by student and confirmed by pharmacist.	OTC medication for pain control?
<b>Issues related to the use of a Pharmacy.</b> Issue raised by student and accepted but with pharmacist input. Discuss home delivery of meds	
<b>Monitoring.</b> Issue raised by student and confirmed by pharmacist.	HbA1c gone up?
Issue raised by pharmacist.	Monitor Dronedarone.
<b>Specific patient advice for use a level 3 medication review.</b> Issue raised by student and confirmed by pharmacist.	Offer M/R metformin if still experiencing adverse reaction

Raised by student but rejected by pharmacist. Suggest paracetamol 1g instead of naproxen & lansoprazole

Issue raised by pharmacist. Change test strips to caresens

**Questions to ask at level 3 medication review not stated elsewhere.**

Issue raised by student and confirmed by pharmacist. Still need for loratadine ?

**Educate patient about medicines.**

Issue raised by student and confirmed by pharmacist. Counsel on methotrexate

**Educate patient about disease state or lifestyle.**

Issue raised by student and confirmed by pharmacist. Lifestyle advice

**Other issues.**

Issue raised by student and confirmed by pharmacist. Remove furosemide from repeat template

Issue raised by student and confirmed by pharmacist. Need for PPI - patient is on NSAID

Outlined below are examples of interventions identified by students during level 3 medication reviews. Pharmacist approval code and intervention code are shown. The issues displayed demonstrate a wide range of type.

**Action and Outcome**

**Example**

**Allergy status (including side-effects).**

Issue raised by student and confirmed by pharmacist. Investigate hypo's with gliclazide.

Issue raised by student and confirmed by pharmacist. Drug induced nausea.

**Compliance aids used or needed.**

Issue raised by student and confirmed by pharmacist. Compliance aid discussed and offered to pt.

**Medical History.**

Issue raised by student and confirmed by pharmacist. Feet feel numb and heel problems

Issue raised by student and confirmed by pharmacist. Ankle oedema, pt wants to wear dresses

**Medication History or issues.**

Raised by student but rejected by pharmacist. Investigate the changed dose of gliclazide

Issue raised by pharmacist. Hb is low - suggest iron supplements

Issue raised by student and accepted but with pharmacist input. Tramadol ineffective for pain



**General compliance issues.**

Issue raised by student and confirmed by pharmacist.

Check compliance with pioglitazone.

**Monitoring.**

Issue raised by student and confirmed by pharmacist.

Reason for taking Ferrous fumarate - Monitor ferritin levels

**Specific patient advice for use at level 3 medication review.**

Issue raised by student and confirmed by pharmacist.

Up-titrate perinopril if BP high/not controlled

**Educate patient about medicines.**

Issue raised by student and confirmed by pharmacist.

Educate when to take DM meds

**Educate patient about disease state or lifestyle.**

Issue raised by student and confirmed by pharmacist.

Patient willing to quit smoking-offer smoking cessation programme

**Other issues.**

Issue raised by student and confirmed by pharmacist.

Injection sites: same place every time?

Issue raised by student and confirmed by pharmacist.

Suggest adding bisacodyl to prescription

Issue raised by student and confirmed by pharmacist.

Take other constipation meds off repeat

No.	Patient	Student	Pharmacist assistance code	Med Rev Level	Intervention Code	Details	BNF class
1	1	S1	A	2	4	Lifestyle advice	
2	1	S1	A	2	7	Query ordering error?	2.9
3	1	S1	A	2	11	Suggest starting simvastatin	2.12
4	1	S1	D	2	11	Change test strips to caresens	6.1.6
5	1	S1	A	2	10	Monitor	
6	2	S1	A	2	11	Change test strips to caresens	6.1.6
7	2	S1	A	2	14	Counsel on diet	
8	2	S1	A	2	11	Suggest starting simvastatin	2.12
9	3	S2	A	2	5	Cold extremities	
10	3	S2	A	2	4	Query exercise with the patient	
11	3	S2	A	2	5	Ongoing medical condition status?	
12	3	S2	A	2	7	Check compliance with simvador	2.12
13	3	S2	A	2	7	Check compliance with metformin	6.1.2
14	3	S2	A	2	1	Check for side effects	
15	3	S2	A	2	7	Check compliance with creams	13
16	3	S2	A	2	5	Ongoing medical condition status	11.8.1
17	3	S2	A	2	4	Check smoking cessation status	
18	3	S2	A	2	4	Check alcohol consumption	
19	4	S3	A	2	1	Check drug allergy status	
20	4	S3	A	2	5	Ongoing medical condition status	
21	4	S3	A	2	15	Find out why patient gets hypos	
22	4	S3	A	2	14	Lifestyle advice	
23	4	S3	A	2	7	Check compliance with anti-depressants	4
24	4	S3	A	2	1	Check for side effects	6.1.2
25	4	S3	A	2	11	Suggest strips for self-testing	
26	5	S3	A	2	5	Eye symptoms	
27	5	S3	A	2	7	Check compliance with gliclazide	6.1.2
28	5	S3	A	2	5	Urinary symptoms	

29	5	S3	A	2	7	General compliance	
30	5	S3	A	2	4	Smoking cessation progress	
31	5	S3	A	2	14	General lifestyle advice	
32	5	S3	A	2	1	Side effects of glyclazide	6.1.2
33	5	S3	A	2	1	Side effects of metformin	6.1.2
34	5	S3	A	2	6	Reason for stopping aspirin	2.9
35	6	S2	A	2	1	Drug induced nausea	6.1.2
36	6	S2	A	2	5	Current medical status of eczema	
37	6	S2	A	2	8	OTC used?	
38	6	S2	A	2	10	Suggest blood glucose monitoring when patient's unwell	
39	6	S2	A	2	1	Side effects of medication	
40	6	S2	A	2	7	Compliance with medication	
41	6	S2	A	2	4	Smoking cessation progress	
42	6	S2	A	2	14	Lifestyle advice	
43	7	S4	A	2	4	Diet records missing	
44	7	S4	A	2	4	Physical activity records missing	
45	7	S4	A	2	6	Suggestion to increase metformin dose	6.1.2
46	8	S4	A	2	15	Change metformin formulation	6.1.2
47	8	S4	B	2	7	Check compliance	
48	8	S4	B	2	9	Discuss home delivery of meds	
49	8	S4	D	2	5	Reason for changing metformin	6.1.2
50	8	S4	D	2	4	Hypos may be due to not eating	
51	8	S4	A	2	7	Reason for taking oxybutynin	7.4.2
52	8	S4	D	2	15	Dose adjustment for angina	
53	9	S5	A	2	6	The need for simvastatin?	2.12
54	9	S5	A	2	6	Reason for taking Co-phenotrope	1.4.1
55	9	S5	A	2	15	Metformin dose adjustment to M/R	6.1.2
56	9	S5	A	2	7	Check compliance with aspirin	2.9
57	9	S5	A	2	12	Change to caresens testing strips	6.1.6
58	10	S6	A	2	2	Difficulty swallowing metformin	6.1.2
59	10	S6	A	2	2	Issues due to dysphagia	
60	10	S6	A	2	7	Compliance issues due to dysphagia	
61	10	S6	A	2	5	Possible neuropathy?	6.1.2

62	10	S6	A	2	3	Need for compliance aids?	
63	10	S6	A	2	6	Suggest the need for beta blocker	
64	10	S6	A	2	6	Add PPI to prevent GI s/e from clopidogrel	1.3.5
65	10	S6	A	2	10	Monitor for lactic acidosis	
66	11	S6	A	2	10	Monitor patient's GFR	
67	11	S6	A	2	10	Monitor lithium levels yearly	4.2.3
68	11	S6	A	2	3	Compliance with dosset box	
69	12	S5	B	2	6	Reason for taking ramipril	2.5.5
70	12	S5	A	2	6	Prednisolone dose adjustments	6.3.2
71	12	S5	A	2	9	The need for numerous Lumigan eye drops packs	11.6
72	12	S5	A	2	6	Reason for staying on Simvador	2.12
73	12	S5	A	2	15	Sterilisation/expiry date for lancets	
74	12	S5	A	2	5	Check patient's asthma status	
75	12	S5	A	2	15	Change to caresens testing strips	
76	12	S5	A	2	2	Check dexterity with opening packaging due to RA	6.1.6
77	12	S5	A	2	14	Lifestyle advice	
78	13	S7	A	2	4	Investigate patient's lifestyle	
79	13	S7	A	2	7	Compliance with metformin	6.1.2
80	13	S7	A	2	13	Educate on when to take DM meds	6.1.2
81	13	S7	A	2	1	Side effects due to meds	
82	13	S7	A	2	14	Lifestyle advice and education	
83	13	S7	A	2	6	Simvastatin - increase the dose	2.12
84	13	S7	A	2	7	Side effects due to Furosemide affect compliance	2.2.2
85	14	S7	A	2	4	Smoking status queried with pt	
86	14	S7	A	2	14	Lifestyle advice	
87	14	S7	A	2	1	Low BP perhaps due to high dose of lisinopril or bendroflumethiazide	2.5.5, 2.2.1
88	14	S7	A	2	15	White coat HT possibility	
89	14	S7	A	2	1	Explore side effects with all meds	
90	15	S8	A	2	14	Discuss alcohol intake with pt	
91	15	S8	B	2	5	Investigate the need for naproxen	10.1.1
92	15	S8	A	2	1	Investigate side effects due to atenolol	2.4
93	15	S8	A	2	11	Consider reducing daily dose of levothyroxine	6.2.2
94	15	S8	A	2	14	Discuss benefits of exercise	

95	16	S8	A	2	14	Advise weight loss, discuss lifestyle issues	
96	16	S8	A	2	14	High triglyceride levels	
97	16	S8	A	2	1	Discuss side effects of nifedipine	2.6.2
98	16	S8	A	2	7	Investigate any adherence issues	
99	16	S8	A	2	13	Counsel on how to take slow-k	9.2.2
100	16	S8	A	2	15	Consider adding CKD to medical history records	
101	16	S8	A	2	11	Consider treatment of the nail fungal infection with antifungal	
102	16	S8	A	2	1	Diarrhoea - metformin	6.1.2
103	16	S8	A	2	14	Reinforce the benefits of exercise	
104	17	S9	A	2	13	Review tamsulosin with pt - reason for taking it	7.4.1
105	17	S9	A	2	5	Review tamsulosin with pt - how is it working for them	7.4.1
106	17	S9	B	2	4	Query general lifestyle issues	
107	17	S9	B	2	15	Discuss reason for not liking pulmonary rehab	
108	17	S9	B	2	10	Monitor kidney function	
109	17	S9	D	2	5	Investigate diabetic foot - causing issues?	
110	18	S9	A	2	10	Reason for taking Ferrous fumarate - Monitor ferritin levels	
111	18	S9	A	2	6	Reason for stopping aspirin	2.9
112	18	S9	A	2	4	General lifestyle investigation	
113	18	S9	B	2	15	Investigate pt's gout management	
114	19	S10	A	2	1	Codeine allergy - investigate nature	4.7.2
115	19	S10	A	2	11	Rationale for simvastatin 20mg - possibly needs to be 40mg?	2.12
116	19	S10	A	2	5	High BP 160/94	
117	19	S10	A	2	6	On lercanidipine	2.9.2
118	19	S10	A	2	6	On lisinopril	2.5.5
119	19	S10	A	2	7	Ask about steroid cream use	13.4
120	19	S10	D	2	6	Past TIA, any medication, why not?	
121	20	S10	B	2	15	No CV risk assessment conducted	
122	20	S10	A	2	13	Discuss new metformin dose	6.1.2
123	20	S10	A	2	10	Re-check BP in 6 months	
124	20	S10	A	2	11	Discuss the need in future statin	2.12
125	20	S10	A	2	14	Lifestyle advice	
126	20	S10	A	2	5	General health - check	
127	20	S10	D	2	6	Terbinafine - working?	5.2.5

128	20	S10	D	2	1	Terbinafine - side effects?	5.2.5
129	21	S11	A	2	6	Reason for stopping ventolin	3.1.1
130	21	S11	A	2	1	Update allergies and drug sensitivities record	2.12
131	21	S11	A	2	14	Lifestyle advice and education	3.4.1
132	21	S11	A	2	12	Still need for loratadine ?	2.12
133	22	S11	A	2	6	Investigate atorvastatin - result of stopping statin	2.8.2
134	22	S11	A	2	1	Investigate presence of hypos	
135	23	S12	A	2	13	Warfarin counselling	
136	23	S12	B	2	14	Counsel on diet - diverticular disease	
137	23	S12	A	2	4	Check smoking cessation status	
138	23	S12	A	2	6	Investigate the need for acute meds: Amoxicillin	5.1.1, 6.3.2
139	23	S12	A	2	7	Investigate compliance and adherence	
140	24	S12	A	2	14	Lifestyle advice	
141	25	S13	A	2	1	Investigate nature of reaction to aspirin	2.9
142	25	S13	A	2	4	Investigate lifestyle	
143	25	S13	A	2	5	Check osteoarthritis status	
144	25	S13	A	2	6	Check use of paracetamol	4.7.1
145	25	S13	D	2	10	Dronedrone - needs monitoring	2.3.2
146	25	S13	A	2	15	Frequency of testing strips usage	
147	25	S13	A	2	15	No record of amiodarone - cause thyroid dysfunction	2.3.2
148	26	S13	A	2	15	Patient prescribed testing strips but no lancets	
149	26	S13	A	2	4	Investigate lifestyle	
150	26	S13	A	2	12	Question diagnosis of glaucoma	
151	26	S13	A	2	11	Suggest increasing metformin/gliclazide dose	6.1.2
152	26	S13	A	2	4	Attempt to lower BG by altering diet	
153	26	S13	A	2	6	RSI - indication for paracetamol	4.7.1
154	26	S13	A	2	13	Educate on metformin	6.1.2
155	26	S13	A	2	13	Educate on glaucoma diagnosis	
156	26	S13	A	2	15	Re-using lancets	
157	27	S14	A	2	4	Check alcohol status	
158	27	S14	A	2	14	Counselling: diet (fibre)	
159	27	S14	A	2	6	Check if liquid paraffin is still used, works, any problems	1.6.3
160	27	S14	A	2	6	Check if MgOH is still used, works, any problems	1.6.4

161	27	S14	A	2	6	Reason for using olmesartan medoxonil	2.5.5
162	27	S14	A	2	6	Reason for change from candesartan	2.5.5.2
163	27	S14	A	2	13	Tramadol - can cause constipation	4.7.2
164	27	S14	A	2	11	Suggest paracetamol instead of tramadol	4.7.1
165	27	S14	A	2	12	Ask pt which painkiller works for them	
166	27	S14	A	2	15	Need for PPI - patient is on NSAID	
167	27	S14	A	2	7	HbA1c = 9, check adherence	
168	27	S14	A	2	14	HbA1c = 9, check understanding	
169	28	S15	A	2	7	Compliance	
170	28	S15	A	2	13	Educate on drugs	
171	28	S15	A	2	6	Check if pt is okay on new dose of pioglitazone	6.1.2
172	28	S15	A	2	14	Discuss patient's diet - encourage high fibre	
173	28	S15	A	2	6	Investigate any problems with their medicines	
174	28	S15	A	2	5	Investigate any health issues	
175	28	S15	A	2	14	Lifestyle advice	
176	29	S15	A	2	4	Investigated patient lifestyle	
177	29	S15	A	2	15	Investigate why alfuzosin is on repeats	7.4.1
178	29	S15	A	2	6	Investigate effectiveness of alfuzosin	7.4.1
179	29	S15	A	2	1	Investigate side effects due to alfuzosin	7.4.1
180	29	S15	A	2	15	Insulin levemir regular repeats	6.1.1.2
181	29	S15	A	2	15	Metformin regular repeats	6.1.2
182	29	S15	A	2	15	Perinopril erbutamine regular repeats	2.5.5
183	29	S15	A	2	5	Investigate any health issues	
184	29	S15	A	2	6	No simvastatin	2.12
185	29	S15	A	2	15	Constipation can cause urinary retention when BPH	
186	29	S15	B	2	5	Keratoacanthoma - skin cancer resolved?	
187	29	S15	A	2	7	Investigate compliance	
188	30	S16	A	2	4	Smoking status queried with pt	
189	30	S16	A	2	10	Pulse, BP, age and BMI investigated	
190	30	S16	A	2	1	Investigate side effects with DM meds	
191	30	S16	A	2	1	Investigate side effects with Olmesartan medoximil	2.5.5
192	30	S16	A	2	6	Reason for stopping furosemide	2.2.2
193	30	S16	A	2	5	Ask pain score	

194	30	S16	A	2	11	Suggest change to paracetamol instead of co-codamol	4.7.1
195	30	S16	A	2	1	Co-codamol and tramadol cause constipation	4.7.1, 4.7.2
196	30	S16	A	2	2	Special needs investigated	
197	30	S16	A	2	7	Compliance	
198	30	S16	A	2	4	Lifestyle	
199	30	S16	A	2	5	Laxido - effectiveness	1.6.4
200	31	S16	A	2	1	Investigate hypos with glucogel	
201	31	S16	A	2	7	Check compliance	
202	31	S16	A	2	7	Check compliance and inhaler technique with clenil modulate	3.2
203	31	S16	A	2	6	Investigate if aspirin has been stopped	2.9
204	31	S16	A	2	1	Investigate any side effects with aspirin, suggest PPI if experienced	2.9
205	31	S16	A	2	4	Lifestyle investigated	
206	31	S16	A	2	15	Patient in grief/depressed	
207	31	S16	A	2	5	Any lipodystrophy lipohypertrophy? Reduce insulin	6.1.1
208	31	S16	D	2	7	Aspirin - collected but not taken	2.9
209	31	S16	D	2	7	Keeps collecting salbutamol, never uses it - stock piles	3.1.1
210	32	S17	A	2	1	Investigate nature of sensitivity to metformin	6.1.2
211	32	S17	A	2	5	Investigate severity of leg pain	2.12
212	32	S17	A	2	4	Lifestyle	
213	32	S17	A	2	7	Check compliance	
214	33	S17	A	2	4	Investigate lifestyle	
215	33	S17	A	2	7	Is the patient using his asthma medication?	
216	33	S17	A	2	5	Is PBH well controlled? Does the patient get AF symptoms?	
217	33	S17	A	2	13	Counsel on medication such as warfarin	2.8.2
218	33	S17	A	2	15	Remove furosemide from repeat template	2.2.2
219	33	S17	A	2	6	Investigate effectiveness of paracetamol	
220	33	S17	A	2	10	Patient's HbA1c was in March 2011 - need to query this	
221	34	S18	A	2	6	Check glipizide effectiveness	6.1.2
222	34	S18	A	2	1	Check for hypos due to glipizide	6.1.2
223	34	S18	A	2	6	Query why patient takes amitriptyline	4.3.1
224	34	S18	A	2	6	Query why patient takes aspirin	2.9
225	34	S18	A	2	4	Lifestyle	
226	35	S18	A	2	5	Patient has neuropathy of feet	



227	35	S18	D	2	11	Suggested paracetamol instead of feldene gel for leg pain	4.7.1
228	35	S18	A	2	1	No allergy status recorded	
229	35	S18	A	2	1	Sensitivity to simvastatin not mentioned in allergies and sensitivities	2.12
230	35	S18	A	2	5	Check if patient still has IBS	
231	35	S18	A	2	6	Pain management - do the tablets help?	
232	36	S19	A	2	14	BMI = 30.96, give advice on healthier diet	
233	36	S19	A	2	1	No allergy status	
234	36	S19	A	2	1	Falls/hypos?	
235	36	S19	A	2	11	Atenolol masks hypos, suggest stopping and introduce ACEi instead	2.4
236	36	S19	A	2	6	Question amitriptyline indication	4.3.1
237	36	S19	A	2	5	Depression control?	
238	36	S19	B	2	5	Pain control/score?	
239	36	S19	B	2	8	Check for OTC medication for pain?	
240	36	S19	C	2	11	Suggest paracetamol 1g instead of naproxen & lansoprazole	4.7.1
241	36	S19	B	2	6	Question gabapentin dose	4.8.1
242	37	S19	A	2	1	No allergy status	
243	37	S19	A	2	6	Question indication of atenolol	2.4
244	37	S19	A	2	6	Question frequency of atenolol in the past	2.4
245	37	S19	A	2	5	Check pain control of gout condition	
246	37	S19	A	2	8	Check for OTC medication for pain?	
247	37	S19	B	2	1	Side effects due to atenolol?	2.4
248	37	S19	C	2	6	Dose of metformin is too high	6.1.2
249	37	S19	A	2	7	Check compliance and eyesight	
250	37	S19	B	2	6	Frequency of perinopril?	2.5.5
251	38	S20	A	2	10	Need to re-test the HbA1c	
252	38	S20	A	2	11	May titrate metformin to maximum later on	6.1.2
253	38	S20	A	2	1	No allergy status for drugs	
254	38	S20	A	2	7	Check compliance and inhaler technique	
255	38	S20	A	2	5	Check if asthma is controlled, if not: step up the guidance ladder	
256	38	S20	A	2	1	Check for side effects due to perinopril	2.5.5
257	38	S20	A	2	5	Check if patient still has IBS	
258	38	S20	A	2	8	Check if patient takes OTC medication	
259	38	S20	A	2	2	Investigate if patient has swallowing difficulties?	

260	38	S20	A	2	14	Lifestyle advice	
261	39	S20	A	2	10	HbA1c gone up?	
262	39	S20	A	2	4	Diet changed?	
263	39	S20	A	2	6	Medication for oosteoarthritis?	
264	39	S20	A	2	8	OTC medication for pain control?	
265	39	S20	A	2	4	Limiting exercise/mobility issues?	
266	39	S20	A	2	5	Examine the foot pain	
267	39	S20	A	2	7	Check compliance	
268	39	S20	A	2	14	Diet advice	
269	39	S20	A	2	11	Up-titrate perinopril if BP high/not controlled	
270	40	S21	B	2	5	Check patient's pain control	
271	40	S21	A	2	15	Patient needs a diabetes and hypertension review	4.3.1
272	40	S21	B	2	6	Question the indication of amitriptyline	1.3.5
273	40	S21	D	2	11	Suggest reducing dose of lansoprazole if GORD controlled	2.5.5
274	40	S21	D	2	11	Suggest adding ACEi (ramipril) for BP	
275	40	S21	A	2	4	Investigate lifestyle	
276	40	S21	D	2	6	Avandamet daily dose too high. Should it still be used?	6.1.2
277	41	S22	A	2	6	No evidence for clopidogrel for primary prevention in type 2 diabetes	2.9
278	41	S22	A	2	6	Investigate why tadalafil was stopped	7.4.5
279	41	S22	A	2	15	Discuss metformin dosing with patient	6.1.2
280	41	S22	A	2	1	Check for side effects due to DM medication that affect compliance	6.1.2
281	41	S22	A	2	4	Lifestyle advice	
282	42	S22	A	2	5	Check pain control/score	
283	42	S22	A	2	6	Reason for taking warfarin	2.8.2
284	42	S22	A	2	6	Check amitriptyline indication	4.3.1
285	42	S22	A	2	6	Investigate the reason for stopping simvastatin	2.12
286	42	S22	A	2	1	Check for side effects due to simvastatin	2.12
287	42	S22	A	2	13	Educate/explain benefits of taking statins	2.12
288	42	S22	A	2	15	Atrial fibrillation management-surgery or medication?	6.1.2
289	42	S22	A	2	1	Check for side effects due to metformin	
290	42	S22	A	2	14	Lifestyle advice	
291	43	S22	A	2	13	Counsel on folic acid	9.1.3
292	43	S23	A	2	13	Counsel on methotrexate	10.1.3

293	43	S23	A	2	5	Check pain relief/score	
294	43	S23	A	2	5	Check how well asthma is controlled	
295	43	S23	A	2	7	Question how often Mepradec is being taken	1.3.5
296	43	S23	A	2	6	Find out why Mepradec is not on regular prescriptions	1.3.5
297	43	S23	A	2	15	Why now only 2 packs of salazopyrin instead of 4 packs	1.5.1
298	43	S23	A	2	6	Check effectiveness of diprobase for eczema	13.2.1
299	43	S23	A	2	6	Is paracetamol needed for background pain relief?	4.7.1
300	43	S23	A	2	4	Check alcohol intake	
301	43	S23	A	2	15	Counsel on rotating patch site	
302	44	S23	A	2	1	Check drug allergy status, inc. to ACE?	2.5.5.1
303	44	S23	A	2	15	How many test strips are you using	
304	44	S23	A	2	5	Last flare up of gout?	
305	44	S23	A	2	8	OTC medication for gout?	
306	44	S23	A	2	15	Patient's wellbeing after metformin dose titrated up	6.2.1
307	44	S23	A	2	6	Effectiveness of clobetasol for itchy scalp	13.4
308	45	S24	A	2	15	Remove unnecessary type of testing strips off repeat	
309	45	S24	A	2	6	Gliclazide dose	6.2.1
310	45	S24	A	2	11	Re-start atorvastatin	2.12
311	45	S24	A	2	15	Any current treatment for psoriasis	
312	45	S24	A	2	7	General compliance counselling	
313	45	S24	A	2	14	Lifestyle advice	
314	46	S24	A	2	5	Pain relief	
315	46	S24	A	2	1	Check for constipation caused by codeine	4.7.2
316	46	S24	A	2	6	Pregabalin - two strengths on repeat	4.8.1
317	46	S24	A	2	7	To improve compliance, suggest pregabalin BD not TDS	4.8.1
318	46	S24	A	2	6	Aqueous cream - effectiveness and how often is it used	13.2.1
319	46	S24	A	2	6	Ramipril dose is low	2.5.5
320	46	S24	A	2	13	Warfarin counselling	2.8.2
321	46	S24	A	2	7	General compliance counselling	
322	46	S24	A	2	14	Lifestyle counselling	
323	47	S25	A	2	6	Pain control with diclofenac?	10.1.1
324	47	S25	A	2	15	Is diclofenac the best choice due to side effects?	10.1.1
325	47	S25	A	2	5	Investigate pain scale	

326	47	S25	A	2	15	Investigate medication patient tried for pain/if it worked	
327	47	S25	A	2	10	Follow up on kidney damage	
328	47	S25	A	2	5	Check diabetes management	
329	47	S25	A	2	4	Lifestyle issues	
330	48	S26	A	2	4	Investigate patient's diet - lacking iron?	2.9
331	48	S26	A	2	6	Is aspirin for secondary prevention still necessary?	7.4.1
332	48	S26	A	2	6	Is paracetamol needed for pain relief	1.6.4
333	48	S26	A	2	6	laxido for constipation - is it working?	10.1.3
334	48	S26	A	2	13	Methotrexate - counselling	
335	48	S26	A	2	6	Omeprazole - correct dose?	
336	48	S26	A	2	15	Test strips - where are they from?	
337	49	S26	A	2	1	Allergic rash - put on front page?	
338	49	S26	A	2	1	Query antibiotic allergies	
339	49	S26	A	2	5	Ask patient about eczema	
340	49	S26	A	2	7	Ask about use of eczema creams, how regularly	
341	49	S26	A	2	15	How is patient getting on with Ketostrips?	6.1.6
342	49	S26	A	2	8	OTC painkillers for pain?	
343	49	S26	A	2	6	Appropriateness of ACEi and spirinolactone in moderate renal failure	2.5.5.1
344	49	S26	A	2	15	Swap statin to simvastatin as cheaper	2.12
345	50	S27	A	2	15	Sildenafil is missing SLS	7.4.5
346	50	S27	A	2	6	The need for sildenafil?	7.4.5
347	50	S27	A	2	15	Educate on using sharps bin and needles appropriately	
348	50	S27	A	2	15	Check expiry dates of medicines for patient's hypos	
349	50	S27	A	2	6	Investigate reason for stopping metformin	
350	50	S27	A	2	10	Needs blood tests done	6.1.2
351	50	S27	A	2	6	Is the pain controlled with Co-codamol	4.7.1
352	50	S27	A	2	11	Suggest NSAID/paracetamol for pain instead of co-codamol if stoppec	4.7.1
353	50	S27	A	2	1	Check for side effects	
354	50	S27	A	2	7	Check for compliance	
355	50	S27	A	2	13	Educate on when to take perinopril	2.5.5
356	51	S26	A	2	6	Check indication of lansoprazole	1.3.5
357	51	S26	A	2	10	How regularly is she testing her blood glucose at home?	
358	51	S26	A	2	7	Investigate compliance issues	

359	51	S26	A	2	4	Investigate lifestyle	
360	52	S28	A	2	6	Quinine bisulphate appropriateness	5.4.1
361	52	S28	A	2	6	Question co-dydramol indication	4.7.1
362	52	S28	A	2	7	Question how much co-dydramol patient is taking	4.7.1
363	52	S28	A	2	5	Check effectiveness of co-dydramol for pain relief	4.7.1
364	52	S28	A	2	1	Check for side effects with co-dydramol	4.7.1
365	52	S28	A	2	6	Diclofenac - does the patient still take it?	10.1.1
366	52	S28	A	2	6	Is sitagliptin effective for patient's diabetes?	6.1.2
367	52	S28	A	2	15	Last time patient had a flu jab?	14.4
368	53	S29	A	2	7	Investigate any compliance issues?	
369	53	S29	A	2	2	Does the patient have special needs (sight)?	
370	53	S29	A	2	1	Check for side effects	
371	53	S29	A	2	15	Check for problems injecting insulin	6.1.1
372	53	S29	A	2	14	Lifestyle advice	
373	54	S30	A	2	1	Check allergies. Clarify ramipril allergy details	2.5.5
374	54	S30	A	2	15	Follow up on diabetic neuropathy	
375	54	S30	A	2	4	Check smoking cessation progress	
376	54	S30	A	2	4	Check alcohol consumption, diet	
377	54	S30	A	2	1	Check for side effects	
378	54	S30	A	2	7	Check adherence of current drugs	
379	55	S30	A	2	2	Investigate special needs	
380	55	S30	A	2	4	Investigate lifestyle	
381	55	S30	A	2	10	Ask about glucose testing	
382	55	S30	A	2	15	Check if lancets are used appropriately	
383	55	S30	A	2	6	Locorten on repeat, appropriate?	12.1.1
384	55	S30	A	2	4	Inquire about hypos and sugar consumption	
385	56	S31	A	2	1	No allergy status	
386	56	S31	A	2	6	Review BP medication	
387	56	S31	A	2	1	Check side effects	
388	56	S31	A	2	7	Check compliance with all medication	
389	56	S31	A	2	11	Could possibly reduce la(?) dose	
390	56	S31	A	2	4	Lifestyle	
391	57	S32	A	2	1	No allergy status	

392	57	S32	A	2	5	Check psoriasis status		
393	57	S32	A	2	11	Patient should use emollient, soap substitute	13.2	
394	57	S32	A	2	6	Reason for starting patient on gliclazide and not metformin	6.1.2	
395	57	S32	A	2	1	Check for side effects/hypos due to gliclazide	6.1.2	
396	57	S32	A	2	4	Lifestyle		
397	57	S32	A	2	14	Educate on alcohol intake		
398	57	S32	A	2	7	Check compliance of all medicines		
399	57	S32	A	2	5	Check if ranitidine is working for dysphagia	1.3.2	
400	58	S32	A	2	1	Check allergy status. Clarify metformin allergy	6.1.2	
401	58	S32	A	2	11	Offer M/R metformin if still experiencing adverse reaction	6.1.2	
402	58	S32	A	2	6	Investigate reason for stopping simvastatin	2.12	
403	58	S32	A	2	6	Investigate reason for regular intake of isphagula husk	1.6.2	
404	58	S32	A	2	4	Lifestyle advice: drink plenty of fluids		
405	58	S32	A	2	13	Educate on drugs		
406	58	S32	A	2	14	Educate on alcohol intake		
407	58	S32	A	2	7	Investigate compliance		
408	59	S33	A	2	15	Reason for not collecting statin	2.12	
409	59	S33	A	2	15	Reason for not collecting aspirin	2.9	
410	59	S33	A	2	5	Is patient still getting headaches?		
411	59	S33	A	2	7	Compliance		
412	59	S33	A	2	1	Side effects		
413	59	S33	A	2	6	Review premarin	6.4.1	
414	60	S33	A	2	6	Reason for not having salbutamol inhaler	3.1.1	
415	60	S33	A	2	1	Discuss allergy to statin with patient	2.12	
416	60	S33	A	2	10	Needs a HbA1c check to see if sitagliptin still working	6.1.2	
417	60	S33	A	2	6	Reason for taking co-codamol, (if still taking)	4.7.1	
418	60	S33	A	2	14	Lifestyle advice		
419	61	S16	A	2	6	Reason for stopping metformin	6.1.2	
420	61	S16	A	2	6	Reason for switching from simvastatin to atorvastatin	2.12	
421	61	S16	A	2	5	HbA1c = 8.4		
422	61	S16	A	2	5	GFR under 40: drugs that are renally cleared		
423	61	S16	A	2	4	Lifestyle issues		
424	61	S16	A	2	1	Allergy to penfine		

425	61	A	2	5	Neuropathic pain control	
426	61	A	2	1	Side effects of amitriptyline	4.3.1
427	61	A	2	10	Check chronic kidney disease status	
428	61	A	2	7	Check compliance with all medication	
429	61	A	2	13	Counsel on how to take alendronic acid	6.6.2
430	61	A	2	6	Reason for issuing glucoGel despite high HbA1c	6.1.4
431	61	A	2	15	Novomix insulin pen - can patient use it	6.1.1
432	61	A	2	11	Possibly add metformin to diabetes regime	6.1.2
433	61	A	2	10	Needs testing strips to check glucose levels	
434	62	A	2	4	Check alcohol status	
435	62	A	2	6	Check lansoprazole indication	1.3.5
436	62	A	2	15	Reason for metformin being M/R	6.1.2
437	62	A	2	14	Educate on lifestyle and drugs	
438	62	A	2	7	Compliance	
439	62	A	2	6	Omacor - effectiveness for high cholesterol	2.12
440	62	A	2	8	Check for OTC medication for allergic rhinitis	
441	62	A	2	5	Check osteoarthritis status	
442	63	A	2	5	Is gout still a problem?	
443	63	A	2	7	Compliance on medication	
444	63	A	2	13	Counsel patient	
445	63	A	2	5	High BP, review medication	
446	63	A	2	5	BPH - resolved/symptoms?	
447	63	A	2	12	Reason for not having medication review	
448	63	A	2	14	Counsel on lifestyle	
449	63	A	2	4	Alcohol status	
450	63	A	2	6	Reason for needing to take allopurinol	10.1.4
451	63	A	2	5	Investigate why patient is hypokalemic	
452	64	A	2	7	Investigate if taking metformin all at once	6.1.2
453	64	A	2	7	Investigate how many times patient takes nateglinide	6.1.2
454	64	A	2	6	Reason for taking nateglinide	6.1.2
455	64	A	2	15	Find out how patient manages hypos	6.4.2

No.	Patient	Student	Pharmacist			Intervention	Code	BNF class
			assistance	Med Rev	Level			
1	2	S1	A	3	5	Find out why patient gets hypos		
2	4	S3	A	3	7	Check compliance with pioglitazone	6.1.2	
3	4	S3	A	3	13	Reason for taking simvastatin	2.12	
4	5	S3	A	3	13	Educate on when to take DM meds		
5	6	S3	A	3	1	Drug induced nausea		
6	7	S4	A	3	5	Cold extremities		
7	8	S4	A	3	14	Discussed physical exercise		
8	8	S4	A	3	6	The need for amitriptyline?	4.3.1	
9	10	S6	A	3	6	Adjust metformin dose	6.1.2	
10	10	S6	A	3	14	Patient willing to quit smoking-offer smoking cessation programme		
11	10	S6	A	3	6	Adjust gliclazide dose to reduce s/e	6.1.2	
12	11	S6	A	3	6	Reason for stopping statin		
13	13	S7	A	3	5	Pain management discussed and offered to pt		
14	13	S7	A	3	3	Compliance aid discussed and offered to pt		
15	13	S7	A	3	2	Metformin sticking to throat	6.1.2	
16	18	S9	A	3	6	Reason for stopping aspirin	2.9	
17	18	S9	A	3	15	Pt will ask for temazepam soon	4.1.1	
18	18	S9	A	3	10	Reason for taking Ferrous fumarate - Monitor ferritin levels	9.1.1	
19	18	S9	A	3	5	Ankle oedema, pt wants to wear dresses		
20	23	S12	D	3	6	Investigate the dose of metformin	6.1.2	
21	23	S13	D	3	6	Investigate the changed dose of gliclazide	6.1.2	
22	24	S12	A	3	1	Diarrhoea with increased dose of metformin	6.1.2	
23	24	S12	A	3	15	Patient doesn't use yellow book		
24	25	S13	A	3	1	Night sweats/hypos due to metformin	6.1.2	
25	25	S13	A	3	5	Dystonia in arm - reason for fall		
26	25	S13	A	3	15	Question diagnosis of osteoarthritis		
27	25	S13	A	3	13	Educate on metformin		
28	27	S14	B	3	6	Tramadol ineffective for pain	4.7.2	
29	27	S14	A	3	5	Constipation is an ongoing problem		
30	27	S14	A	3	15	Suggest adding bisacodyl to prescription	1.6.2	



31	27	S14	A	3	15	Take off other constipation meds off repeat	
32	27	S14	A	3	14	Educate on alcohol	
33	39	S20	A	3	11	Up-titrate perinopril if BP high/not controlled	2.5.5
34	39	S20	A	3	1	Metformin may cause diarrhoea	6.1.2
35	39	S20	A	3	15	Suggest change to M/R metformin to reduce s/e and improve complia	6.1.2
36	39	S20	A	3	15	Recommend to take perinopril in the morning	2.5.5
37	39	S20	A	3	15	Injection sites: same place every time?	
38	34	S18	A	3	5	Feet feel numb and heel problems	
39	41	S22	A	3	6	Investigate why tadalafil was stopped	7.4.5
40	42	S22	A	3	6	Investigate why metformin stopped by patient	6.1.2
41	45	S24	A	3	1	Investigate hypos with gliclazide	6.2.1
42	45	S24	A	3	15	Suggested trying a statin again	2.12
43	48	S26	D	3	6	Hb is low - suggest iron supplements	9.1.1
	48	S26	A	3	6	Omeprazole - correct dose?	1.3.5

Intervention Ref. no.	Patient ref. no.	Student ref. no.	Pharmacist assistance code	Level 2 or 3	Intervention class from RH study	Type of Intervention Code	Details	BNF class
1	1	S1	A	2	1	4	Lifestyle advice	
2	1	S1	A	2	9	7	Query ordering error?	2.9
3	1	S1	A	2	4	11	Suggest starting simvastatin	2.12
4	1	S1	D	2	4	11	Change test strips to caresens	6.1.6
5	1	S1	A	2	8	10	Monitor	
6	2	S1	A	2	4	11	Change test strips to caresens	6.1.6
7	2	S1	A	2	11	14	Counsel on diet	
8	2	S1	A	2	4	11	Suggest starting simvastatin	
9	2	S1	A	3	10	5	Find out why patient gets hypos	
10	3	S2	A	2	10	5	Cold extremities	
11	3	S2	A	2	1	4	Query exercise with the patient	
12	3	S2	A	2	10	5	Ongoing medical condition status	
13	3	S2	A	2	2	7	Check compliance with simvador	2.12
14	3	S2	A	2	2	7	Check compliance with metformin	6.1.2
15	3	S2	A	2	7	1	Check for side effects	
16	3	S2	A	2	2	7	Check compliance with creams	
17	3	S2	A	2	10	5	Ongoing medical condition status	
18	3	S2	A	2	10	5	Ongoing medical condition status	11.8.1
19	3	S2	A	2	1	4	Check smoking cessation status	
20	3	S2	A	2	1	4	Check alcohol consumption	
21	4	S3	A	2	12	1	Check drug allergy status	
22	4	S3	A	2	10	5	Ongoing medical condition status	
23	4	S3	A	2	7	1	Find out why patient gets hypos	
24	4	S3	A	2	1	4	Lifestyle advice	
25	4	S3	A	2	2	7	Check compliance with anti-depressants	
26	4	S3	A	2	7	1	Check for side effects	6.1.2
27	4	S3	A	2	4	11	Suggest strips for self-testing	
28	4	S3	A	3	2	13	Check compliance with pioglitazone	6.1.2
29	4	S3	A	3	11	13	Reason for taking simvastatin	2.12
30	5	S3	A	2	10	5	Eye symptoms	

31	5	S3	A	2	2	7	Check compliance with gliclazide	6.1.2
32	5	S3	A	2	10	5	Urinary symptoms	
33	5	S3	A	2	2	7	General compliance	
34	5	S3	A	2	1	4	Smoking cessation progress	
35	5	S3	A	2	1	4	General lifestyle advice	
36	5	S3	A	2	7	1	Side effects of gliclazide	6.1.2
37	5	S3	A	2	7	1	Side effects of metformin	6.1.2
38	5	S3	A	2	2	7	Reason for stopping aspirin	2.9
39	5	S3	A	3	11	13	Educate on when to take DM meds	
40	6	S2	A	2&3	7	1	Drug induced nausea	6.1.2
41	6	S2	A	2	10	5	Current medical status of eczema	
42	6	S2	A	2	5	8	OTC?	
43	6	S2	A	2	8	10	Suggest blood glucose monitoring when patient's unwell	
44	6	S2	A	2	7	1	Side effects of medication	
45	6	S2	A	2	2	7	Compliance with medication	
46	6	S2	A	2	1	4	Smoking cessation progress	
47	6	S2	A	2	1	4	Lifestyle advice	
48	7	S4	A	2	1	4	Diet records missing	
49	7	S4	A	2	1	4	Physical activity records missing	
50	7	S4	A	2	4	6	Suggestion to increase metformin dose	6.1.2
51	7	S4	A	3	10	5	Cold extremities	
52	8	S4	A	2	12	15	Change metformin formulation	6.1.2
53	8	S4	B	2	2	7	Check compliance	
54	8	S4	B	2	9	9	Discuss home delivery of meds	
55	8	S4	D	2	7	1	Reason for changing metformin	6.1.2
56	8	S4	D	2	1	4	Hypos may be due to not eating	
57	8	S4	A	2	6	6	Reason for taking oxybutynin	7.4.2
58	8	S4	D	2	12	15	Dose adjustment for angina	
59	8	S4	A	3	1	4	Discussed physical exercise	
60	8	S4	A	3	6	6	The need for amitriptylline?	4.3.1
61	9	S5	A	2	6	6	The need for simvastatin?	2.12
62	9	S5	A	2	6	6	Reason for taking Co-phenotrope	1.4.1
63	9	S5	A	2	12	15	Metformin dose adjustment to M/R	6.1.2
64	9	S5	A	2	2	7	Check compliance with aspirin	2.9
65	9	S5	A	2	4	11	Change to caresens testing strips	6.1.6

66	10	S6	A	2	10	2	Difficulty swallowing metformin	6.1.2
67	10	S6	A	2	2	2&3	Compliance issues due to dysphagia	6.1.2
68	10	S6	A	2	10	5	Possible neuropathy?	
69	10	S6	A	2	12	3	Need for compliance aids?	
70	10	S6	A	2	4	6	Suggest the need for beta blocker	
71	10	S6	A	2	4	6	Add PPI to prevent GI s/e from clopidogrel	1.3.5
72	10	S6	A	2	8	10	Monitor for lactic acidosis	
73	10	S6	A	3	4	6	Adjust metformin dose	6.1.2
74	10	S6	A	3	1	4	Patient willing to quit smoking-offer smoking cessation programme	
75	10	S6	A	3	4	6	Adjust gliclazide dose to reduce s/e	6.1.2
76	11	S6	A	2	8	10	Monitor patient's GFR	
77	11	S6	A	2	8	10	Monitor lithium levels yearly	4.2.3
78	11	S6	A	2	2	3	Compliance with dosset box	
79	11	S6	A	3	7	1	Reason for stopping statin	
80	12	S5	B	2	3	6	Reason for taking ramipril	2.5.5
81	12	S5	A	2	3	6	Prednisolone dose adjustments	6.3.2
82	12	S5	A	2	9	9	The need for numerous Lumigan eye drops packs	11.6
83	12	S5	A	2	6	6	Reason for staying on Simvador	2.12
84	12	S5	A	2	12	15	Sterilisation date for lancets	
84	12	S5	A	2	10	5	Check patient's asthma status	
85	12	S5	A	2	4	11	Change to caresens testing strips	
86	12	S5	A	2	12	2	Check dexterity with opening packaging due to RA	6.1.6
87	12	S5	A	2	1	4	Lifestyle advice	
88	13	S7	A	2	1	4	Investigate patient's lifestyle	
89	13	S7	A	2	2	7	Compliance with metformin	6.1.2
90	13	S7	A	2	11	13	Educate on when to take DM meds	6.1.2
91	13	S7	A	2	7	1	Side effects due to meds	
92	13	S7	A	2	1	4	Lifestyle advice and education	
93	13	S7	A	2	4	6	Simvastatin - increase the dose	2.12
94	13	S7	A	2	7	7	Side effects due to Furosemide affect compliance	2.2.2
95	13	S7	A	3	10	5	Pain management discussed and offered to pt	
96	13	S7	A	3	2	3	Compliance aid discussed and offered to pt	
97	13	S7	A	3	12	15	Metformin sticking to throat	6.1.2
98	14	S7	A	2	1	4	Smoking status queried with pt	

99	14	S7	A	2	1	4	Lifestyle advice		2.5.5, 2.2.1
100	14	S7	A	2	7	1	bendroflumethiazide		
101	14	S7	A	2	12	15	White coat HT possibility		
102	14	S7	A	2	7	1	Explore side effects with all meds		
103	15	S8	A	2	1	4	Discuss alcohol intake with pt		
104	15	S8	B	2	10	5	Investigate the need for naproxen		10.1.1
105	15	S8	A	2	7	1	Investigate side effects due to atenolol		2.4
106	15	S8	A	2	4	11	Consider reducing daily dose of levothyroxine		6.2.2
107	15	S8	A	2	7	4	Discuss benefits of exercise		
108	16	S8	A	2	1	4	Advise weight loss, discuss lifestyle issues		
109	16	S8	A	2	1	4	High triglyceride levels		
110	16	S8	A	2	7	1	Discuss side effects of nifedipine		2.6.2
111	16	S8	A	2	12	15	Investigate any adherence issues		
112	16	S8	A	2	11	13	Counsel on how to take slow-k		9.2.2
113	16	S8	A	2	12	15	Consider adding CMD to medical history records		
114	16	S8	A	2	4	11	Consider treatment of the nail fungal infection with antifungal		
115	16	S8	A	2	7	1	Diarrhoea - metformin		6.1.2
116	16	S8	A	2	1	4	Reinforce the benefits of exercise		
117	17	S9	A	2	11	13	Review tamsulosin with pt - reason for taking it		7.4.1
118	17	S9	A	2	10	5	Review tamsulosin with pt - how is it working for them		7.4.1
119	17	S9	B	2	1	4	Query general lifestyle issues		
120	17	S9	B	2	1	4	Discuss reason for not liking pulmonary rehab		
121	17	S9	B	2	8	10	Monitor kidney function		
122	17	S9	D	2	10	5	Investigate diabetic foot - causing issues?		
123	18	S9	A	2&3	8	10	Reason for taking Ferrrous fumarate - Monitor ferritin levels		9.1.1
124	18	S9	A	2&3	6	6	Reason for stopping aspirin		2.9
125	18	S9	A	2	1	4	General lifestyle investigation and advice		
126	18	S9	B	2	12	15	Investigate pt's gout management		
127	18	S9	A	3	10	5	Ankle oedema, pt wants to wear dresses		
128	18	S9	A	3	12	15	Pt will ask for temazepam soon		4.1.1
129	19	S10	A	2	12	1	Codeine allergy - investigate nature		4.7.2
130	19	S10	A	2	4	11	Rationale for simvastatin 20mg - possibly needs to be 40mg?		2.12

131	19	S10	A	2	10	5	High BP 160/94		
132	19	S10	A	2	6	6	On lercanidipine		2.9.2
132	19	S10	A	2	6	6	On lisinopril		2.5.5
133	19	S10	A	2	2	7	Ask about steroid cream use		
134	19	S10	D	2	6	6	Past TIA, any medication, why not?		
135	20	S10	B	2	12	15	No CV risk assessment conducted		
136	20	S10	A	2	11	13	Discuss new metformin dose		6.1.2
137	20	S10	A	2	8	10	Re-check BP in 6 months		
138	20	S10	A	2	4	11	Discuss the need in future ACEi and statin		2.5.5, 2.12
139	20	S10	A	2	1	4	Lifestyle advice		
140	20	S10	A	2	10	5	General health - check		
141	20	S10	D	2	10	5	Terbinafine - working?		5.2.5
142	20	S10	D	2	7	1	Terbinafine - side effects?		5.2.5
143	21	S11	A	2	3	6	Reason for stopping ventolin		3.1.1
144	21	S11	A	2	12	1	Update allergies and drug sensitivities record		2.12
145	21	S11	A	2	1	4	Lifestyle advice and education		
146	21	S11	A	2	12	12	The need for loratadine		3.4.1
147	22	S11	A	2	3	6	Investigate atorvastatin - result of stopping statin		2.12
148	22	S11	A	2	7	1	Investigate presence of hypos		
149	23	S12	A	2	11	13	Warfarin counselling		2.8.2
150	23	S12	B	2	1	4	Counsel on diet - diverticular disease		
151	23	S12	A	2	1	4	Check smoking cessation status		
152	23	S12	A	2	6	6	Investigate the need for acute meds: Amoxicillin and prednisolone		5.1.1, 6.3.2
153	23	S12	A	2	2	7	Investigate compliance and adherence		
154	23	S12	D	3	6	6	Investigate the dose of metformin		6.1.2
155	23	S13	D	3	6	6	Investigate the changed dose of gliclazide		6.1.2
156	24	S12	A	2	1	4	Lifestyle advice		
157	24	S12	A	3	12	15	Patient doesn't use yellow book		
158	24	S12	A	3	7	1	Diarrhoea with increased dose of metformin		6.1.2
159	25	S13	A	2	12	1	Investigate nature of reaction to aspirin		2.9
160	25	S13	A	2	1	4	Investigate lifestyle		
161	25	S13	A	2	10	5	Check osteoarthritis status		
162	25	S13	A	2	6	6	Check use of paracetamol		4.7.1
163	25	S13	D	2	8	10	Dronedarone - needs monitoring		2.3.2

164	25	S13	A	2	12	15	Frequency of testing strips usage	
165	25	S13	A	2	12	15	No record of amiodarone - cause thyroid dysfunction	2.3.2
166	25	S13	A	3	7	1	Night sweats/hypos due to metformin	6.1.2
167	25	S13	A	3	10	5	Dystonia in arm - reason for fall	
168	25	S13	A	3	12	15	Question diagnosis of osteoarthritis	
169	25	S13	A	3	11	13	Educate on metformin	
170	26	S13	A	2	12	15	Patient prescribed testing strips but no lancets	
171	26	S13	A	2	1	4	Investigate lifestyle	
172	26	S13	A	2	12	12	Question diagnosis of glaucoma	
173	26	S13	A	2	4	11	Suggest increasing metformin/gliclazide dose	6.1.2
174	26	S13	A	2	1	4	Attempt to lower BG by altering diet	
175	26	S13	A	2	6	6	RSI - indication for paracetamol	4.7.1
176	26	S13	A	2	11	13	Educate on metformin	6.1.2
177	26	S13	A	2	11	13	Educate on glaucoma diagnosis	
178	26	S13	A	2	12	15	Re-using lancets	
179	27	S14	A	2	1	4	Check alcohol status	
180	27	S14	A	2	1	4	Counselling: diet (fibre)	
181	27	S14	A	2	3	6	Check if liquid paraffin is still used, works, any problems	1.6.3
182	27	S14	A	2	3	6	Check if MgOH is still used, works, any problems	1.6.4
183	27	S14	A	2	6	6	Reason for using olmesartan medoxonil	2.5.5
184	27	S14	A	2	6	6	Reason for change from candesartan	2.5.5.2
185	27	S14	A	2	7	1	Tramadol - can cause constipation	4.7.2
186	27	S14	A	2	4	11	Suggest paracetamol instead of tramadol	4.7.1
187	27	S14	A	2	12	12	Ask pt which painkiller works for them	
188	27	S14	A	2	4	15	Need for PPI - patient is on NSAID	
189	27	S14	A	2	2	7	HbA1c = 9, check adherence	
190	27	S14	A	2	11	14	HbA1c = 9, check understanding	
191	27	S14	B	3	10	5	Tramadol ineffective for pain	4.7.2
192	27	S14	A	3	10	5	Constipation is an ongoing problem	
193	27	S14	A	3	4	15	Suggest adding bisacodyl to prescription	1.6.2
194	27	S14	A	3	12	15	Take off other constipation meds off repeat	
195	27	S14	A	3	11	14	Educate on alcohol	
196	28	S15	A	2	2	7	Compliance	
197	28	S15	A	2	11	13	Educate on drugs	
198	28	S15	A	2	7	1	Check if pt is okay on new dose of pioglitazone	6.1.2

199	28	S15	A	2	1	4	Discuss patient's diet - encourage high fibre	
200	28	S15	A	2	12	6	Investigate any problems with their medicines	
200	28	S15	A	2	10	5	Investigate any health issues	
201	28	S15	A	2	1	4	Lifestyle advice	
202	29	S15	A	2	1	4	Investigated patient lifestyle	
203	29	S15	A	2	12	15	Investigate why alfuzosin is on repeats	7.4.1
204	29	S15	A	2	10	5	Investigate effectiveness of alfuzosin	7.4.1
205	29	S15	A	2	7	1	Investigate side effects due to alfuzosin	7.4.1
206	29	S15	A	2	12	15	Insulin levemir regular repeats	6.1.1.2
207	29	S15	A	2	12	15	Metformin regular repeats	6.1.2
208	29	S15	A	2	12	15	Perinopril erbutamine regular repeats	2.5.5
209	29	S15	A	2	10	5	Investigate any health issues	
210	29	S15	A	2	12	15	No simvastatin	2.12
211	29	S15	A	2	12	15	Constipation can cause urinary retention when BPH	
212	29	S15	B	2	10	5	Keratoacanthoma - skin cancer resolved?	
213	29	S15	A	2	2	7	Investigate compliance	
214	30	S16	A	2	1	4	Smoking status queried with pt	
215	30	S16	A	2	1	4	Pulse, BP, age and BMI investigated	
216	30	S16	A	2	7	1	Investigate side effects with DM meds	
217	30	S16	A	2	7	1	Investigate side effects with Olmesartan medoximil	2.5.5
218	30	S16	A	2	6	6	Reason for stopping furosemide	2.2.2
219	30	S16	A	2	10	5	Ask pain score	
220	30	S16	A	2	4	11	Suggest change to paracetamol instead of co-codamol	4.7.1
221	30	S16	A	2	7	1	Co-codamol and tramadol cause constipation	4.7.1, 4.7.2
222	30	S16	A	2	12	2	Special needs investigated	
223	30	S16	A	2	2	7	Compliance	
224	30	S16	A	2	1	4	Lifestyle	
225	30	S16	A	2	10	5	Laxido - effectiveness	1.6.4
226	31	S16	A	2	7	1	Investigate hypos with glucogel	
227	31	S16	A	2	2	7	Check compliance	
228	31	S16	A	2	2	7	Check compliance and inhaler technique with clenil modulate	3.2
229	31	S16	A	2	6	6	Investigate if aspirin has been stopped	2.9
230	31	S16	A	2	7	1	Investigate any side effects with aspirin, suggest PPI if experienced	2.9



231	31	S16	A	2	1	4	Lifestyle investigated	
232	31	S16	A	2	12	15	Patient in grief/depressed	
233	31	S16	A	2	10	5	Any lipodystrophy lipohypertrophy? Reduce insulin	6.1.1
234	31	S16	D	2	2	7	Aspirin - collected but not taken	2.9
235	31	S16	D	2	12	15	Keeps collecting salbutamol, never uses it - stock piles	3.1.1
236	32	S17	A	2	12	1	Investigate nature of sensitivity to metformin	6.1.2
237	32	S17	A	2	7	1	Investigate severity of leg pain	2.12
238	32	S17	A	2	12	15	If patient intolerant to this, add this info to pt's notes	
239	32	S17	A	2	1	4	Lifestyle advice	
240	32	S17	A	2	2	7	Check compliance	
241	33	S17	A	2	1	4	Investigate lifestyle	
242	33	S17	A	2	2	7	Is the patient using his asthma medication?	
243	33	S17	A	2	10	5	Is PBH well controlled? Does the patient get AF symptoms?	
244	33	S17	A	2	11	13	Counsel on medication such as warfarin	2.8.2
245	33	S17	A	2	12	15	Remove furosemide from repeat template	2.2.2
246	33	S17	A	2	10	5	Investigate effectiveness of paracetamol	
247	33	S17	A	2	8	10	Patient's HbA1c was in March 2011 - need to query this	
248	34	S18	A	2	10	5	Check glipizide effectiveness	6.1.2
249	34	S18	A	2	7	1	Check for hypos due to glipizide	6.1.2
250	34	S18	A	2	3	6	Query why patient takes amitriptyline	4.3.1
251	34	S18	A	2	3	6	Query why patient takes aspirin	2.9
252	34	S18	A	2	1	4	Lifestyle	
253	34	S18	A	3	10	5	Feet feel numb and heel problems	
254	35	S18	A	2	10	5	Patient has neuropathy of feet	
255	35	S18	D	2	4	11	Suggested paracetamol instead of feldene gel for leg pain	4.7.1
256	35	S18	A	2	12	1	No allergy status	
257	35	S18	A	2	12	1	Sensitivity to simvastatin not mentioned in allergies and sensitivities	2.12
258	35	S18	A	2	10	5	Check if patient still has IBS	
259	35	S18	A	2	10	5	Pain management - do the tablets help?	
260	36	S19	A	2	1	4	BMI = 30.96, give advice on healthier diet	
261	36	S19	A	2	12	1	No allergy status	
262	36	S19	A	2	7	1	Falls/hypos?	

263	36	\$19	A	2	4	11	Atenolol masks hypos, suggest stopping and introduce ACEi instead	2.4
264	36	\$19	A	2	3	6	Question amitriptyline indication	4.3.1
265	36	\$19	A	2	10	5	Depression control?	
266	36	\$19	B	2	10	5	Pain control/score?	
267	36	\$19	B	2	5	8	Check for OTC medication for pain?	
268	36	\$19	C	2	4	11	Suggest paracetamol 1g instead of naproxen & lansoprazole	4.7.1
269	36	\$19	B	2	3	6	Question gabapentin dose	4.8.1
270	37	\$19	A	2	12	1	No allergy status	
271	37	\$19	A	2	3	6	Question indication of atenolol	2.4
272	37	\$19	A	2	3	6	Question frequency of atenolol in the past	2.4
273	37	\$19	A	2	10	5	Check pain control of gout condition	
274	37	\$19	A	2	5	8	Check for OTC medication for pain?	
275	37	\$19	B	2	7	1	Side effects due to atenolol?	2.4
276	37	\$19	C	2	12	15	Dose of metformin is too high	6.1.2
277	37	\$19	A	2	2	2	Check compliance and eyesight	
278	37	\$19	B	2	3	6	Frequency of perinopril?	2.5.5
279	38	\$20	A	2	8	10	Need to re-test the HbA1c	
280	38	\$20	A	2	4	11	May titrate metformin to maximum later on	6.1.2
281	38	\$20	A	2	12	1	No allergy status for drugs	
282	38	\$20	A	2	2	7	Check compliance and inhaler technique	
283	38	\$20	A	2	10	5	Check if asthma is controlled, if not: step up the guidance ladder	
284	38	\$20	A	2	7	1	Check for side effects due to perinopril	2.5.5
285	38	\$20	A	2	10	5	Check if patient still has IBS	
286	38	\$20	A	2	5	8	Check if patient takes OTC medication	
287	38	\$20	A	2	12	2	Investigate if patient has swallowing difficulties?	
288	38	\$20	A	2	1	4	Lifestyle advice	
289	39	\$20	A	2	8	10	HbA1c gone up?	
290	39	\$20	A	2	1	4	Diet changed?	
291	39	\$20	A	2	3	6	Medication for osteoarthritis?	
292	39	\$20	A	2	5	8	OTC medication for pain control?	
293	39	\$20	A	2	1	4	Limiting exercise/mobility issues	
294	39	\$20	A	2	10	5	Examine the foot pain	

295	39	S20	A	2	2	7	Check compliance	
296	39	S20	A	2	1	4	Diet advice	
297	39	S20	A	2&3	4	11	Up-titrate perinopril if BP high/not controlled	2.5.5
298	39	S20	A	3	7	1	Metformin may cause diarrhoea	6.1.2
299	39	S20	A	3	4	15	Suggest change to M/R metformin to reduce s/e and improve compliance	6.1.2
300	39	S20	A	3	4	15	Recommend to take perinopril in the morning	2.5.5
301	39	S20	A	3	12	15	Injection sites: same place every time?	
302	40	S21	B	2	10	5	Check patient's pain control	
303	40	S21	A	2	8	10	Patient needs a diabetes and hypertension review	
304	40	S21	B	2	3	6	Question the indication of amitriptyline	
305	40	S21	D	2	4	11	Suggest reducing dose of lansoprazole if GORD controlled	
306	40	S21	D	2	4	11	Suggest adding ACEi (ramipril) for BP	2.5.5
307	40	S21	A	2	1	4	Investigate lifestyle	
308	40	S21	D	2	6	6	Avandamet daily dose too high	
309	41	S22	A	2	3	6	No evidence for clopidogrel for primary prevention in type 2 diabetes-stop	2.9
310	41	S22	A	2&3	6	6	Investigate why tadalafil was stopped	7.4.5
311	41	S22	A	2	12	15	Discuss metformin dosing with patient	6.1.2
312	41	S22	A	2	7	1	Check for side effects due to DM medication that affect compliance	6.1.2
313	41	S22	A	2	1	4	Lifestyle advice	
314	42	S22	A	2	10	5	Check pain control/score	
315	42	S22	A	2	6	6	Reason for taking warfarin	2.8.2
316	42	S22	A	2	3	6	Check amitriptyline indication	4.3.1
317	42	S22	A	2	3	6	Investigate the reason for stopping simvastatin	2.12
318	42	S22	A	2	7	1	Check for side effects due to simvastatin	2.12
319	42	S22	A	2	11	13	Educate/explain benefits of taking statins	2.12
320	42	S22	A	2	12	15	Atrial fibrillation management-surgery or medication?	
321	42	S22	A	2	7	1	Check for side effects due to metformin	6.1.2
322	42	S22	A	2	1	4	Lifestyle advice	
323	42	S22	A	3	3	6	Investigate why metformin stopped by patient	6.1.2
324	43	S23	A	2	11	13	Counsel on methotrexate and folic acid	10.1.3, 9.1.3
325	43	S23	A	2	10	5	Check pain relief/score	
326	43	S23	A	2	10	5	Check how well asthma is controlled	

327	43	S23	A	2	5	8	Question how often Mepradec is being taken	1.3.5
328	43	S23	A	2	3	6	Find out why Mepradec is not on regular prescriptions	1.3.5
329	43	S23	A	2	9	15	Why now only 2 packs of salazopyrin instead of 4 packs	1.5.1
330	43	S23	A	2	10	5	Check effectiveness of diprobase for eczema	13.2.1
331	43	S23	A	2	6	6	Is paracetamol needed for background pain relief?	4.7.1
332	43	S23	A	2	1	4	Check alcohol intake	
333	43	S23	A	2	11	13	Counsel on rotating patch site	
334	44	S23	A	2	12	1	Check drug allergy status, inc. to ACE?	
335	44	S23	A	2	12	15	How many test strips are you using	
336	44	S23	A	2	10	5	Last flare up of gout?	
337	44	S23	A	2	5	8	OTC medication for gout?	
338	44	S23	A	2	7	1	Patient's wellbeing after metformin dose titrated up	6.2.1
339	44	S23	A	2	10	5	Effectiveness of clobetasol for itchy scalp	13.4
340	45	S24	A	2	12	6	Remove unnecessary type of testing strips off repeat	
341	45	S24	A	2	3	6	Gliclazide dose	6.2.1
342	45	S24	A	2	4	11	Re-start atorvastatin	2.12
343	45	S24	A	2	12	15	Any current treatment for psoriasis	
344	45	S24	A	2	11	13	General compliance counselling	
345	45	S24	A	2	1	4	Lifestyle advice	
346	45	S24	A	3	7	1	Investigate hypos with gliclazide	6.2.1
347	45	S24	A	3	4	15	Suggested trying a statin again	
348	46	S24	A	2	10	5	Pain relief	
349	46	S24	A	2	7	1	Check for constipation caused by codeine	4.7.2
350	46	S24	A	2	3	6	Pregabalin - two strengths on repeat	4.8.1
351	46	S24	A	2	2	7	To improve compliance, suggest pregabalin BD not TDS	4.8.1
352	46	S24	A	2	3	5	Aqueous cream - effectiveness and how often is it used	13.2.1
353	46	S24	A	2	6	6	Ramipril dose is low	2.5.5
354	46	S24	A	2	11	13	Warfarin counselling	2.8.2
355	46	S24	A	2	11	13	General compliance counselling	
356	46	S24	A	2	1	4	Lifestyle counselling	
357	47	S25	A	2	10	5	Pain control with diclofenac?	10.1.1
358	47	S25	A	2	6	15	Is diclofenac the best choice due to side effects?	10.1.1
359	47	S25	A	2	10	5	Investigate pain scale	
360	47	S25	A	2	12	15	Investigate medication patient tried for pain/if it worked	
361	47	S25	A	2	10	5	Follow up on kidney damage	

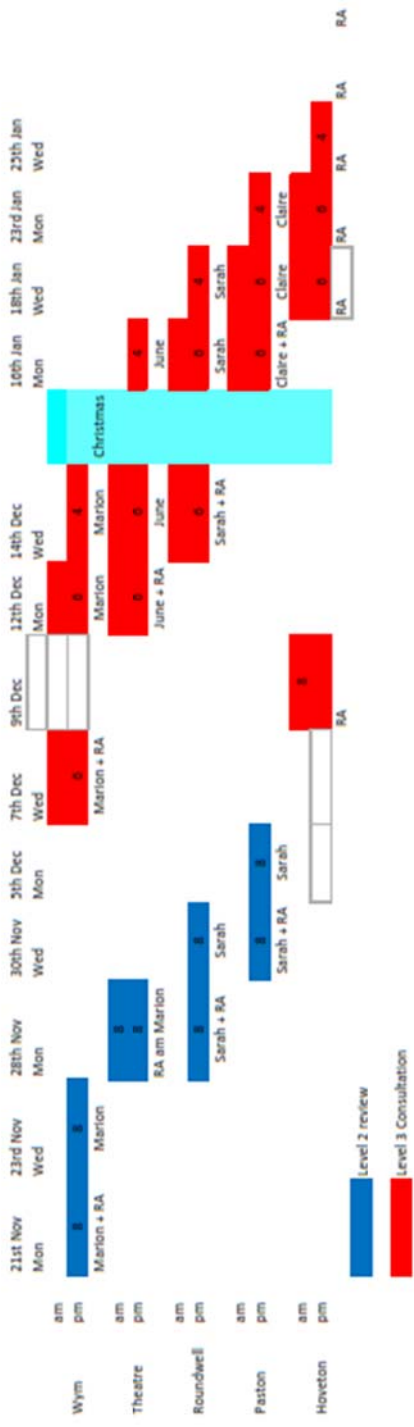
362	47	S25	A	2	10	5	Check diabetes management	
363	47	S25	A	2	1	4	Lifestyle issues	
364	48	S26	A	2	1	4	Investigate patient's diet - lacking iron?	
365	48	S26	A	2	6	6	Is aspirin for secondary prevention still necessary?	2.9
366	48	S26	A	2	6	6	Is paracetamol needed for pain relief	7.4.1
367	48	S26	A	2	10	5	laxido for constipation - is it working?	1.6.4
368	48	S26	A	2	11	13	Methotrexate - counselling	10.1.3
369	48	S26	A	2&3	6	6	Omeprazole - correct dose?	1.3.5
370	48	S26	A	2	12	15	Test strips - where are they from?	
371	48	S26	D	3	4	15	Hb is low - suggest iron supplements	
372	49	S26	A	2	12	6	Allergic rash - put on front page?	
373	49	S26	A	2	12	1	Query antibiotic allergies	
374	49	S26	A	2	10	5	Ask patient about eczema	
375	49	S26	A	2	2	7	Ask about use of eczema creams, how regularly	
376	49	S26	A	2	3	15	How is patient getting on with Ketostrips?	6.1.6
377	49	S26	A	2	5	8	OTC painkillers for pain?	
378	49	S26	A	2	6	6	Appropriateness of ACEI and spironolactone in moderate renal failure	
379	49	S26	A	2	12	15	Swap statin to simvastatin as cheaper	2.12
380	50	S27	A	2	12	15	Sildenafil is missing SLS	7.4.5
381	50	S27	A	2	3	6	The need for sildenafil?	7.4.5
382	50	S27	A	2	11	13	Educate on using sharps bin and needles appropriately	
383	50	S27	A	2	12	15	Check expiry dates of medicines for patient's hypos	
384	50	S27	A	2	3	15	Investigate reason for stopping metformin	6.1.2
385	50	S27	A	2	8	10	Needs blood tests done	
386	50	S27	A	2	10	5	Is the pain controlled with Co-codamol	4.7.1
387	50	S27	A	2	4	11	Suggest NSAID/paracetamol for pain instead of co-codamol if stopped due to s/e	4.7.1
388	50	S27	A	2	7	1	Check for side effects	
389	50	S27	A	2	2	7	Check for compliance	
390	50	S27	A	2	11	13	Educate on when to take perinopril	2.5.5
391	51	S26	A	2	3	6	Check indication of lansoprazole	1.3.5
392	51	S26	A	2	8	10	How regularly is she testing her blood glucose at home?	
393	51	S26	A	2	2	7	Investigate compliance issues	
394	51	S26	A	2	1	4	Investigate lifestyle	

395	52	S28	A	2	6	15	Quinine bisulphate appropriateness	5.4.1
396	52	S28	A	2	3	6	Question co-dydramol indication	4.7.1
397	52	S28	A	2	3	6	Question how much co-dydramol patient is taking	4.7.1
398	52	S28	A	2	10	5	Check effectiveness of co-dydramol for pain relief	4.7.1
399	52	S28	A	2	7	1	Check for side effects with co-dydramol	4.7.1
400	52	S28	A	2	3	6	Diclofenac - does the patient still take it?	10.1.1
401	52	S28	A	2	10	5	Is sitagliptin effective for patient's diabetes?	6.1.2
402	52	S28	A	2	12	15	Last time patient had a flu jab?	
403	53	S29	A	2	2	7	Investigate any compliance issues?	
404	53	S29	A	2	12	2	Does the patient have special needs (sight)?	
405	53	S29	A	2	7	1	Check for side effects	
406	53	S29	A	2	7	1	Check for problems injecting insulin	6.1.1
407	53	S29	A	2	1	4	Lifestyle advice	
408	54	S30	A	2	12	1	Check allergies. Clarify ramipril allergy details	2.5.5
409	54	S30	A	2	12	15	Follow up on diabetic neuropathy	
410	54	S30	A	2	1	4	Check smoking cessation progress	
411	54	S30	A	2	1	4	Check alcohol consumption, diet	
412	54	S30	A	2	7	1	Check for side effects	
413	54	S30	A	2	2	7	Check adherence of current drugs	
414	55	S30	A	2	2	7	Check compliance	
415	55	S30	A	2	12	2	Investigate special needs	
416	55	S30	A	2	1	4	Investigate lifestyle	
417	55	S30	A	2	8	10	Ask about glucose testing	
418	55	S30	A	2	12	15	Check if lancets are used appropriately	
419	55	S30	A	2	6	6	Locorten on repeat, appropriate?	12.1.1
420	55	S30	A	2	7	1	Inquire about hypos and sugar consumption	
421	56	S31	A	2	12	1	No allergy status	
422	56	S31	A	2	6	6	Review BP medication	
423	56	S31	A	2	7	1	Check side effects	
424	56	S31	A	2	2	7	Check compliance with all medication	
425	56	S31	A	2	4	11	Could possibly reduce la(?) dose	
426	56	S31	A	2	1	4	Lifestyle	
427	57	S32	A	2	12	1	No allergy status	
428	57	S32	A	2	10	5	Check psoriasis status	
429	57	S32	A	2	4	11	Patient should use emollient, soap substitute	

430	57	S32	A	2	6	6	Reason for starting patient on gliclazide and not metformin	6.1.2
431	57	S32	A	2	7	1	Check for side effects/hypos due to gliclazide	6.1.2
432	57	S32	A	2	1	4	Lifestyle	
433	57	S32	A	2	11	14	Educate on alcohol intake	
434	57	S32	A	2	2	7	Check compliance of all medicines	
435	57	S32	A	2	10	5	Check if ranitidine is working for dysphagia	1.3.2
436	58	S32	A	2	12	1	Check allergy status. Clarify metformin allergy	6.1.2
437	58	S32	A	2	4	11	Offer M/R metformin if still experiencing adverse reaction	6.1.2
438	58	S32	A	2	3	6	Investigate reason for stopping simvastatin	2.12
439	58	S32	A	2	3	6	Investigate reason for regular intake of isphagula husk	1.6.2
440	58	S32	A	2	1	4	Lifestyle advice: drink plenty of fluids	
441	58	S32	A	2	11	13&14	Educate on drugs and alcohol intake	
442	58	S32	A	2	2	7	Investigate compliance	
443	59	S33	A	2	12	15	Reason for not collecting statin	
444	59	S33	A	2	12	15	Reason for not collecting aspirin	2.9
445	59	S33	A	2	10	5	Is patient still getting headaches?	
446	59	S33	A	2	2	7	Compliance	
447	59	S33	A	2	7	1	Side effects	
448	59	S33	A	2	6	15	Review premarin	6.4.1
449	60	S33	A	2	3	6	Reason for not having salbutamol inhaler	3.1.1
450	60	S33	A	2	12	1	Discuss allergy to statin with patient	
451	60	S33	A	2	8	10	Needs a HbA1c check to see if sitagliptin still working	6.1.2
452	60	S33	A	2	6	6	Reason for taking co-codamol, (if still taking)	4.7.1
453	60	S33	A	2	1	4	Lifestyle advice	
454	61	SS16	A	2	3	6	Reason for stopping metformin	6.1.2
455	61	SS16	A	2	3	6	Reason for switching from simvastatin to atorvastatin	2.12
456	61	SS16	A	2	10	5	HbA1c = 8.4	
547	61	SS16	A	2	10	5	GFR under 40: drugs that are renally cleared	
548	61	SS16	A	2	1	4	Lifestyle issues	
549	61	SS16	A	2	12	1	Allergy to penfene	
550	61	SS16	A	2	10	5	Neuropathic pain control	
551	61	SS16	A	2	7	1	Side-effects of amitriptyline	4.3.1
552	61	SS16	A	2	10	5	Check chronic kidney disease status	

553	61	SS16	A	2	2	7	Check compliance with all medication	
554	61	SS16	A	2	11	13	Counsel on how to take alendronic acid	
555	61	SS16	A	2	6	6	Reason for issuing glucocoid despite high HbA1c	6.1.4
556	61	SS16	A	2	12	15	Novomix insulin pen - can patient use it	6.1.1
557	61	SS16	A	2	4	11	Possibly add metformin to diabetes regime	6.1.2
558	61	SS16	A	2	8	10	Needs testing strips to check glucose levels	
559	62	S14	A	2	1	4	Check alcohol status	
560	62	S14	A	2	3	6	Check lansoprazole indication	1.3.5
561	62	S14	A	2	3	6	Reason for metformin being M/R	6.1.2
562	62	S14	A	2	11	138.14	Educate on lifestyle and drugs	
563	62	S14	A	2	2	7	Compliance	
564	62	S14	A	2	10	5	Omacor - effectiveness for high cholesterol	2.12
565	62	S14	A	2	5	8	Check for OTC medication for allergic rhinitis	
566	62	S14	A	2	10	5	Check osteoarthritis status	
567	63	S16	A	2	10	5	Is gout still a problem?	
568	63	S14	A	2	2	7	Compliance on medication	
569	63	S14	A	2	11	13	Counsel patient	
570	63	S14	A	2	10	5	High BP, review medication	
571	63	S14	A	2	10	5	BPH - resolved/symptoms?	
572	63	S14	A	2	12	12	Reason for not having medication review	
573	63	S14	A	2	11	14	Counsel on lifestyle	
574	63	S14	A	2	1	4	Alcohol status	
575	63	S14	A	2	3	6	Reason for needing to take allopurinol	10.1.4
576	63	S14	A	2	10	5	Investigate why patient is hypokalaemic	
577	64	S35	A	2	3	12	Investigate if taking metformin all at once	6.1.2
578	64	S35	A	2	3	12	Investigate how many times patient takes nateglinide	6.1.2
579	64	S35	A	2	3	6	Reason for taking nateglinide	6.1.2
580	64	S35	A	2	7	1	Find out how patient manages hypos	6.4.2





Version 4 5.9.11

# Appendix G: Tools

NCR Pad for Feedback to Medical Practice

On-line Surveys of Students Post Intervention

Questionnaires – Immediately Post-Consultation

Care Plan

MRCF (For use during role play and Level 3 Medication Review)

OSCE Assessments

### Instructions

**Student:** This form will be returned to the UEA so do not include patient identifiable data other than patient reference number on both copies and the patient's name on the **bottom** copy only. Use each form for ONE patient only, so if more than 5 care issues use an extra form. Please complete the care issues and hand the form to the Pharmacist to check

**Pharmacist:** Please accept the completed form from the student; ensure that the patient's reference number is stated on the form and that their name is on the bottom copy only. Check care issues, make corrections if necessary and record the intervention code (see below)

- A Raised by the student & confirmed by the Pharmacist      B Raised by student. Accepted but with Pharmacist input  
C Raised by the student rejected by the pharmacist      D Not raised by the student, but raised by the pharmacist

**GP or Specialist Nurse:** Please take the verbal care issue feedback from the student, give them your opinion and record on this form if you accept or reject each issue as well as brief reasons.

Top copy returned to Rick Adams by the Pharmacist. Bottom copy to GP or Specialist Nurse

Patient reference no.:		Patient's name (on bottom copy ONLY):			Write only with a ball point pen. Use card between pairs of sheets.	
Date	Care Issue	Student signature	Intervention by Pharmacist State intervention code. Please add basic details and sign	G.P. or Specialist Nurse State Acceptance/Rejection of issues. Please add basic details and sign		

Evaluation of training programme - consultation skills

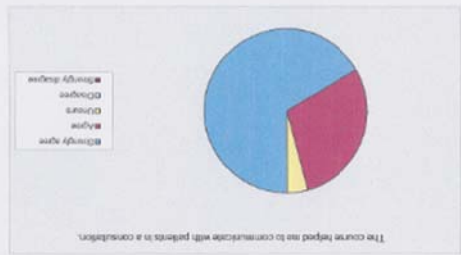
Skill one

Response Count	Answer Options
17	answered question
7	skipped question

Evaluation of training programme - consultation skills research study

The course helped me to communicate with patients in a consultation.

Response Count	Answer Options
16	Strongly agree
7	Agree
1	Disagree
0	Strongly disagree
0	skipped question
0	answered question



Evaluation of training programme - consultation skills  
research study

Skill two

Response Count	Answer Options
14	answered question
10	skipped question

Evaluation of training programme - consultation skills  
research study

Skill three

Response Count	Answer Options
7	answered question
17	skipped question

Evaluation of training programme - consultation skills  
 research study  
 What has been the most rewarding or useful aspect of your experience?

Answer Options	Response Count
answered question	17
skipped question	7

Evaluation of training programme - consultation skills  
 research study  
 What has been the least rewarding or useful aspect of your experience?

Answer Options	Response Count
answered question	14
skipped question	10

Evaluation of training programme - consultation skills  
 research study  
 Looking back to the first day of your programme experience, how do you  
 remember feeling?

Response	Count
	17
answered question	
17	
skipped question	
7	

Evaluation of training programme - consultation skills  
 research study  
 Compared to the first day of your programme experience, how differently  
 do you feel today? (What has changed, if anything?)

Response	Count
	17
answered question	
17	
skipped question	
7	



Evaluation of training programme - consultation skills

research study

Please state why you answered Yes or No to the last question

Response	Count
Answered question	16
skipped question	8

Evaluation of training programme - consultation skills research study

Would you recommend the programme to another student?

Answer Options	Response Count	Percent
YES	17	100.0%
NO	0	0.0%



Evaluation of training programme - consultation skills

research study

If we repeated the programme either as part of the course or as another research project what would you want changed? You can put more than

Answer Options	Response Count
answered question	15
skipped question	9

Evaluation of training programme - consultation skills

research study

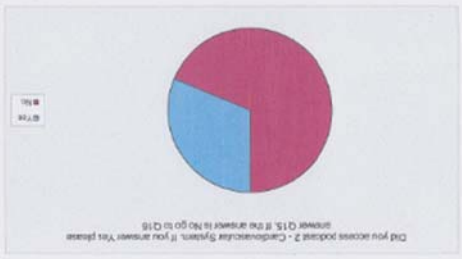
If we repeated the programme either as part of the course or as another research project what would you want changed? You can put more than

Answer Options	Response Count
answered question	15
skipped question	9

Evaluation of training programme - consultation skills research study

Did you access podcast 2 - Cardiovascular System. If you answer 'Yes please answer Q15. If the answer is No go to Q16

Response	Count	Percent
Yes	5	31.2%
No	11	58.8%
Unanswered question	16	



Evaluation of training programme - consultation skills research study

If you accessed podcast 1 (Print Outcast) please answer the question below

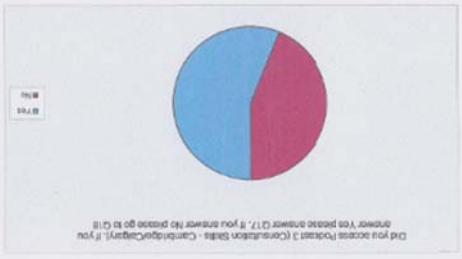
Response	Count	Percent
Strongly agree	0	0%
Agree	1	5.9%
Disagree	2	11.8%
Strongly disagree	0	0%
Unanswered question	14	78.3%



Evaluation of training programme - consultation skills research study

Did you access Podcast 3 (Consultation Skills - Cambridge/Cagary)? If you answer Yes please answer Q17, if you answer No please go to Q18

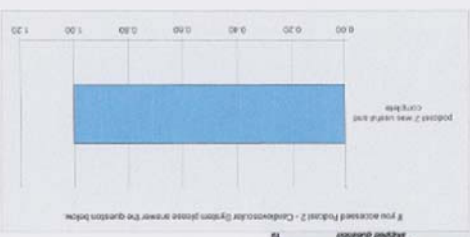
Response	Count	Percent
Yes	7	43.8%
No	9	56.2%
answered question	16	
skipped question	8	



Evaluation of training programme - consultation skills research study

If you accessed Podcast 2 - Cambridge/Cagary please answer the question below

Response	Count	Percent
Strongly agree	0	0%
Agree	2	100%
Disagree	0	0%
Strongly disagree	0	0%
answered question	2	
skipped question	18	



Evaluation of training programme - consultation with research study

What is your opinion of the session when you were taught how to use the IT record review system?

Response	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Number of responses	0	0	1	8	6
Mean	0	0	1	10	6
Standard deviation	0	0	1	1	1
95% CI	0	0	0	1	1

Comments:  
The content was useful and concise  
The format was appropriate to this learning  
The time allocated was sufficient to learn all that I needed

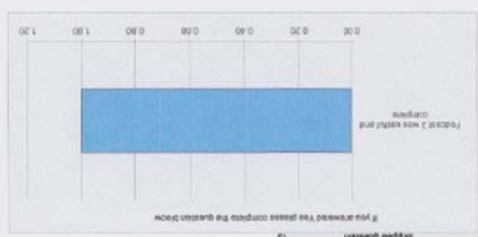


Evaluation of training programme - consultation with research study

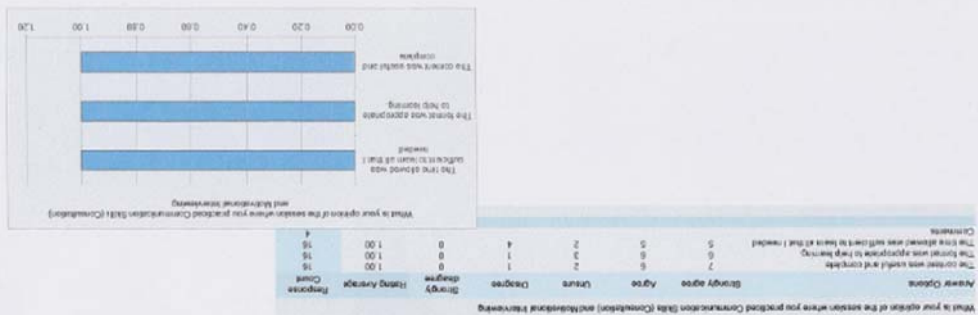
If you answered 'Yes please compare the question bank'

Response	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Number of responses	0	0	0	5	4
Mean	0	0	0	5	4
Standard deviation	0	0	0	1	1
95% CI	0	0	0	1	1

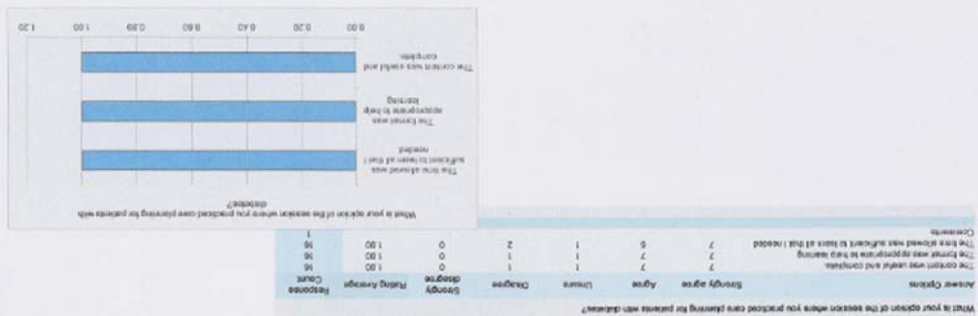
Comments:  
Project 3 was useful and concise  
Project 3 was useful and concise



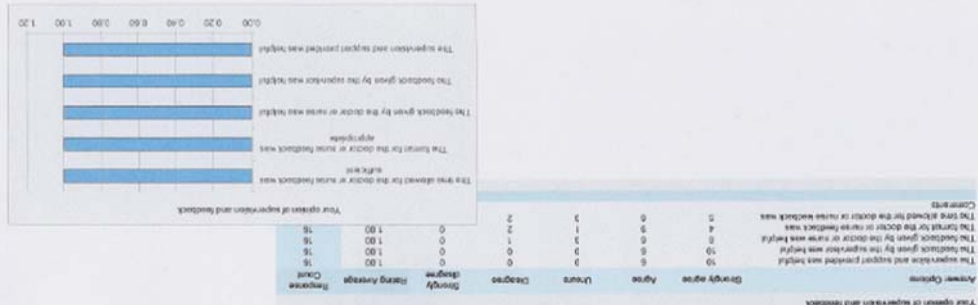
Evaluation of training programme - consultation skills research study



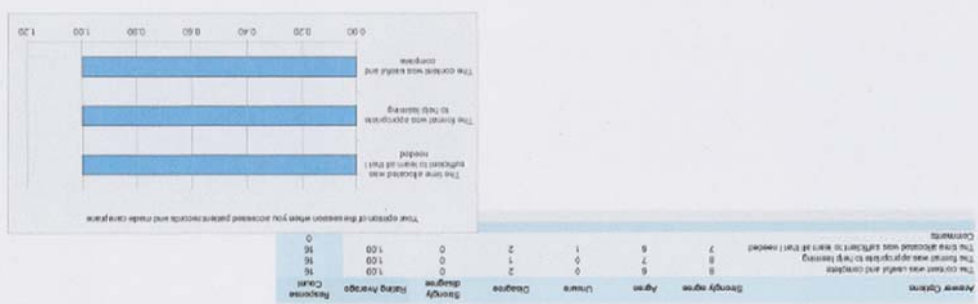
Evaluation of training programme - consultation skills research study



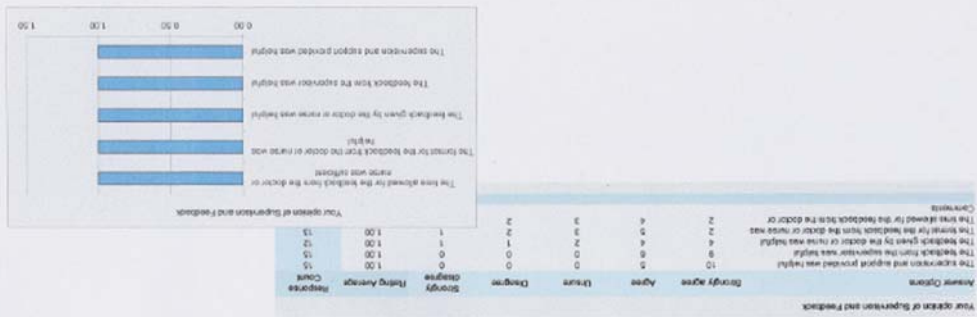
Evaluation of training programme - consultation skills research study



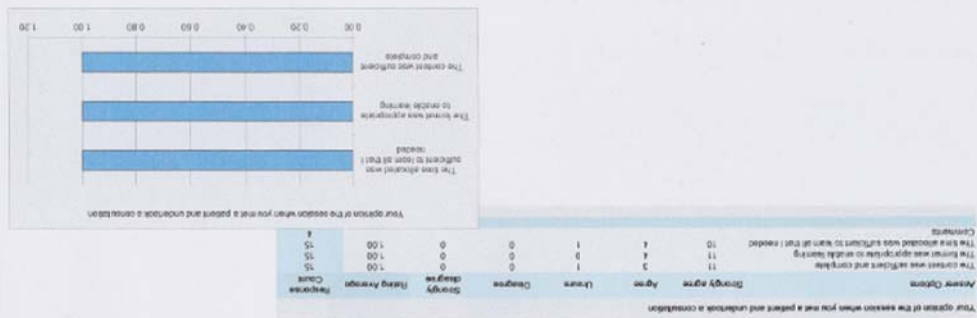
Evaluation of training programme - consultation skills research study



Evaluation of training programme - consultation skills research study



Evaluation of training programme - consultation skills research study





Response Count	Answer Options
3	research study
21	That is the end of the survey. Thank you very much for your help. The information provided will enable us to evaluate the project and make
3	skipped question
21	skipped question

Evaluation of training programme - consultation skills

Review of the training session in Nov with actor/patients

I was sent support information about the training session to know what to expect in advance

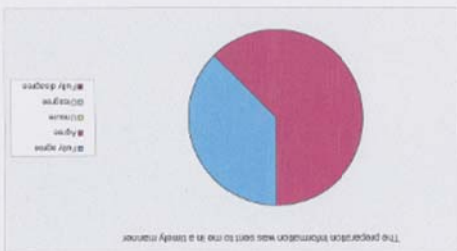
Response	Percent	Count
Fully agree	43.8%	7
Agree	25.0%	4
Disagree	12.5%	2
Fully disagree	12.5%	2
Other	0.0%	0
<b>answered question</b>		<b>16</b>



Review of the training session in Nov with actor/patients

The preparation information was sent to me in a timely manner

Response	Percent	Count
Fully agree	37.5%	6
Agree	62.5%	10
Disagree	0.0%	0
Fully disagree	0.0%	0
<b>answered question</b>		<b>16</b>



The clinical trials unit at the medical school was an ideal location in which to learn consultation skills.

Review of the training session in Nov with actor/patients

Answer Options	Response Count	Percent
Fully agree	13	81.3%
Agree	3	18.8%
Disagree	0	0.0%
Unsure	0	0.0%
Fully disagree	0	0.0%

answered question 16  
skipped question 1

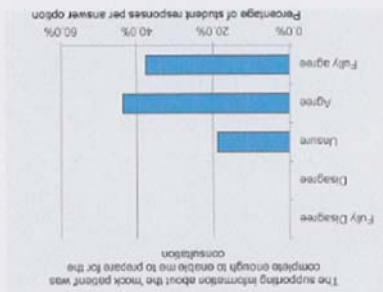


The supporting information about the 'mock patient' was complete enough to enable me to prepare for the consultation.

Review of the training session in Nov with actor/patients

Answer Options	Response Count	Percent
Fully agree	6	37.5%
Agree	7	43.8%
Disagree	3	18.8%
Unsure	0	0.0%
Fully Disagree	0	0.0%

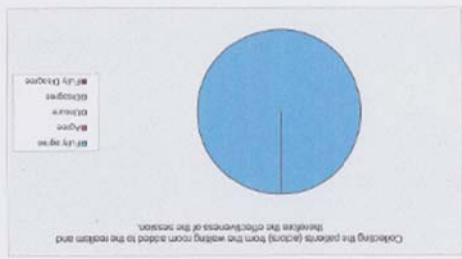
answered question 16  
skipped question 1



Review of the training session in Nov with actor/patients  
Collecting the patient's (actors) from the waiting room added to the realism and therefore the effectiveness of the session.

Response	Count	Percent
Fully agree	16	100.0%
Agree	0	0.0%
Disagree	0	0.0%
Fully Disagree	0	0.0%

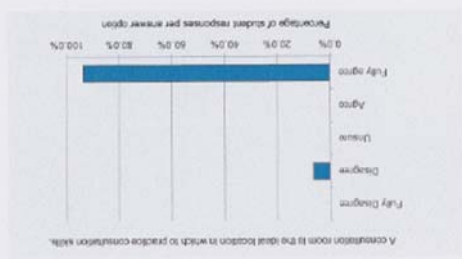
assigned question



Review of the training session in Nov with actor/patients  
A consultation room is the ideal location in which to practice consultation skills.

Response	Count	Percent
Fully agree	15	93.8%
Agree	1	6.3%
Disagree	0	0.0%
Fully Disagree	0	0.0%

assigned question

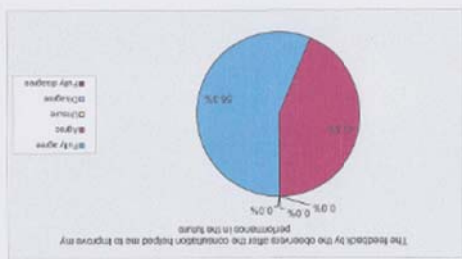




Review of the training session in Nov with actor/patients

The feedback by the observers after the consultation helped me to improve my performance in the future

Response	Percent	Count
Fully agree	56.2%	9
Agree	43.8%	7
Disagree	0.0%	0
Strongly disagree	0.0%	0
Refuse to answer	0.0%	0
Other	0.0%	0
Response	Percent	Count

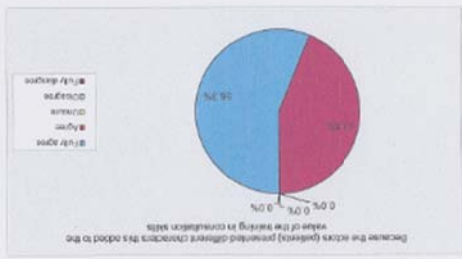


Review of the training session in Nov with actor/patients

Because the actors (patients) presented different characters this added to the value of the training in consultation skills

Please use the space provided below to explain any of the responses you

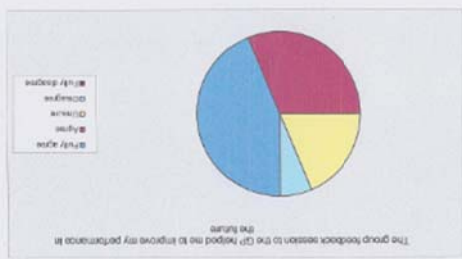
Response	Percent	Count
Fully agree	56.3%	9
Agree	43.8%	7
Disagree	0.0%	0
Strongly disagree	0.0%	0
Refuse to answer	0.0%	0
Other	0.0%	0
Response	Percent	Count



Review of the training session in Nov with act/clients

The group feedback session to the GP helped me to improve my performance in the

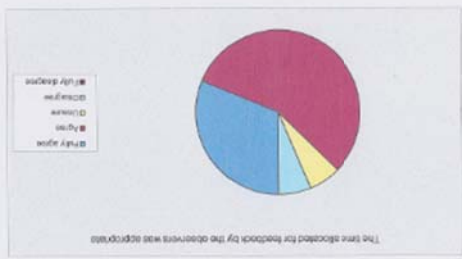
Answer Options	Response Count	Percent
Strongly agree	7	43.8%
Agree	5	31.3%
Disagree	3	18.8%
Strongly disagree	1	6.3%
answered question	0	0.0%
skipped question	16	



Review of the training session in Nov with act/clients

The time allocated for feedback by the observers was appropriate

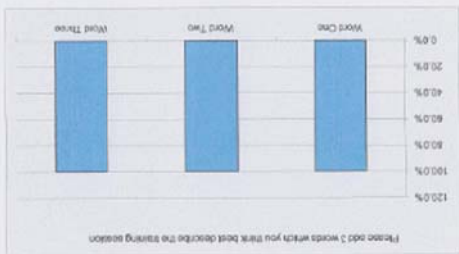
Answer Options	Response Count	Percent
Strongly agree	8	50.0%
Agree	5	31.3%
Disagree	1	6.3%
Strongly disagree	0	0.0%
answered question	16	
skipped question	1	



Review of the training session in Nov with actors/patients

Please add 3 words which you think best describe the training session

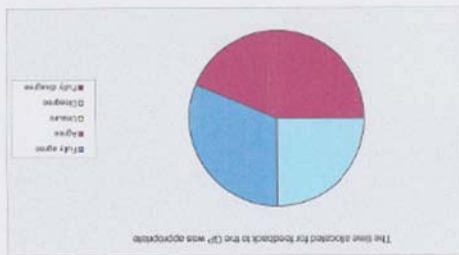
Response	Count	Percent
Answer Options	11	100.0%
Word One	11	100.0%
Word Two	11	100.0%
Word Three	11	100.0%
answered question	14	
skip/quit question	3	



Review of the training session in Nov with actors/patients

The time allocated for feedback to the GP was appropriate

Response	Count	Percent
Answer Options	5	31.3%
Fully agree	7	43.8%
Disagree	4	25.0%
Fully disagree	0	0.0%
Please use the space provided below to explain any of the responses you	3	
answered question	16	
skip/quit question	1	

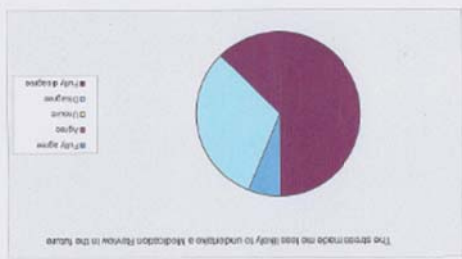




Review of the training session in Nov with actor/patients

The actors made me less likely to undertake a Medication Review in the future

Response	Count	Percent
Strongly agree	1	6.25%
Agree	0	0.00%
Disagree	0	0.00%
Strongly disagree	5	31.25%
Skipped question	10	62.50%

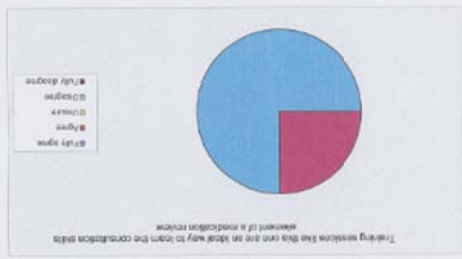


Review of the training session in Nov with actor/patients

Training sessions like this are an ideal way to learn the consultation skills element of a medication review

Please use the space provided below to explain any of the responses you

Response	Count	Percent
Strongly agree	12	75.00%
Agree	2	12.50%
Disagree	0	0.00%
Strongly disagree	0	0.00%
Skipped question	1	6.25%



Review of the training session in Nov with actors/patients  
 Doing with the week during this training day made it easier to deal with it when I met a  
 real patient for a Medication Review

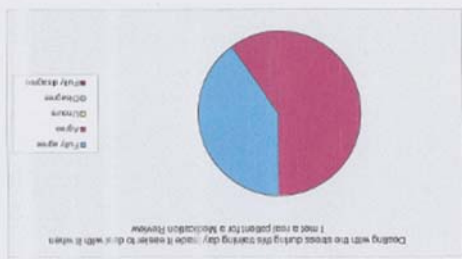
Answer Options

Response	Percent	Count
Fully agree	40.0%	1
Agree	60.0%	1
Disagree	0.0%	0
Fully disagree	0.0%	0

Please use the scores provided below to explain any of the responses you  
 assigned question

Response	Percent	Count
Fully agree	40.0%	1
Agree	60.0%	1
Disagree	0.0%	0
Fully disagree	0.0%	0

Assigned question  
 15



## Questionnaire for Students

Now that you have met the patient for a consultation we would like to ask if you would complete a short questionnaire. You do not have to complete the questionnaire but it would help us to see how useful the consultation was and how useful our training course was.

Please tick **ONE** box one on **EACH** line

Statement	Please tick the box which most represents how much you agree with the statement about the consultation <b>5 = strongly agree 1 = strongly disagree</b>				
I was well organised.	5	4	3	2	1
I had a very professional attitude.	5	4	3	2	1
I communicated well.	5	4	3	2	1
I showed good confidence.	5	4	3	2	1
I was comfortable with the level of knowledge that I had to carry out this review.	5	4	3	2	1
I was an appropriate person to review the patient's medicines.	5	4	3	2	1
I think that the patient learnt something useful about their medicines.	5	4	3	2	1

**Please turn over**

This questionnaire was developed from a publication by Boyatis & Batty. Domiciliary medication reviews by fourth year pharmacy students in Western Australia. *JPP* 2004;12: 73-81

I made the review of the patient's medicines interesting.	5	4	3	2	1
The review of medicines was important for the patient's health.	5	4	3	2	1
I think that the patient would recommend this medication review to other people.	5	4	3	2	1

Any other comments .....

.....

Student's Name.....

Date:.....

Thank you.

Rick Adams, UEA

[Richard.adams@uea.ac.uk](mailto:Richard.adams@uea.ac.uk)

This questionnaire was developed from a publication by Boyatis & Batty. Domiciliary medication reviews by fourth year pharmacy students in Western Australia. JPP 2004;12: 73-81

## Questionnaire for Patients

Now that you have met the student for a consultation we would like to ask if you would complete a short questionnaire. You do not have to complete the questionnaire, and it will not affect your care if you do not do so. But it would help us to see how useful the consultation was and if you decided to do so it would take about 2 minutes. Please tick ONE box on EACH line

Statement	Please circle the number in the box which most represents how much you agree with the statement about the student consultation 5 = strongly agree 1 = strongly disagree				
The student was well organised.	5	4	3	2	1
The student had a very professional attitude.	5	4	3	2	1
The student communicated well	5	4	3	2	1
The student showed good confidence	5	4	3	2	1
The student was an appropriate person to review my medicines.	5	4	3	2	1
I learnt something useful about my medicines	5	4	3	2	1
The review of my medicines was interesting	5	4	3	2	1
The review of my medicines was important for my health	5	4	3	2	1
I would recommend this medication review to other people	5	4	3	2	1

Any other comments .....

.....

Thank you Rick Adams UEA

This questionnaire was developed from a publication by Boyatis & Batty. Domiciliary medication reviews by fourth year pharmacy students in Western Australia. JPP 2004;12: 73-81

Reference No.

Care Plan for Individual Patient								
Contact Information	Name							
	Address							
	City/Town				Post code			
	Telephone	Home			Mobile			
Demographics	DOB			Age			Gender	
	Weight				Height			
	Occupation		Choose an item.			Comments		
	Living arrangements		Choose an item.			Comments		
	Accommodation		Choose an item.			Comments		
Allergies and Alerts	Allergies or side effects reported: state drug, reaction, severity, date reported.							
	Allergies reported other than to drugs, e.g. food, pollen, latex, etc.							
Special Needs and Assistance	State special needs	Mobility	Dexterity	Swallowing	Hearing	Sight	Literacy/Reading	
	Compliance aids used, e.g. multi compartment aids (dosette, Venalink, Medidose, etc.), electronic reminders, paper charts, etc.							
Lifestyle	Smoking status		Choose an item.		Details			
	Alcohol status		Choose an item.		Details			
	Diet: specify including: five/day, salt, fat intake.							
	Are there special diets, e.g. low fat, vegetarian, lactose free, etc.							
Exercise: please specify amount and frequency.								

<b>Relevant Past Medical History</b>	<b>Condition</b>	<b>Date commenced</b>	<b>Currently active condition</b>
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.
<b>General Compliance or Concordance Issues</b>	<b>Issue</b>		<b>Needs action in care plan</b>
	Are there unmet information needs with respect to medicines? - including what they are for?		
	General description of medicine taking behaviour – including adherence.		
	Any administration issues, e.g. swallowing? Give details.		
<b>Pharmacy</b>	If the patient uses a preferred pharmacy, please state which.		
	Collection of prescriptions.	Choose an item.	

Current Medications (includes oral, topical, inhalers, ENT, pr, pv)	Drug	Dose and frequency	Route	Indication as stated in records or by the patient	Start date	Comments, e.g. efficacy, side effects
OTC/Herbal/ Homeopathic	Specify any over the counter medicines used.					
	State name, usual dose, frequency of use and indication.					
	Specify any herbal products used.					
	State name, usual dose, frequency of use and indication.					
Specify any homeopathic products used.						
State name, usual dose, frequency of use and indication.						



Care Plan	Date	Issue	Details of plan	Expected outcome and monitoring required
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
	Click here to enter a date.	Choose an item.		
<b>Form completed by</b>				
Signature			Date Click here to enter a date.	
<b>Update completed by</b>				
Signature			Date Click here to enter a date.	
<b>Update 2 completed by</b>				
Signature			Date Click here to enter a date.	

### Medication Related Consultation Framework (MRCF)

**Student** **Assessor**

First name ..... First name .....

Last name ..... Last name .....

Tick here if Self Assessment

How well did the student undertake the following activities when consulting with the patient?

#### (A) INTRODUCTION

- A.1 Introduces self
- A.2 Discusses purpose and structure of the consultation
- A.3 Invites patient to discuss medication or health related issue
- A.4 Negotiates shared agenda

The practitioner was **not** able to build a therapeutic relationship with the patient 0 1 2 3 4 The practitioner was **fully** able to build a therapeutic relationship with the patient

Grade (A):

Comments:

#### (B) DATA COLLECTION & PROBLEM IDENTIFICATION

- B.1 Medication history, social history
- B.2 Patient's understanding of the rationale for prescribed treatment
- B.3 Patient's (lay) understanding of his/her illness
- B.4 How often patient misses dose(s) of treatment
- B.5 Reasons for missed dose(s) (*unintentional or intentional*)
- B.6 Identifies and prioritises patient's pharmaceutical problems (summarizing)

The practitioner was **not** able to identify the patient's pharmaceutical needs 0 1 2 3 4 The practitioner was **fully** able to identify the patient's pharmaceutical needs

Grade (B):

Comments:

#### (C) ACTIONS & SOLUTIONS

- C.1 Relates information to patient's illness & treatment beliefs (risk – benefit discussion)
- C.2 Involves patient in designing a management plan
- C.3 Gives advice on how & when to take medication, length of treatment & negotiates follow up
- C.4 Checks patient's ability to follow plan (are any problems anticipated?)
- C.5 Checks patient's understanding
- C.6 Refers appropriately to other healthcare professional(s)

The practitioner was **not** able to establish an acceptable management plan with the patient

0 1 2 3 4

Grade (C):

The practitioner was **fully** able to establish an acceptable management plan with the patient

Comments:

#### (D) CLOSING

- D.1 Explains what to do if patient has difficulties to follow plan and whom to contact
- D.2 Provides further appointment or contact point
- D.3 Offers opportunity to ask further questions

The practitioner was **not** able to negotiate 'safety netting' strategies with the patient

0 1 2 3 4

Grade (D):

The practitioner was **fully** able to negotiate 'safety netting' strategies with the patient

Comments:

#### (E) CONSULTATION BEHAVIOURS

*Did the practitioner demonstrate the following consultation behaviours?*

- E.1 Listens actively & allows patient to complete statements
- E.2 Uses open & closed questions appropriately
- E.3 Demonstrates empathy & supports patient
- E.4 Accepts patient (i.e. respects patient, is not judgemental or patronising)
- E.5 Adopts a structured & logical approach to the consultation
- E.6 Manages time effectively (works well within the time available)

The practitioner was **not** able to demonstrate any of these consultation behaviours

0 1 2 3 4

Grade (E):

The practitioner was **fully** able to demonstrate these consultation behaviours

Comments:

#### OVERALL IMPRESSION

Overall the practitioner's ability to consult was...

Not competent      Not competent      Competent      Competent      Competent  
Poor       Borderline       Satisfactory       Good       Very good

Additional comments:

**Assessor signature** (student pharmacist signature if self-assessment)

.....

**Date**

.....

**RESPONDING TO SYMPTOMS SESSION RECORDING FORM**

**Session details**

Student name	
Date	
Assessor name	
Assessor signature	

Clinical criteria	Quality	Score
Demonstrating any of the following will result in a failed assessment:	Poor practice (eg guessing answers to patient questions)	Absent
	Incorrect, inappropriate or dangerous information given to the patient	Present (= FAIL)
	Criteria overleaf marked *	

**Scores**

	Pass	Fail	Score (P/F)
<b>Penalty criteria</b> (see box on left)	Absent	Present	
<b>Content criteria – Essential</b> (in bold) (see overleaf)	All met	Some not met	

	Available score	Pass mark	Score (%)
<b>Content criteria – Other</b> (see overleaf)	100	70	
<b>Delivery &amp; style criteria</b> (see overleaf)	100	70	

Y4 only: Distinction requires 90% or more for both the 'Content' and the 'Delivery & style' sections.

Staff use only

**Peer evaluation skills**

Compare student and staff marks for the 'Delivery & style criteria' and tick the relevant box below.

Equal marks given by student and staff observers	
Marks are within 2.5%	
Marks are within 5%	
Marks are within 10%	

**RESPONDING TO SYMPTOMS SESSION RECORDING FORM**

Content criteria	Quality	Available score	Score	Delivery & style criteria	0	5	Comments
Introduce self (name and role)	Absent	0		Professional in demeanour	0	5	
	Name or role only	5					
	Name & role	10					
Explain the need to ask questions	Absent	0		Demonstrates appropriate non-verbal behaviour. o Eye-contact (maintains but does not stare). Starts all questions with eye contact. o Open body language (open posture and no inappropriate head / hand gestures).	0	5	10
	Explained	10					
Confirm who has the symptoms	Checked	Y	N	Demonstrates listening skills and awareness of patient issues: o Appropriate non-verbal behaviour (eg smile & acknowledgement to demonstrate listening). o Respond to additional patient information and /or issues as they arise as a result of listening. Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
Establish/confirm presence, nature and duration of all symptoms.	Presence	Y	N				
	Nature	Y	N				
	Duration	Y	N				
Establish presence of other associated symptoms	Absent	0		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
Established	10						
Determine action(s) already taken	Absent	0		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
Asked	10						
Ask about patient's medical history	Absent	0		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
Asked	10						
Is/has the patient taken any other medication?	Absent	0		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
Asked	10						
Establish indication of other medication(s)	Absent	0		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
Asked	10						
Explores patient management preferences	Absent	0		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
Asked	5						
<b>*Offers appropriate treatment options</b>	Referral and/or intervention as appropriate	Y	N	Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
	Absent	0					
Explains course of action recommended	Explained	10		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
	Absent	0					
Offers appropriate non-pharmaceutical advice (eg lifestyle advice)	Explained	5		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
	Absent	0					
Check patient understanding	Absent	0		Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner). Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> . Avoids the use of <b>jargon</b> / inappropriate terminology. Allows patient opportunity to ask <b>questions</b> at the end and throughout. Uses appropriate <b>concluding remarks</b> at end of interview/ consultation. Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10
	Checked	10					
<b>Total / 100</b>				<b>Total / 100</b>			

For all criteria, partial marks may be awarded at the discretion of the marker

**COUNSELLING SESSION RECORDING FORM**

**Session details**

Student name	
Date	
Assessor name	
Assessor signature	

Clinical criteria	Quality	Score
Demonstrating any of the following will result in a failed assessment:	Poor practice (eg guessing answers to patient questions)	Absent
	Incorrect, inappropriate or dangerous information given to the patient	Present (= FAIL)
	Criteria overleaf marked *	

**Scores**

	Pass	Fail	Score (P/F)
<b>Penalty criteria</b> (see box on left)	Absent	Present	
<b>Content criteria – Essential</b> (in bold) (see overleaf)	All met	Some not met	

	Available score	Pass mark	Score (%)
<b>Content criteria – Other</b> (see overleaf)	100	70	
<b>Delivery &amp; style criteria</b> (see overleaf)	100	70	

Y4 only: Distinction requires 90% or more for both the 'Content' and the 'Delivery & style' sections.

Staff use only

**Peer evaluation skills**

Compare student and staff marks for the 'Delivery & style criteria' and tick the relevant box below:

Equal marks given by student and staff observers	
Marks are within 2.5%	
Marks are within 5%	
Marks are within 10%	

**COUNSELLING SESSION RECORDING FORM**

Content criteria	Quality	Available score	Score
Introduce self (name and role)	Absent	0	
	Name or role only	5	
	Name & role	10	
Confirm patient identity	Full name & address requested	Y N	
	Absent	0	
Confirm whether patient has had the medication before	Leading question asked	5	
	Confirmed fully	10	
Explain purpose of conversation	Absent	0	
	Partly explained	5	
	Fully explained	10	
Negotiate shared agenda	Absent	0	
	Agreed	10	
Establish name, strength, dose / frequency of medication(s).	Name	Y N	
	Strength	Y N	
	Dose/frequency	Y N	
*Establish indication of medication(s)	Absent	0	
	Jargon used	5	
*Inform patient about the duration of therapy prescribed and time taken for medication to have effect.	Described appropriately	10	
	Absent	0	
*Emphasise the benefit of taking the medication	Duration/time only	5	
	Duration and time	10	
*Explain additional necessary directions/precautions for use	Absent	0	
	Explained	10	
	Not explained	0	
*Explain side effects/warnings	Explained partly	5	
	Explained fully	10	
	Absent	0	
	Jargon/unnecessarily alarming	5	
	Lay terms + appropriate	10	

Check patient :	Absent	0
1. Understanding of the regimen	Either 1 or 2 checked but poorly	2.5
2. Ability to adhere to the regimen	Either 1 or 2 checked adequately	5
	Both 1 & 2 checked but poorly	7.5
	Both 1 & 2 checked adequately	10
	<b>Total / 100</b>	

Delivery & style criteria	0	5	Comments
Professional in demeanour	0	5	
Demonstrates appropriate non-verbal behaviour.			
o Eye-contact (maintains but does not stare).	0	5 10	
o Starts all questions with eye contact.	0	5 10	
o Open body language (open posture and no inappropriate head / hand gestures).	0	5 10	
Demonstrates listening skills and awareness of patient issues:			
o Appropriate non-verbal behaviour (eg smile & acknowledgement to demonstrate listening).	0	5 10	
o Respond to additional patient information and /or issues as they arise as a result of listening.	0	5 10	
Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner).	0	5	
Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> .	0	5 10	
Avoids the use of <b>jargon / inappropriate terminology</b> .	0	5 10	
Allows patient opportunity to ask <b>questions</b> at the end and throughout.	0	5 10	
Uses appropriate <b>concluding remarks</b> at end of interview/ consultation.	0	5 10	
Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5 10	
	<b>Total / 100</b>		

For all criteria, partial marks may be awarded at the discretion of the marker

**MEDICATION HISTORY TAKING SESSION RECORDING FORM**

**Session details**

Student name	
Date	
Assessor name	
Assessor signature	

Penalty criteria	Quality	Score
Demonstrating any of the following will result in a failed assessment:	Poor practice (eg guessing answers to patient questions) Incorrect, inappropriate or dangerous information given to the patient	Absent  Present (= FAIL)

**Scores**

	Pass	Fail	Score (P/F)
<b>Penalty criteria</b> <i>(see box on left)</i>	Absent	Present	
<b>Content criteria – Essential</b> <i>(in bold)</i> <i>(see overleaf)</i>	All met	Some not met	

	Available score	Pass mark	Score (%)
<b>Content criteria – Other</b> <i>(see overleaf)</i>	100	70	
<b>Delivery &amp; style criteria</b> <i>(see overleaf)</i>	100	70	

Y4 only: Distinction requires 90% or more for both the 'Content' and the 'Delivery & style' sections.

Staff use only

**Peer evaluation skills**

Compare student and staff marks for the 'Delivery & style criteria' and tick the relevant box below.

Equal marks given by student and staff observers	
Marks are within 2.5%	
Marks are within 5%	
Marks are within 10%	



**MEDICATION HISTORY TAKING SESSION RECORDING FORM**

Content criteria	Quality	Available score	Score
Introduce self (name and role)	Absent	0	
	Name or role only	5	
	Name & role	10	
Confirm patient identity	Full name & address requested	Y N	
	Absent	0	
Tell patient purpose of interview	Partly explained	5	
	Fully explained	10	
Negotiate shared agenda	Absent	0	
	Agreed	10	
Establish name, strength, dose / frequency of <u>all</u> oral medications.	Name	Y N	
	Strength	Y N	
	Dose/frequency	Y N	
	Name	Y N	
Establish name, strength, dose / frequency of <u>any</u> non oral preparations eg creams, suppositories, eye drops, inhalers etc.	Strength	Y N	
	Dose/frequency	Y N	
	Name	Y N	
	Strength	Y N	
Establish forms of <u>all</u> medications (oral and non oral)	Absent	0	
	All checked	5	
Establish indication of medication(s)	Absent	0	
	Oral medications only	5	
	All medications	10	
Establish whether patient uses OTC/ herbal/ homeopathic medication	Absent	0	
	1 or 2 checked	5	
	All 3 checked	10	
Determine the reasons(s) for any recently discontinued medications	Absent	0	
	Asked	10	
<b>Check for any drug allergies</b>	Checked	Y N	
	Absent	0	
Establish the effect of any drug allergy reported (score 10 if no allergies)	Asked	10	
	Absent	0	
Establish if patient has any history of ADRs/ side-effects to any medication	Absent	0	
	Asked	5	

Delivery & style criteria	0	5	Comments	
Investigate tobacco / alcohol	Absent	0		
	Only 1 checked	5		
	All checked	10		
Investigate any adherence issues	Absent	0		
	Partially investigated	5		
	Fully investigated	10		
<b>Total / 100</b>				
<b>Delivery &amp; style criteria</b>				
Professional in demeanour	0	5		
Demonstrates appropriate non-verbal behaviour.				
	o Eye-contact (maintains but does not stare).	0	5	10
	o Starts all questions with eye contact.	0	5	10
o Open body language (open posture and no inappropriate head / hand gestures).	0	5	10	
Demonstrates listening skills and awareness of patient issues:				
o Appropriate non-verbal behaviour (eg smile & acknowledgement to demonstrate listening).	0	5	10	
o Respond to additional patient information and /or issues as they arise as a result of listening.	0	5	10	
Information gathering follows a <b>logical progression</b> (eg starts with an open question and responds in a logical manner).	0	5		
Demonstrates appropriate changes in tone, clarity and volume of <b>voice</b> .	0	5	10	
Avoids the use of <b>jargon</b> / inappropriate terminology.	0	5	10	
Allows patient opportunity to ask <b>questions</b> at the end and throughout.	0	5	10	
Uses appropriate <b>concluding remarks</b> at end of interview/ consultation.	0	5	10	
Discretionary mark based on level of <b>rapport, empathy and interest</b> shown in patient.	0	5	10	
<b>Total / 100</b>				

For all criteria, partial marks may be awarded at the discretion of the marker

# Appendix H: Review Stage Focus

## Groups

Medical Practices

Students

Pharmacists

Patients

### GP/Practice Nurse Focus Group Questions

1. Can you tell me your thoughts about the sessions when pharmacy students met patients to undertake a medication review?

Follow on:

Expand.

Explain

How could that be improved?

Student competence?

2. What are your thoughts on the process of recruiting patients that you undertook for us?

Follow on:

Did you experience any problems assessing the list of patients to identify exclusions?

What are your views on the number of patients recruited?

What are your thoughts about the timescales?

What are your views about the appointment process?

If we repeated the exercise would it be practical to recruit patients in the same way that medical students currently do?

3. If you were able to interact with students at the time or had contact with patients later, what was your opinion of the quality or effectiveness of the medication review?

Follow on:

Do you think that they provided any patient benefit?

Did they communicate appropriately?

Did they show suitable knowledge and skills?

Do you think that the patients had preconceived ideas about the meeting?

4. What are your views about the feedback from students

Follow on

What is your opinion of the items fed back to you or a colleague after the medication reviews?

What do you think of the process?

Why do you think that we did not get feedback all the time?

Did we need to allocate and book more time?

5. What are your views on the inclusion or otherwise of which Practice staff should be involved in the study?

Follow on:

Do you think they should have been included or not?

How do you think that we could have obtained more doctor participation?

6. What are your views of repeating the exercise?

Follow on:

If no, why

If yes would you make any changes?

7. Is there anything that you wanted to say that you have not had the chance to say or is there a question that I should have asked?

Transcription of Meeting at Paston (Nurse) on 18 July 2012

RA: First, general question, can you tell me your thoughts about the sessions when the pharmacy students met the patients and started to take a medication review?

N: Yeah, I saw them at the end of the session and they seemed to have enjoyed the interaction with the patients and there didn't seem to be a great deal of problem. They had found some things that maybe had been overlooked, which was good for us, so it was helpful both ways.

RA: Could we have improved the process in any way?

N: I think that the best thing that could have come out of it was that you maybe needed a GP rather than a specialist diabetes nurse because they weren't just looking at diabetes' drugs, they were looking at patients with diabetes but have obviously got other co-morbidities and they were asking me questions that I simply didn't know the answer to.

RA: Okay, now I was going to ask this question later on any way, so I'll ask it now. How do you think we could have encouraged GPs to get involved?

N: I'm sure that you can, to be honest. You are going to have to have a GP who's very keen on research and who's got the time to do it. that is the issue, you know you're looking at a system where there is no give in the system for extra patient slots, taking out three or four patient slots to talk to the students is probably not going to be very likely.

RA: Okay, so really you're saying it's unlikely that we'd get a GP involved?

N: Again I might be misrepresenting them, but I think at this practice I don't think they would take half an hour or more out of their clinic sessions in order to do the feedback sessions, which means that you are stuck with me, or maybe a nurse practitioner, which might be a bit more useful.

RA: Okay.

N: You know as not a prescribing person myself...

RA: And why would the nurse practitioner be more useful?

N: She's a prescribing nurse, so I'm very used to the drugs I use every day in my work, which is mostly the diabetic ones and soon to be asthma possibly but certain other things I'm not so offay with and I couldn't tell you why they were on them or why they weren't on them or you know because I'm not familiar with the condition, because I'm more of a specialist in certain, one or two sort of disease areas rather than like a GP who knows everything. So from that point of view for me there were one or two tough questions where I put my hands up and said I don't know, but I could always find out, you know if the worst comes to the worst, I can always find out from somebody you know why did you put the patient on this and hopefully the doctor will tell me.

RA: Would it have been of value if we'd communicated, for want of a better word, via patient notes? Do you think we should have recorded in the patient notes or not?

N: I think yes you should record in the patient notes. You've reviewed the patient, you've had access to the patient notes, I think yes you should record in the patient notes.

RA: So am I right in taking that as that means on every occasion?

N: On every occasion, yes. If I have a telephone call from a patient, I have to document that. Or if I talk to another party about a patient, I have to document that, so if you are making any, or suggesting any changes then yes it is documented. There is also no way of it being swept under the carpet.

RA: Okay, and if a student put a note in the patient's records, is it likely that will be looked at and acted upon by a GP, for instances?

N: There is the facility on System 1, which I think most people use now, where you can task the doctor. In fact you can task the doctor without having to enter anything on the patient notes because the task actually records on the notes, so you could maybe just send a task to the doctor saying I think this, why have you done that? Send them the task in the patient's record, so it's got the patient attached to it electronically, and then it stays on their notes that you've sent that task. So whilst you might not need to or want to record anything on their main page, the task will be recorded for posterity, so you could always prove it at a later date by saying what's on the task list, they can't be deleted.

RA: And whether it's via task or via just into the notes...

N: I think you'd have to send a task to alert the doctor, certainly.

RA: Okay, and even record if nothing happens?

N: Yes.

RA: Yes? Okay. Fine. Having met the students, do you feel they were competent?

N: Yes, yeah. They were very...

RA: Did anything make you think particularly yes or no, then?

N: Most of them were quite confident. I think there's one young man who was a bit less confident but they seemed quite confident, but also did seem to know their limitations. There wasn't anyone saying it's all wrong, I'm going to do this, you know they were quite thoughtful in their process, I think.

RA: Okay, because that's one of the things I was going to ask after you said confident, they weren't confident but not competent?

N: No, they knew their boundaries, didn't they? They knew their limitations and where they had to ask, I think for help rather than just saying well I would do that, you know, why, because I would, you know they were quite open to listening to why maybe a patient is on saxgloptin(?), not metformin or a suthnilerea(?) you know, well that's not right, well it is if they've tried them before and they listened to that so.

RA: Okay. Onto the process. The practice recruited for us, were you involved in that?

N: No.

RA: Okay, I probably need to ask somebody else about that.

N: The IT manager did the searches.

RA: So is that Olly?

N: It is Olly, yes.

RA: I might see if I can ask him then. Do you think the medication reviews were of any use? Were they effective?

N: There were one or two things that were picked up that had been overlooked. I don't think that they made any great changes to the diabetic prescribing, I don't think anyone picked anything up that I recall saying yeah you're right, they shouldn't be on this, or they should have that added, but there were one or two other things that they'd maybe been on the meprazol(?) for longer than required, or you know various other bits and pieces, but only one or two. But, no, it was good, I think you know it's good to have a third party looking at these things sometimes, things do get missed if you see the same patients every day.

RA: Okay, so I've asked some of the things around this. Do you think, from your experience, that the patients would have had a pre-conceived idea about the quality of the meeting beforehand?

N: No. No, I don't think they would have done. We've never had pharmacy students come in and discuss with patients before, I don't think they would have. I think they do with the medical students maybe because we tend to use the same patients over and over again, so they would have an expectation.

RA: And with those students, do they have a higher or lower expectation?

N: I'm not sure they have a great deal of expectation other than just the joy of the ability to talk about their ailments for a little while (laughter), if you know what I mean, they just like talking about themselves. The medical students don't diagnose so much, they more you know looking at history taking and bits and pieces, so I don't think they had a pre-conceived idea of what they were going to get out of it.

RA: Okay, and do you think there would be any benefit in a pharmacy student maybe seeing the same patients as a medical student, either separately or at the same time?

N: There's an interesting idea. I think they could work together quite nicely actually.

RA: In what way?

N: Well there will be certain areas that they are learning at certain times that could tie in maybe with your study, you know your diabetes and they could learn, there's no harm in, I'm assuming the pharmacy students learn some physiology and bits and pieces along with their drug knowledge, and I think it will probably interact quite nicely. And most of all, from the point of view of those are the next generation of doctors and the next generation of pharmacists who might work more closely together if they've more of an understanding of each other's jobs.

RA: Okay. So going back to the feedback, what about the actual process? So...

N: I know I was a bit lax in sending back some of the yellow forms, I didn't have a great deal of time for it, that was the main issue, and the forms came back with queries and also some of the things that they were picking up so far in the past, I couldn't comment on it, I wasn't here, I don't think I was trained on one of the occasion, you know going back over twenty years. You can't comment on why those things were done at point and it was quite time consuming. With regards the fact I only have half an hour a day for admin, that's not your fault, that's our you know failure to put time aside for it.

RA: Okay, so two questions really. The first one is if they talked about things way back in the past, were they raising issues that really didn't need to be raised?

N: Probably, yes.

RA: Okay.

N: Or just, not necessarily always that it didn't need to be raised, but I just couldn't comment on it, I really couldn't tell them you know, the staff member wasn't here any longer, would they remember fifteen years ago even, if I had of asked them? I couldn't comment on, there was a few things I think I emailed you and said look I can't comment on these, I don't know.

RA: Is that, therefore, something we need to put into the training or advice before they see patients and/or nurses or doctors?

N: No, not necessarily, but they might need to be told that sometimes we're just not going to know because it's just so far in the past. You know on the other hand, it might be somebody that I saw nine years ago and I might well be able to remember so it might be worth asking, but don't always expect a useful answer, if it's going to be that far in the past.

RA: That's a useful comment. If we wanted to guarantee access, should we actually book more time, and in effect should we come to the practice and say can we buy x amount of time, or is that practical?

N: Yeah, that's quite practical. I mean we worked out a nice schedule last time, didn't we with the half days? Obviously that would have to go through the practice manager and senior receptionist who does the room allocation, but I can't see why not, I can't see why they wouldn't be able to help.

RA: And do you think, if they ring-fenced or protected more time for feedback, do you think that would provide more benefit, either for the students or the patients or the practice? Or none?

N: I think that I'm not sure how useful it is for the patients to be honest, because like I say you know they're not really getting anything out of it, because the changes still have to be done by the GP ultimately. But from the practice point of view it does make you a little bit more aware of the things you should be doing and maybe have become a bit lax with and certainly from a feedback point of view for the students if more time was ring-fenced it would be much more useful for them. So I think from a practice point of view, and don't forget we have our senior partner who's very keen on education, in fact he spends more time at the UEA lecturing than he does here now, so you know he's quite keen to help the students so I think you know we can work on that one.

RA: Okay. I was going to ask you a different question, but in fact since you've mentioned that he's involved in education and we earlier talked about the fact that it would be difficult getting more...

N: ...a GP...

RA: ...time, is there any, it just makes me wonder whether there is any way of (unclear)?

N: Well I was thinking, that's when you mentioned to me about working with the medical students, two of the GPs work with the medical students on the days that they're here. I don't think they'd take more time out than that, but I can't promise anything because it's none of my business really, but if there was some way of working them into that schedule, then maybe a GP could help feedback. You see with the extra commitments that the GPs have at the moment, for example like I say the senior partner's only here two days a week, taking out another half session or a quarter of a session even, is unlikely to happen, I think.

RA: Okay. What are your views about possibly repeating the exercise?

N: I think it's brilliant, yeah. I think, as I've said before, the more disciplines that understand each other's jobs, the better.

RA: Okay, so the first benefit, you're saying is inter-professional learning...

N: ...yes, yes...



RA: ...or knowledge or whatever. Is there any other benefit?

N: Well of course, I mean the students are going to be dealing with patients every single day and as far as I'm aware until you did this study, they didn't deal with anybody. They need to learn to interact with the patients, because the patient's the other half of the medication, if you can do the medication but not the patients, then you're not maybe in the right job, so meeting people and understanding they're not all the same as you is always a good idea in any job.

RA: And if we repeated it, should we change what we did?

N: Obviously, more time for feedback. I actually prefer the feedback when I'm speaking to the student at the time than having the sheets of paper to look at on my own later. It's more useful.

RA: Important point. Right. Anything else that we should change?

N: No.

RA: Okay, that then just leads me to really the couple of last bits, is there anything that you want to say that you haven't had a chance to say?

N: No.

RA: And are there any questions that you think I should have asked that I haven't asked?

N: No, I don't think so.

RA: Okay, that's great, thank you very much.

N: You're very welcome.

**Transcript of meeting held at Dereham on 3 August 2012**

RA: So first question is, general question, can you tell me your thoughts about the sessions when the students met the patients, or the whole project?

?: Interesting, yes, the students seemed very thorough, they often highlighted issues that weren't diabetes related and then I felt oh I don't know the answer to that, but that's not a problem is it? I probably hadn't expected that, I'd expected it to be purely the diabetic sort of medication, but yeah interesting. Patients seemed quite keen to help out as well, so the feedback or what I've heard from them they were quite keen to help.

RA: Okay, I'll follow that one on later if I can. So if I start and go through specifics. What are your thoughts about the recruitment process that you undertook for us?

?: That's fine, I mean the searches and things were easy, I know it's always hard getting people, isn't it, you know you get a number of people who probably express interest but never quite materialise, but that's the nature of research, isn't it. But it wasn't a problem from this end, for me anyway.

RA: And were the patient criteria sufficient to either filter out the patients who weren't appropriate, or...

?: ...yes, yes I think you didn't want anyone who was too near the beginning of their diagnosis so yeah.

RA: And do you think that was correct or not?

?: Yes, I think it's a very steep learning curve at the beginning and there's a lot, you could probably get people worried fairly early on so you did want people who were a little way down the road and also because it acts as a refresher for them as well.

RA: Okay. Do you think the numbers recruited were as expected then or...?

?: I suspect you probably didn't get as many as you wanted but that is the nature of research isn't it, you always hope but it's a struggle to get those last lot.

RA: Okay. Do you think there's anything we could have done to have encouraged a higher recruitment?

?: I think it's very hard in general practice because people don't want to be pushed into things, they've got to do it off their own back and they've got to feel that you know they'll benefit as well as other people will benefit, and if you start, I mean the only thing you could do is start phoning people up but then you're kind of pressurising aren't you. So no you know, how many letters do you want to send in today's day and age, so you've probably got the balance.

RA: And the time scales, do you think it worked within reasonable timescales?

?: Yes, it worked within a reasonable timescale. I know that we had issues with rooms so from our point of view you were, I think we had to delay it a bit didn't we, so we could've probably been a bit smoother from you but yeah, yeah, it seemed to go quite quickly really.

RA: I know you were able to interact with some of the students at the time, but I don't know whether you from your comments you, I assume you've had contact with the patients later, so do you have any views on the quality of the actual interaction or medication review?

?: I thought it was interesting and it seemed very thorough, yeah it seemed very thorough the quality.

RA: So interesting from what perspective?

?: Well from my perspective, you know, partly that they were flagging up all these things and you think oh dear, oh dear something else we need to look at, you know because you come in, you do the same, I suppose I had the same role, I know my patients quite well and you do sometimes you do overlook things because you know someone, or maybe make more allowances because you know someone, well actually is there any point in me mentioning that to Mr Bloggs because he won't pay any attention or you know when really I probably should still say it because maybe you know five

years down the line the drip feeding might pay off a bit more. But so it was interesting you know it was good because the second one I couldn't meet them the tasks were sent which went on and then I flagged those in the notes so that when people came in I could discuss the issues raised.

RA: So following on from that then, do you think they showed a suitable level of knowledge and skills?

?: Certainly from looking through the you know the theoretical because I didn't actually see of their other consultation skills but theoretically they seemed to be showing good skills, I mean you're the pharmacist though so I can only at it from (unclear) point of view and think oh yeah you know highlighting (over-talking).

RA: It's important for us to see it from your point of view as well. Do you think they provided any patient benefit?

?: Yes, how much I don't know and how you'd be able to quantify it, but patients did come back and say they found it interesting and came back saying that they had you know when they'd had these meetings certain medications had been queried and why was that, so yeah, so I think there were benefits to the patients.

RA: Okay, so following on from the patients comments, were they universally in one direction or the other or were there patients, some who said some good and some bad?

?: No I didn't hear any negative comments, I can't say that you know that probably the people who come in have positive comments and maybe the ones that didn't have such a sort of you know the ones who felt neither way I probably didn't hear from, but I didn't hear any negative comments.

RA: Okay. Do you think from your knowledge of these patients, because obviously you meet them quite a lot, do you think they would have had a preconceived idea about the meeting?

?: Some of them would have, yes.

RA: And do you think that would have been a high or low expectation?

?: Interesting... yes, I don't think they'd have a particularly, I think it would be fairly central, the younger ones would have a higher expectation whereas the older ones would feel that oh we're here to help you out, if that makes sense...

RA: ...yes, it does...

?: ...so we've got some who are in their sort of 50s I think would have much higher expectations of what they would get out of it.

RA: Okay, and just so I'm absolutely certain what I mean or what I understand by that, so the younger ones would expect to benefit, would hope to benefit more...

?: ...yes, and the older ones would think well we're just helping you out and you know I don't think they'd come in thinking they'd potentially get any benefit at all, they're there to help you know.

RA: That's an interesting point.

?: Whatever you say, love, sort of...

RA: Okay. And you met some of the students to talk to, do you think they communicated in an appropriate manner?

?: Yes, I didn't have any qualms about them.

RA: Was it professional or ...?

?: Yes, I didn't think any of them were unprofessional, certainly they seemed highly professional and the paperwork was all completed and everything, the sheets.

RA: Okay, so following that through then, you talked about the items fed back to you. What, no I'll say it as an open question. We've already talked about it a bit, what was your opinion of the items fed back?

?: A lot of it was things that you do, so quite often it was things like you know diet and exercise, because you tend to do these things and not necessarily record them, so it's made me think about you know do I, how I record my consultations because you tend to just put down the problems and not necessarily that you've been back over the diet and exercise, so it was quite good to highlight to me oh you know are there things I should be doing. And then medication wise, you do you tend to look at results, and I often look at results and think oh cholesterol is fine, sugar level a bit high, I must talk to them about their diabetic medications and then don't actually go and check that they might actually be on a cholesterol tablet, so quite a few things sort of flagged, although their cholesterol was up five they weren't actually on a statin so a lot of it was things that you actually think oh if I had the time I'd sit there and run a report and flag all those notes, that was quite nice to have that. Some of the medication was stuff I didn't know anything about so I felt a bit like oh I don't know the answer to that, so you just have to pass that on you know, but if you're doing a thorough medication review you should be looking at all the medications, shouldn't you, not just at the ones that interest me, because when I look at someone's medications that I tend to do, is I tend to look at the ones I'm doing and ask them about side effects of the ones I know about and re-authorise the ones I know about but I wouldn't do the inhalers or the depression tablets or the others because I don't feel I have enough depth of knowledge, so when I get asked questions about them I get thrown.

RA: Okay. So the practicalities of the process of feeding back, well first of all an open question, what did you think of the process? Could we have improved it in any way?

?: I think the hardness was with me working part time on the days you could get rooms so you know that could obviously have been improved but I'm not quite sure how smoothly it could ever run because you know I don't work every day, you had set days that you could get in here and it didn't always coincide with me being here so that was a bit of an issue. And then of course with running clinics you're fitting in around me doing what I'm paid to be doing which I think we met at the end of mornings but it was harder in the afternoons to meet because I tended to then be in clinic at the end of the time that the students were going to be here. So I'm sure there was room for improvement but whether it had an impact, I don't know.

RA: So if the exercise was ever repeated, do you think we would need to either book or allocate time of health care professionals in a different way?

?: It would have been nice to have had a meeting with all of the students after every single session so yes but it's always going to be tricky, because you know we're all busy aren't we, you're busy, we're busy and even if you book or allocate a time, that doesn't mean that it will run to schedule, does it?

RA: So following that through then, and I think that in a way you might have already answered it, but what are your views about the inclusion of other practice staff? When I say practice staff I mean staff from the GP practice.

?: It depends how many people are involved in the diabetes because here it's only me, so therefore there isn't if you're just dealing with diabetes then I'm the main, then I'm the person that should be involved, but if you're going to have a broader perspective then you probably need to get some of the GPs involved.

RA: And what do you think is the likelihood of being able to get hold of a GP?

?: Very low.

RA: And is that simply a time thing?

?: It's a time issue, yes, so then you'd just have to use us as a filter really.

RA: Okay, so is there any way that we could obtain any GP time or is that too difficult?

?: No, Dr Kinaryd(?) here is our research leader and she does, she would meet but whether, in many ways, if you're wanting to talk about specific medication the person they should be speaking to is that patient's actual GP and not just a doctor from the practice.

RA: And do people with all the difficulties of booking do they always see their own GP?

?: No, they see whoever they can or whoever they want which may not actually be their GP anyway.

RA: Okay.

?: So the practicalities are difficult.

RA: What are your views about a possible repeat of the exercise?

?: I would be quite happy to be involved again, you know I'd probably like to try and schedule it for days I know I'm going to be here so that I could feel a bit more involved in the discussions at the end, but yes.

RA: Do you think it's worthwhile repeating it?

?: I feel that would be very hard to answer until you have the results.

RA: Okay.

?: And would you just get the same people again?

RA: It would be different students.

?: Right, different students but it could be the same patients?

RA: Because these ones have all finished and left.

?: Graduated, but you might just get the same patients every time. I don't know if that would be an issue, okay you're getting the same ones with the same...

RA: That's an important comment. What about if we chose either a condition or even just said any reasonable condition?

?: Yes, any long term condition, yes, I'm sure there's plenty out there.

RA: A suggestion I've had from one of the other practices is that it might be worth doing something along the lines of the med students sessions, do you think that's practical or feasible?

?: I think that again it comes down to time issues because we struggle with the medical students finding people for them to talk to, so you'd have the same issues, wouldn't you.

RA: What if the pharmacy students spoke to the same patient but at a different...

?: ...time, but then you kind of always feel that you're always getting the same volunteers, I'm sure the doctors seem to have the same list of people who are happy to come up here, but it's always them, always the same patients.

RA: So it's quite a limited range?

?: Hmm, hmm, for a practice this size it's still always the same few that come up to help with any of these.

RA: So are they seen more than once by med students?

?: Quite often every year the same condition, the same patients.

RA: Right, okay. They're very good at giving up their time then.

?: They are very good, yes. What else do you do when you're retired, I suppose.

RA: So, that's more or less my questions, all I need to ask now is is there anything that you think I should have asked that I haven't asked, or is there anything that you wanted to say that you weren't able to say?

?: No, I mean I know there were certainly some patients who would liked to have helped but because I think it was around Christmas or before Christmas felt that they couldn't at that time of year, but then you could've done the same in the spring and they'd be doing something else, we've certainly got a few who came in and said oh I'd like to have helped but I didn't have the time or couldn't do it at that point.

RA: And one thing I'd possibly go back to that I didn't quite cover, the appointment process, did you get any feedback from either receptions or patients about the appointment process?

?: No.

RA: Okay, so I won't take (unclear)...

?: You'd have certainly heard if it was bad, that would be my stance, I think you would find the biggest issue with this building is rooms...

RA: ...yes, I know the place well.

?: But you'd have certainly heard if there'd been any issues with appointments.

RA: That's all my questions, anything else you have to say?

?: I don't think I have anything, no.

RA: Okay, thank you very much.

?: I hope it all goes well really, I hope they enjoyed it.

Transcription of meeting at Wymondham on 22 August 2012

RA: First question, general one, can you tell me thought, have you got any general thoughts about the study? So the one where the students came out and met patients for a consultation?

N: The patients were fine with it, I think they found it useful to get an outside view of what was happening with their medication and things, as you know as well as on top of then coming to see Jenny and myself, they found it quite interesting to have a bit more in depth conversation perhaps about their medication. They quite enjoyed doing it, the patients.

RA: So you say you think it was useful and enjoyable, so useful in what way?

N: The patients found it useful talking about their medication, yeah, when they came back they'd say ooh this was pointed out and this was explained again, even though I've probably spoken to them about it a hundred times.

N: I think they're quite interested in how it works and why they're taking it, whereas I probably wouldn't explain, I'd say why you're taking it but I probably wouldn't know how it works or explain that and they were more interested than I thought they were going to be, the ones that I saw.

RA: Okay. that's interesting, so you think they liked it?

N: Yeah, the patients that were involved, yeah, all of them had no issues, they all came back fine with it.

N: The ones that I saw as well, they all said the patients seemed to have, well I don't know if the students were just good at getting this out of people, they seemed to have concerns about some of their medication and about why they were taking it and was it causing certain things, but they'd never mentioned that...

N: ...yeah, I had that with a couple of turns...

N: ...or to me, but there were obviously things they wanted to ask and they obviously, for some reason, felt they could ask a pharmacy student about it. Maybe they thought the pharmacy student would know the answer...

N: ...but they probably wouldn't...

N: ...I always say to them are you getting on with your medication, are you taking them regularly, have you got any questions and, I don't always, and they'll go no everything's fine and then there was these things come back to me and I was thinking I only saw them the other day and I asked them, you know, and so things were coming back...

N: ...it was quite strange...

N: ...yeah.

RA: So they were actually asking, they were saying things to the students that they wouldn't dare to say to you?

N: I suppose they do, yes.

N: (Unclear) to me about a side effect something, they were worried that something was a side effect of something when I would have only just seen them and asked them if they were having any side effects or problems with any medications, they'd have said no and then I was, they were seeing the students and then the students were saying this, this and I'm saying I've only just seen that person.

N: One of mine was buying something abroad in Belgium, one of the patients, and they'd never said that to either Jenny or Sam but said it to the pharmacy student. I can't remember what it was now, it was some kind of supplement or something, but they'd never told us that.

RA: That's odd, isn't it?

N: Hmm.

N: (Unclear) they're asking the right questions, they're probably asking the right questions or in a way that the patients feel they've got to say something...

N: ...I wonder if it's time, I wonder if it's time?

N: ...because if we say we've got an hour to discuss all your medication, they presumed they could say well actually sometimes my finger nail hurts, is that anything to do with the medication, whereas they know that you're pushed for time.

RA: Okay, yeah, it's an interesting one. I might come back to some of those issues later and this might be more of a question for you, but I don't know how much other people were involved, but the recruiting process. Was it a problem?

N: It took a reasonable amount of time to search for patients, but I can't remember the numbers, was it about two hundred and something?

RA: I think your practice was just over two hundred.

N: Yeah, I mean it was reasonably straight forward once we'd done it.

RA: Okay, and what are your thoughts about the numbers we recruited? Was it about what you expected or not?

N: Yeah, I mean you're sort of what was it, looking at was it ten per cent? Which is about the ballpark figure for the pick work(?) really.

RA: Okay, yeah, yeah. Were there any problems with the appointment process?

N: No one talked, I don't think so, I don't think there was.

RA: Because, I mean, we in fact made an appointment for a room and then within that just contact for the patients.

N: I don't think so.

N: Was there a chap who showed up when he shouldn't have?

N: I don't know, when I did it there was....

RA: Yes.

N: (Unclear), but that's all I heard.

RA: Okay.

N: I can't even remember the...



N: (Unclear).

N: There are often problems here with the rooms so that wouldn't surprise me.

RA: If we repeated the exercise and the student then wasn't part of the study, would you think there was a better way of recruiting?

N: As in advertising it and for patients to come forward themselves?

RA: Well, really sort of over to you, sort of you know would there be a better way either for yourselves or the patients, or both?

N: I think by mailing patients was the most sort of sure fire way of getting the information to them.

RA: Okay.

N: If you just have a look at a poster people will fleetingly look at it and then kind of disregard it and forget about it, whereas a bit paper addressed to them, they're more likely to at least read it even if they then discard it afterwards, and if they're perhaps newly diagnosed there'd be something that they're interested, I think. Again their age and other factors come into it.

RA: Okay. Because I mean I understand that medical students, you just have a poster, or you ask patients, or...?

N: We just tell them that there's a medical student sitting in with the doctor or the nurse. We didn't used to do that, we used to tell everybody as they came, it was just taking too long so then they just put up a poster, because all the rules and regulations say that they need to be informed and then they'd have to kind of, if they hadn't read that poster for some reason, they could then decline once they came into the room, but we made it clear.

RA: But your medical students here don't see patients as part of the clinic?

N: Oh, if they're seeing patients on their own, they're the patients that the doctor has invited in, so they're patients that the doctor knows, yeah, or that we've searched for. So if we wanted lots of pregnant people, we'd search for them and then phone them or write to them to bring them in.

RA: Okay.

N: And still get let down by people who say they will come and then don't.

RA: And would that be a practical way to do it for pharmacy?

N: I think if you had someone in charge of doing it, because it's usually the doctor who's teaching the students who, Leona does some, I think, searches for them and then we, the couple of times I've took medical students I've found the patients and I've called them in, it's quite time consuming.

RA: Okay, moving on then, if you were able to interact with the students, either directly or indirectly by maybe messages or via patients, or whatever, did you get any feeling about what the quality of the interaction was with the patient?

N: I don't know.

N: I'd have said it was very thorough.

N: Good, I would have thought.

N: Do you mean, like when I spoke to the students afterwards they were very knowledgeable.

RA: Okay, well maybe just move on to that then, because that was part of the feedback, wasn't it?

N: Yes, very you know amicable, very you know found it easy talking to the person's feedback so I presume they'd have been like that with the patients, I didn't find that they were monosyllabic or you know bored or not wanting to be there, they were very you know bright and interactive and quite up for it, I think.

RA: Do you think, did you get a feel about what their knowledge level was? Sufficient, or not?

N: I'd have thought it was, yeah sufficient.

N: Well, yeah, sometimes they'd ask us things a clinicians, but I think that's fair enough because that's not their, because they'd obviously, I don't know, I didn't do that many, the ones that I did do they would have found a problem, or the patient had said they'd got a problem, with such and such and then I could say oh well I didn't think that was important or that's not the point, or the patient thought it was important, or you know that we could feed that back, so they seemed to have been able to get the information but I think sometimes they didn't know whether that information was important information, does that make sense?

RA: Yeah, there's a possible gap there.

N: Yeah, but then I think that's probably why we were there to bridge that gap.

RA: Okay. Do you think the patients had pre-conceived ideas about what they would get or about the quality of it before they came?

N: I think some did, I think some did, I don't think that all of them did.

RA: And do you think the pre-conceived idea would be good, bad or indifferent?

N: I think the pre-conceived ideas would probably more that we would be working to a guidance and sticking to certain pathway which doesn't happen with all patients, you have to vary treatments and advise according to who you've got in front of you and I think, I think that some of them were thinking well why me, I don't understand why they're not doing that because that's the next step, but actually you would, we wouldn't be doing that for you know somebody's age or somebody's ability to cope with certain medications and things, so we wouldn't necessarily almost follow a pathway and I think sometimes they were a bit surprised that we didn't just do what...

N: ...and I think that's where the, not lack of knowledge, it's just experience, I think, and it's probably why we were there to say well actually that wouldn't work in them because you know they're ninety and they're blind, that type of thing.

N: I had a few of those.

RA: Looking at the feedback process from your point view, we were asking for the feedback at the end of sessions, is that something that's practical for a practise to achieve?

N: As long as we have time out to do it, yeah.

RA: And are there sufficient people around to create that time?

N: Usually, yeah, I would say there were, I don't know about for the nursing...

N: ...I think it would, I think it would be day dependent...

N: ...do it every day, yeah, it would depend which day and how many people were here. I had a few, talking about cock up in the system, there was just a couple when I'd got my time for feeding back was completely different from what time they'd finished, so they had to wait for me which they didn't seem to mind but I felt bad that they were then hanging around. I guess that was just administrative, or maybe it was because it wasn't you know maybe it was supposed to you or Jenny and then for some reason it was changed.

RA: And you think if, I mean if we were to repeat it would it be practical to leave the feedback thing in or not?

(Unclear, over-talking but general feeling that feedback session needed for students' understanding of the experience.)

N: And for us to be able to then deal with what the problems were because there was a few things that I then had to go off and you know phone the patient or pass it on, things that they'd found out, it was helpful.

RA: Okay. Was there anything that came up from the feedback you felt was of value for the patient?

N: Yeah.

RA: So, because this is something we weren't sure at all at the beginning of the process, do you think there is any benefit for patients in this, or is it purely an educational exercise?

N: No, I felt there was some benefit for patients.

N: I thought that there was, yeah.

N: I can't remember details but I remember I had got three or four notes that I made that I then followed up with the patients, or with their, or let their doctor know. I can't remember what they were.

N: I can't give you specifics but I can remember patients coming and speaking to me about something that they had talked to them about in there then we had a separate conversation about it later and so it had brought something, I can't remember what it was, it brought something up which meant that the patient wanted to clarify something and things like that are always good, aren't they, (unclear – over-talking).

N: There was a couple of things where I thought it was what they'd found out was yeah that I needed to act on.

RA: Okay, that's interesting to hear. So then following through really the practicalities of the study, which practise staff do you think should be involved, you know whether it's nurses or doctors or both or anyone else?

N: I guess if it's, was it all diabetes? Yeah? I guess if it was diabetes then I guess that diabetic nurses probably the better people.

RA: What if it was another group? I mean on this occasion you know patients with diabetes were chosen as a group, that was representative.

N: Either a specialist nurse with an interest or a doctor who's got some interest I would think.

RA: Okay. Now other practises we were lucky enough to have a doctor involved, do you think there is something we could, because we involved other practises, do you think there is anything we could have done to make it more inclusive?

N: I'd imagine most of them it was just a time thing...

N: ...I was going to say (unclear, over-talking)...

N: ...and I think the times I was asked to do it was because you guys weren't available so it was probably a day thing you know that someone else wasn't here, but I mean it wasn't a problem to me because it just meant that I had less patients booked into my surgery and I just did that in the middle, and I did find it quite interesting and it's nice doing something different. I imagine, we're a big practice so we can probably absorb that whereas if you're a practice with four doctors and you took one of them out to do that on an afternoon when there's only two doctors there, it just wouldn't be practical.

N: Could it be the same for the nurses, if it's a smaller practise then...

N: ...yeah, absolutely...

N: ...there are less nurses, I mean it's all relative, so I wouldn't have thought, I guess one you've got to be interested and two your system has got to be able to cope.

N: But it didn't take long. It was just timing, as I said they had to hang around a couple of times.

RA: So it's more a matter of, well at least for this practise, more a matter of planning.

N: Yeah, it's just planning and it's usually because, we are a big practise, we can you know the same as if I'll need to take the afternoon off for x, y and z, it can be usually can be organised because we're quite a big practise, but I can't imagine that's the same in lots of practises.

RA: Okay. So if we thought about repeating the exercise, do you think we ought to make changes in the way we ran it?

N: So the patient met with the student and then we fed back, that's what, they met about three patients, didn't they?

RA: Yes, so the actual process was the students had a training programme, during that time patients were recruited, the students came out and accessed the records and made a care plan and then a student met a patient for a medication review.

N: Do the patients get to provide any feedback via a questionnaire or, I can't quite remember?

RA: There was a short questionnaire at the end of the consultation, but it was a simple nine question questionnaire.

N: And did the students find it useful meeting us afterwards?

RA: Yes.

N: They do? As long as they found it useful, yeah.

RA: Definitely. I can say that in situations where in practises where they, on occasion weren't able to, they found it a problem.

N: Yeah, and presumably that's a little bit of their kind of wanting to hand over what they found to somebody because if you find these things and you don't know if they're you know important or how important.

RA: Something we talked about previously was making notes in the patient records. Have your views changed on that? Do you think they should or shouldn't make a record?

N: I made notes in the record afterwards so if I thought it was important I put a note in the records. I don't know if they should be doing that, but that's because the medical students don't do that.

N: I know it's all a big hot potato, isn't it, who writes in the notes, who sees the notes, who shares the notes.

RA: So, should this be part of the feedback process that the person to whom the feedback is made is responsible for making a record if appropriate?

N: I think so, yeah, because there's a huge confidentiality issue with the students and the notes.

RA: If there was a qualified pharmacist who was authorised to have access, you know such as the PCT pharmacist, would that be appropriate, do you think?

N: Yeah, I think that would be fine if they'd got authorisation to have it, as long as then someone sort of read it I suppose who was going to do something with that information, but if they just made a note and expected us to act on it we wouldn't (unclear), they'd have to make a note and then, if it was System 1, task the relevant clinician to say I've made a note in these, can you have a look, because it's ultimately the clinician's responsibility for what happens to those.

RA: And this comment is in response to something said at another practise, do you think there should be a simple record that the patient has seen a student as part of a study at this place and time?

N: Yeah.

N: Yeah, I think any contact with the patient should be...

RA: Irrespective of making comments?

N: ...yeah.

RA: Okay.

N: Because I think even anything now, so you know if we have to do a report for someone, anything like that I would make a note saying report done, I wouldn't even have had to see the patient, I just think medically legally that would need to be put that they'd just seen them.

RA: Okay, that's useful. I've covered most of my questions, so I suppose this is sort of a catch all, is there anything that you wanted to say that you didn't get the chance to say, or is there anything that you think I possibly should have asked about or commented on?

N: Just go back to the records because I'm thinking about it now. That's the one thing, they are very difficult because I'd meet them and then they'd feed this stuff back to me and I had a bit of paper with all this stuff on and I didn't know what to do with that information because I thought I've been given this information about this patient and now I don't know what to do with it, so now I think that is when I put it on the notes as a kind of admin entry for myself, so I think then if there was some kind of note entered by somebody that they'd even met, I think that would be useful and then I think perhaps the clinician or the pharmacist should enter something to say, I don't know even if they just put medicines review done by student and then if anything came up...

N: ...it seems like it's all about health promotion though, isn't it...

N: ...yes, because if they put anything relevant we can, one we could use that in our kind of records of what we're doing and also I just think any kind of information should be noted that we'd found out about them, but I think you're right that someone needs to note that and I'm not sure whether that should be, it could either be the clinician they meet with or it should be the, I can't remember the lady's name, who was sitting with them, you know...

RA: ...yeah, whether it's the PCT pharmacist or...

N: ...yeah, just something, yeah.

RA: So you would like a record to say...

N: ...I suppose really what would be good would be for them to make a note of their consultation so as we would write what we've talked about and things that we've highlighted...

N: ...and then we could enter what we thought was relevant...

N: ...we could enter the relevant bits (unclear)...

N: ...(unclear) the template, I remember a discussion in the very early days about template change, that it could accommodate the consultations...

N: ...yeah, change, yeah...

N: ...has that ever happened?

N: No, I don't think it ever happened but I think we were thinking about having a point on the template where we could have added any consultation, that was all.

N: Because although we didn't want them enter clinical information, because we're saying they're only students so they shouldn't do that, I think there does need to be some record of what's gone on (unclear, over-talking), if they were in a drug trial you wouldn't, would you, if they were just in a trial but you'd have the notes from that...

N: ...but if there was a paper record that we could just look through and highlight anything that was...

N: ...relevant to us that we could use. Do they keep all those notes, presumably they're kept because it's a research (unclear)?

RA: Yes, I mean they obviously they're locked away...

N: ...there is a record somewhere?

RA: ...they're locked away in a...

N: ...yeah, but there is a record somewhere if something happened, not that I suppose anything would.

N: I'm just trying to think of the easiest way of doing it.

RA: Am I interpreting correctly then to say that as a minimum you'd like to say, well obviously different words, but patient met student as part of a study, undertook medication review and they spoke about the following items and just say what they were (murmurs of agreement). But am I interpreting correctly?

N: I think it would be appropriate, don't you?

N: I actually thought that was happening, that's why (over-talking)...

RA: ...we do make a record but I'm just checking what you think would be appropriate in the future.

N: Yeah, I think it would be...

N: ... because it's actually useful stuff, that's one thing and secondly I just think when we meet with the patient under the guise of Wyndham Medical Practise then we need to be (unclear)...

N: ...it's handy to know what's been spoken about as well so that...

N: ...it's still counted as a clinical consultation, isn't it?

N: ...yeah, so they might think, I mean this happens all the time anyway, so I had two patients this morning came in for their medical review sent by Boots but I've done it you know a month ago and I, so that type of thing, so if the patient perceives they've had a fantastic review and then they're sent in to see us they might be slightly marked but that happens all the time.

RA: Okay, so the last thing then about the record, would you, and again I'm checking whether I've interpreted correctly, would you want any clinical findings or recommendations to be not put into the records but to be fed back to a clinician, whether that's a nurse or a doctor at the end of the session?

N: Yeah, they give us something and then we enter it, I think (general agreement).

N: But then you know we'd be discussing seeing that patient anyway and then we'd come away with the...

N: ...information, yeah...

N: ...the paperwork that they'd...

RA: So really what you're saying, from the safety aspect, you would act as a filter between an unqualified student and a permanent record in the patient's notes?

N: Yeah.

N: Because having said that, when the medical students you know take the patient into a room like this and talk to them I don't think we make any record of it at all, but that is just a kind of teaching thing where everyone understands that they're just coming to take the history and they're not going to do anything to the patient, so I think because you are actually engaging in some kind of recommendation sometimes or discussion, then I think it probably needs to be a bit more formalised, and the medical student who just the same as them going to hospital and just pitching up at someone's bed and having a chat, I mean no record would be made of that, but I think this is a bit more...

RA: I think that's an interesting definition or differentiation because...

N: ...yeah, because they wouldn't write anything, no...

RA: ...our students do meet patients in the hospital and take a drug history and talk about counselling, about their medication, but they don't do this which is a medication review, so this is very different.

N: It is different I think and it's different from what our medical students do.

RA: Okay, no that's...

N: ...you know I think if they meet with patients and they might examine them, they might talk to them but they don't advise them anything or tell them anything or refer them on or do anything other than talk to the GP about it (unclear) so they then feedback to their supervisor, who's the doctor or nurse, and then they might have found out something interesting that they then feedback to the doctor and then obviously up to that doctor that he might enter into the notes, you know Mrs Brown was feeling unwell I'm going to repeat her

blood test, but it would be his responsibility to do that rather than the students, because they presumably can't differentiate quite yet what's important.

N: But it would be a shame not to capture sort of side effects and the diet that they've had with the student that they wouldn't have with you guys and then it's kind of got lost then if it's not been documented (unclear)...

N: ...because a lot of it is clinically relevant to us so, like Sam said, lots of that stuff we can use.

RA: Okay, no that was a really useful discussion actually. So are there any other issues that you think are worthy of discussion?

N: The ones I met were very nice, very nice students.

N: But they're self-selected, weren't they?

RA: They were, yes, they were all volunteers.

N: They were motivated, they were all quite motivated.

N: Didn't have any kind of students that didn't talk to you.

RA: No? Thank you. I'll turn off.



Transcription of meeting at Wroxham on 29 August 2012

RA: First question, it's a general one, do you have any general thoughts about the study where the students met patients.

N: I think it's a good idea.

RA: Why?

N: I think it's, well it's like everything, it's a good idea to get out and do a bit of the job with the real people, isn't it? I also think that it's very different being in a class room and looking at things on paper about what you should do, but that could be very different to actually doing the job and trying to do it with real people that have their own health beliefs, problems and all that sort of thing, so I just think it makes the whole thing real, doesn't it, when you start dealing with the patients.

RA: And you mentioned things like health beliefs and such like, can they be taught in the class room, should they be taught beforehand?

N: I think, yes, you get your underpinning basic knowledge in the class room but it's not until you deal with real people that you start gaining your skills, do you, because you might know that you should do x, y and z but not many people fit into the criteria of doing x, y and z because they have so many other things either wrong with them or that their beliefs about things.

RA: So really one of the things they're learning is...?

N: It's the theory to practice, isn't it?

RA: Yeah.

N: Hugely.

RA: And also to not do it in a set way, to have to adapt to individuals.

N: Absolutely, but you have to have the theory to underpin what you're then doing because if you have good theoretical knowledge you can then ease and tweak, can't you, with the person, but unless you've got a good underpinning knowledge, you can't do that because you're just doing whatever you feel like, so I think you really need the inflation and the knowledge but then to apply that to people you have to meet people and listen to people.

RA: Okay. Now I know you didn't have a lot of contact with students, did that, from the little contact you had or maybe from things patients said to you, did you form any idea of their competence level?

N: I think some of the things I've commented on were, they were very specific when somebody starts this medication. For example, this, this and this should happen, so that's good, but I also think that, certainly from our records point of view, I think there's an awful lot of places to find information in records and I think it highlighted a little bit that we know our patients quite well, this group of patients in particular, so we know certain things about them and we know where to find that information about them and I think because they're new to it and they're new probably to the system and all that sort of thing, they didn't perhaps know where to look for the information about people. I can't remember what that first question was.

RA: No, is that simply experience then?

N: I think that's absolutely simply experience, yes.

RA: Okay, and again that's something, would they gain that from repeating?

N: Absolutely, and to have got a bit of that experience while they're doing their training is brilliant, isn't it?

RA: And do you feel that they needed more knowledge, or more ability to interpret knowledge before they did this, or was it okay?

N: No. What I would have liked to have done from a personal point of view, although I know it's not feasible, would have been to have sat on their shoulder when they were going through listening to what they're saying, or listening to their thought process and then saying oh look at this, and oh what about that, and what about this. I would have quite liked to have been there at the time to point out things that they weren't thinking about about the patient.

RA: Okay. Do you have any examples?

N: I'm trying to see if I have got a specific example. I would have done if I'd thought about it nearer the time.

RA: No, it doesn't matter.

N: I mean there were some things, for example, where I think one of them commented that there was no allergies comment noted and I think that that's slightly a failing of our system because if you haven't got an allergy it just leaves it blank, there isn't a way of putting in no allergies so it would have been nice to be able to say to them and that's how our system works, and that's a fault in the system. So it was those sorts of things, but most of them were more clinical things, because some of the things that they said oh they should have had x but they've got why but they should have had x, if you go back in time usually you can see somewhere that somebody has put why that is and that may be in the bulk of the conversation with them as opposed to a specific read code or something, but they need looking for as opposed to just assuming somebody's done it incorrectly.

RA: So something else they need to learn is how to look in patient records?

N: Yes, I think so because also, on our system, if somebody on the medications it can appear differently when you're looking at the medication list and all the ones that they've had, sometimes it's different names and that sort of thing and I think if you go, sometimes if you're thinking well this wasn't the right medication, if you go back to the journal entry where it was the first time it was given you might find out why it was absolutely that one that was picked, even if it's that Great Aunt Ethel had had the one we wanted and hated it and I'm not taking it, because that happens, you know. Or in the press they said this, I'm not taking it, you know, and sometimes it doesn't matter what you say they'll believe their neighbour or the paper. So there's lots to think about like that.

RA: Okay. So I'll come back to some of these other things. Moving on, the recruitment process, did you get involved yourself in recruiting patients or was that the office?

N: I don't think the specific patients, I think I probably gave a loose please pick these of our patients, but not the specifics, I don't think, not the specific patient.

RA: Right. So would you know how the process went from the practice point of view?

N: Oh as in they just did a search and came up with some? Yes, yes, and I think, I'm fairly sure, I was asked to peruse the list of people because we tend to pick out people who've had a recent bereavement or you know something you know it was obviously or a recent unpleasant diagnosis or something and we tend, so I think probably I did that on the list that they produced, I probably did the no not them because.

RA: Any thoughts about the numbers of patients we recruited?

N: I think it would be really interesting to do it with significantly more patients. Just from the students being able to see more and more and more and more, because again, that's the real world, isn't it? It's lots.

RA: Do you think there's anything we could have done to have recruited more patients?

N: I think, well probably if you'd asked us for more we'd have probably found more, I suspect. Did we, was it a specific number that we were asked for?

RA: Well we were hoping for more, but...

N: ...were we? Okay, because we do do quite a lot of recruiting for research and stuff like that, so...

RA: ...okay. In terms of the appointment process, we undertook to make the appointments with the patients ourselves, did you get any feedback?

N: No, I haven't heard anything from any of them, to be honest.

RA: So well we can assume that there was nothing dramatic then?

N: I think so. That's the way I would assume it, yes.

RA: Okay. And if we were to repeat the exercise, maybe not as a research study, do you think it's feasible or practical to recruit patients in the same way that, for instance, they're recruited for medical students?

N: Yes, yeah.

RA: And would there be enough patients, do you think, willing to come in?

N: I think so because, certainly for the medical students, we often, one of our secretaries often just phones them up over a period of time and just say look we've got medical students, their focus is this, how would you feel about. And that for us has worked quite well because then you get an immediate oh no thank you or yeah, that'd be great.

RA: Okay, because obviously, as part of the study, one has to go through all the ethical work.

N: And I just think from the learning point, I think if you're going to do something like that as a learning tool for them, then I think fairly immediate feedback or discussion is the best way, because as I say from point of view it was a long time ago and there were several points I could remember when I was writing my notes, there were several points that I would have really liked to have mentioned at the time. It wasn't, there was nothing, it wasn't bad but it was just like well actually if you'd looked here, your query was here.

RA: Okay. So let's talk about the feedback. How could we organise feedback in a more immediate manner, do you think?

N: Well I think probably just one of us being available for an hour at the end of your session to do it immediately while it's fresh in everybody's mind and also you see if you've got somebody doing it there, because I sat, I opened everybody's notes up and went back and had a little look and then they would see where I was looking for the information that I wanted to comment on what they'd said.

RA: How many students do you think it's feasible to feedback to in an hour? Or maybe put it the other way round, how many patients could you feedback on in that hour?

N: I think it really depends how much information comes up from one patient because sometimes you'll get lots of learning points, either clinical learning points or system learning points or whatever from one person and then another person might not have anything, so I think it's probably just how long is a piece of

string, you could potentially go on forever on these sort of patients because there's so many issues with them, so I think probably you could go on for as long as you wanted.

RA: But you think maybe if we were able to book the time with somebody for an hour?

N: Yeah, I think so, because I think you can have the opportunity to just whip, because some of them will be repetitive because again some of them were repetitive, their queries were you know repeated throughout the patients so you wouldn't necessarily going over all of them, but, yeah.

RA: Okay. And some practices we didn't get feedback, obviously you'd have to be guessing here, but would you have any idea why we weren't able to get feedback from people?

N: What, they just didn't give you any? Or refused to give you some?

RA: Hmm.

N: I don't know. I found it quite an interesting thing because as I say it's always, there is a certain element of you feel slightly protective over something if you're feeling you're being criticised, especially if you're feeling that you're being criticised by people who don't know anything, although from a personal point of view I think that people who are new into something are full of enthusiasm and actually will pick up on lots of things, so I found it really interesting. So I think possibly lack of time, but also potentially maybe there was some discomfort about something, because some of the things they were saying, I mean I read through some of them and thought surely not, we couldn't possibly do it like that and you know you're thinking well that's not right, surely that doesn't happen here? So, I don't know, or maybe just time.

RA: So, taking one of those points there, (unclear) naturally felt a bit protective...

N: ...well, you do, don't you, yes?

RA: ...but did the students need to think more about how they communicate with health care professionals? Do you think they may have (unclear) appropriately?

N: Yeah, but the problem was is that my slight feelings like that were on the written but not at all on the face to face because we didn't have very long, but we did have a few minutes, didn't we? So not at all on a face to face, so I think if you had something where you had some immediate feedback, you wouldn't have that because you're totally appreciating that they're students and learning and they were keen and they were pleasant and all that sort of thing, but when it's in black and white on a piece of paper, you, there's none of that feeling coming through, is there? So I think you'd get over that by doing the feedback immediately, or relatively.

RA: And were any of the comments or interventions, or whatever they recommended, of value?

N: There was one in particular where I went oh I didn't know that, which was nothing to do with diabetes it was to do with another medication that had been started, and not by myself, by somebody else, but I didn't know, although again I'm the sort of person where my BNF sits on my desk and if I don't know I would've looked it up, but it definitely highlighted a particular shortcoming in one point, but it's always useful.

RA: Okay. And do you think the feedback should be to a practice nurse? To a doctor? Or both?

N: I think, in this surgery, the feedback should be, potentially, back to the nurse practitioners, partly because we're all prescribers and we generally see all the chronic disease and oversee all the chronic disease management. I mean we do do other things, but I think it would sit potentially better with us, if you're doing it on that sort of patient.

RA: Okay. If we were to repeat the exercise, would you make any changes?

N: Making a specific arrangement to be around to follow-up afterwards, because I think when I was...

RA: ...okay, this is feedback thing?

N: ...yes, I think so, because I think that the thing is I think when you asked me to be around I think you were told by the reception staff that I'd gone home, whereas I hadn't, I was here so that was a shame because I think that time got shortened, so that's what I would do specifically is to be here to look at these at the time, or fairly near the time.

RA: Okay. Do you think there was ever any patient benefit from this?

N: I think they're a group of patients that would always benefit from it because they're a group of patients who will be on lots of medications and lots of people sit there and say oh I can't remember why I'm taking that, so anybody who sits down and spends a bit of time re-focusing on why they're taking them and when they should be taking them, is always of great benefit. I also do think that sometimes though if you'd followed every medication's absolute how you should take it to the letter, some people would spend all day taking tablets and I think that's where a bit of experience might say to them yeah now that's really, really important so just take all the others at that time as well, because there are ones, aren't they, a half an hour before a meal, an hour before a meal, an hour after meal, not within two hours of that medication.

RA: So really it's coming back to this issue of experience and knowing when to be practical rather than following the exact guidance?

N: Yes, because from most medicines, I don't know that I wanted to be quoted on this really, but most medicines the most important thing is taking it regularly, isn't it, and then there are some medicines where it's extremely important that you do certain things, but for most medicines it's take it regularly, don't forget.

RA: Okay.

N: (Unclear) law of thirteen medicines like you know because they are, aren't they, how many diabetics are?

RA: Yeah, that's right because they have a lot of disease states.

N: Yes, yes, even though diabetic medicines if they're on you know metformin a thousand times, whatever that's for and the you know they are on a lot so it's yeah, sometimes it has to be just down the hatch.

RA: Okay, that's nearly all my questions. Two catch-alls at the end. Is there anything that you wanted to say that you haven't had the chance to say? Or are there any questions you think I should have asked about the study?

N: No and no, I think.

RA: No, okay. In that case, thank you.

N: Excellent, good, thank you.

#### A. Student Focus Group Questions

1. Can you tell me your thoughts about the training scheme that you volunteered to join i.e. where you received podcasts, three workshops and then after accessing the medical records had a consultation with a patient?

Follow on:

Expand.

Explain

How could that be improved?

Why do you think that happened?

What impact did that have on you/the patient/the study as applicable?

2. Can you tell me what your motivation was to join this study (ie this programme of training leading to a consultation with a patient)

3. What are your thoughts about the preparation that you received?

Follow on:

Did you feel confident to meet a patient.

Did you feel suitably prepared (enough information or skills) to meet a patient?

What are your thoughts about how the patients perceived your level of preparation?

Please explain further (if no real explanation)

What could have been done better to prepare you?

What if anything was ideal and should be kept as part of the preparation?

4. What are your thoughts about your expectations of your performance in the consultation prior to meeting the patient?

Follow on:

Did you have expectations about your performance beforehand?

If the students do not understand what I am after then try "did you think that you would perform well" ?

Did you think that you would get it wrong ?

Then – do you think that you exceeded your expectations or fell below them?

5. All students were asked to complete a short questionnaire at the end of the consultation. Do you have any thoughts about the scores that you gave yourself?

Follow on could include:

The patient scores were all higher than students'. What are your thoughts about this?

Do you think that the patient had expectations for this consultation? If so what?

Do you think that this was formed by previous experience – maybe when they have met Pharmacists previously?

Why did you score as you did?

Was it a true reflection of the activity or were you embarrassed to mark high or over enthusiastic in terms of scoring?

6. Do you have any thoughts about possible effects on the patient from this consultation?

Follow on:

If not addressed – were there any benefits or otherwise for patients?

Do you think that these patients would repeat the consultation with you if asked? Why?

7. Do you think that students similar to yourself should undertake training like this in the future with patients?

Follow on:

Why? Please explain further.

What benefit is there for you or the patient?

8. Is there anything that you want to say that you have not had a chance to, or are there any questions that you think we should have asked?



Intro notes for Student Focus Group Review Phase

Thank you for attending

The reason for this Focus group is to obtain more in-depth views and opinions that you hold about the study (explain what the study is i.e. prep training through to consultation)

For that reason both Dave Wright and I will not be present as that could affect what you have to say. We really need your views.

Heidi and Steven have kindly offered to run the session for me. They are both PhD students in the School of Pharmacy, although neither is a Pharmacist. Heidi is a research nurse looking into adherence in ophthalmology and Steven is a social scientist (psychology) also looking into adherence issues. They will ask your names and write them down as they do not know you and there may be reference to the names for the tape. However, the recording will be transcribed by Frances (Dave's PA) without me being able to hear or see names. So, when I receive the typed transcript none of you will be identifiable and also for that reason none of you will be identifiable in any publications.

My aim is to find out any benefit or otherwise to either students or patients.

I would like to know what was good and what was bad and if you think you know how to improve it then great.

You have all signed a consent form but can I check that you are all willing to be recorded?

You all know each other, but that can make it hard for those running the session. Please try to talk one at a time as otherwise it is very hard to transcribe accurately.

Also please try to let each other put their views and if you want to speak and there is not an obvious break to let you into the conversation simply indicate to Heidi or Steven and they will make sure that you can make your point.

Once again, you all know each other, so this should be easier but if anyone makes what appears to be a confidential statement please keep it confidential.

I will return at the end of the session and you can ask questions about the study if you want.

Once again thank you.

Short explanation of the study

Supervised Pharmacy Student-led Medication Review of Patients with Diabetes in Primary Care: A pilot study to ascertain the potential costs and effects

The primary aim of this pilot study therefore is to estimate the costs and effects of pharmacy student-led medication review and medicines related consultation.

We recruited 5 GP Practices (Wymondham, Dereham, North Walsham, Costessey and Hoveton & Wroxham). They recruited patients for us. Target 160 – actual 137.

Aim for 50:50 split of intervention and control.

Control receive standard care

Intervention receive a consultation with a student to review medicines which could include general health, lifestyle etc.

Student prep –

Podcast on Diabetes and Cardiovascular over the summer.

3 workshops each of 3 hours in first term on :-

- How to use the IT system and access patient records at GP Practices. This was provided by the IT dept at the PCT and was done at Dereham Hospital (only one of 2 training rooms available).
- Care planning. In IT lab.
- Consultation skills and motivational interviewing.

Then a session at a GP Practice. 2 students together access records of 4 intervention (consented) patients.

Randomised the patients and then each student met 2 of the 4 patients whose records they had seen at the GP Practice for a consultation. This planned to be 3 weeks after the access of records

Notes. These are here so that you can understand some of the replies. I know that there were problems and expect (want?) problems highlighted so that we can improve.

There are students present who attended 4 of the 5 practices. The one missing is North Walsham (longest travel)

Plans changed frequently, as recruitment varied. Two Practices recruited large numbers early and others were up to 3 months behind with low numbers. This seriously affected the schedules and meant that students meetings had to be changed. This also meant that the gap between the training and meeting patients was sometimes long.

After making care plans and also after the consultation the Practices had agreed that a nurse or doctor would be available for feedback from the student. This frequently did not happen due to other commitments (patients).

Meetings were changed due to supervisors not allowing the students to go.

Due to lack of patients, three students (including one who will be at the focus group) only met one patient.

All travel to practices was by taxi (paid by study)

At the end of the consultation the student and the patient were asked to complete a questionnaire each (copies attached). They were told that the results would not be used to assess individual students but to assess the training when all the results were combined. The patients scored mainly 5 with one or two questions lower on occasion and the students scored 2 or 3 and sometimes 4.

#### Student Focus Group – held Friday, 8 June 2012-06-13

HC: Your names, we'll try and get your names right and also, for the purposes of trying to get this transcribed so that Rick doesn't know who anyone is speaking, I think what we'll do is, we'll go around the table, I'll give you a number and when Frances goes to type it up she will always refer to you as a number, but obviously we all know who you are and you can use each other's names and things while you're talking if you want to, that's fine and Frances will obviously know to substitute a name for a number, if that's all right. It might be nice for you just to tell me why you got involved in this study. So just one or two sentences as we go round to tell me why you wanted to take part in this. So if we start with, we'll give you number one and you'll be stuck with number one, which will be totally confusing.

1: The reason I signed up to do this study was because I felt that it would be, I thought it was a really good idea to see if this would work for pharmacy students because from the way I learn it's kind of through experiential type, if I'm doing something I learn it better than if I'm just reading it, so I was like you know this would be perfect for people like me and also I thought this is an opportunity for me to actually get involved, to do this and this would be useful kind of development of skills that will be useful like when I'm a pharmacist, so I'd learn all these skills.

2: I wanted to take part because I thought the idea behind the study was quite interesting and I think pharmacists are under-utilised and so it would be an opportunity to show what a pharmacist can do and show our skills and how we can be integrated into doing things like that, something that we're specialists in and looking at medications and dealing with patients on a one to one basis and we don't often get the opportunity to do that in practice as a pharmacist or a student, so I wanted to take that opportunity to be with the public and practice my consultation skills and communication skills.

3: I really wanted to take part because I felt I needed to improve my communication skills, we do quite a lot at uni on communication skills but it's always with other students, and this was an opportunity to practice those skills with a real life patient, as you said we don't often get the chance to meet real patients. And also to help make it less scary I suppose when you start work.

4: I also wanted to do it just to help me like with my skills for during the year because well when we have the OSCE then it's kind of you need to know how to communicate, it's easier to do it with a person than it is with like a fake person...

?: An actor?

4: Yeah, that'll do, yeah, that's it.

5: I guess I just wanted to get involved in something that was sort of extra-curricular and it just seemed to be something sensible to improve my pharmaceutical skills. To be honest I kind of knew Rick as well before so it gave me a more intimate knowledge of what was going on in the study and I really agreed with a lot of the goals that he was going for.

HC: He sort of inspired you?

5: Yeah.

6: I think like everyone else is saying I think any opportunity where we can use your communication skills is really important to take at the moment. And not only that, I think when you're looking at patient details and talking about them, it's also clinical skills that you're picking up, I think any opportunity to do that, because it wasn't just diabetes they were on other medication as well, so you were kind of picking up more clinical knowledge as you went along as well. I think especially this year when we had that project and things it was a really nice extra thing to do (unclear).

7: I think I pretty much wanted to do it to improve my patient skills and actually like everyone else says to kind of get into that real life situation, but also it gave us the chance to do care plans and like that's been a massive

thing all throughout so it's really good to kind of improve, ..... my confidence in doing those, so yeah, it's pretty much what everyone's already covered, I think.

8: It's all the above really, build my communication skills, care plans, spending more time with Rick.

9: Much the same, quite a lot like (1) in that I learn by doing it, the experience and like throughout university you don't really get much chance to do it with real patients, so it's really good.

HC: Thanks for that, actually it's quite nice to start from the very beginning and go back to what motivated you do this in the first place, it's a nice place to start. As Rick's already said, we are recording this and also just bear in mind that anything that goes on in here is all confidential, so don't discuss it outside the room afterwards. I don't think we're discussing anything really sensitive, but just bear that in mind. So I'm interested on your thoughts about the actual training scheme that you've been involved in as a whole so I'm thinking about the podcasts and then you also did the workshops and then accessing the patient medical records and so that training scheme, as a whole, what are your thoughts about it, anyone can kick off. Just your initial thoughts.

S: In terms of the podcasts, I'll be honest, I don't think I found them that useful. I think I listened to one and half another one and that's partly because my internet at home is really bad, but I think, because it was on diabetes and we've done so much, I don't know if anyone else agrees, but over the last kind of three, four years, we've done so much on it, I think we probably had that basic knowledge already. So I guess it helps maybe just having a lecture notes read through might be more useful, because you have to sit there and actually listen whereas if you're reading it you can take however much time you want to take on it. But I found the, because we had some sessions with actors, and we got to practice our skills then, I found that really useful, but maybe if that had been a little bit closer to when we did the real sessions, it'd be more useful because there was quite a big gap and I think I forgot quite a few points and I always do better the second time I do it, so if that could have been...

HC: ...so you had one session with the actors?

S: Yeah...

HC: ...and you feel perhaps another session...

S: ...another session or just moving it so it's closer together so you have the session with the real patients and the session with the actors maybe kind of within two weeks or something, just so it's still fresh, because I think there was over a month and you start to forget.

S: But it's different for different people, I think, because some people had it a lot later than others. I don't think, I mean I didn't mind too much having it quite far apart, just because it fitted in with my time table a bit better.

S: In terms of the workshops we had quite early on, I kind of felt that they could have been condensed quite a lot more, especially like ? was saying, we could have had just a quick overview of diabetes. I think it was because our time table was really, really packed in the first semester and I think they were important but I think it could have been just like one or two sessions, a bit more condensed, I don't know whether anyone else think that?

Murmurs of agreement.

S: I think I need a bit of a refresher – what workshops were these?

Various students over-talking, laughing.

S: There was one like on computer with the care plan and there was one like teaching...

S: ...where we were taught how to use System1?

S: ...no, no there was that one and there was the one where we were like just in there in the ITC and then we were doing the care plans. And then there was that other one where we were told about like how to consultation skills.

S: There were a couple in T Paine weren't they?

S: I don't remember that one.

S: That was in Thomas Paine?

S: Yeah. I think is that the one where Debi, Paul Grassby were involved in teaching the consultation skills. General agreement to this.

S: You might not have necessarily been there, I noticed like some people left didn't they, they had labs or whatever, so not everyone went.

S: I don't remember what I did.

S: I think it was useful that one because it did show you how it was going to be different because obviously we knew how to do counselling and stuff but then it's slightly different structure this one, so this was quite good this session because it showed you what you needed to ask before you had the practice session.

S: Yes, because you always need a bit of theory before you go into (unclear, over-talking) because you don't where to start otherwise.

HC: So being more specific then, the workshop about the consulting skills was quite useful?

Murmurs of agreement.

S: I think it was quite useful but I seem to remember that was a long afternoon, was it not over three hours?

Murmurs of agreement.

S: It was a long, we did have a break and have food in between, but in some respects I think you lose your concentration when that happens and it was hard to then, and because we were doing little miniature role plays in between so it was stopping and starting and it was quite difficult, I found it quite difficult to follow.

S: I do think though this like what we've done throughout is really informal and like Rick's like really laid back so if it was actually taught to us, I think it would be like you said a lot more condensed, a lot more structured, maybe, so I think maybe you should take the fact that this was a study and we are all like volunteers, I think that's why it's so laid back and took so long maybe.

S: I think the start is an overview of that, I think that the content was fine, what we were taught, if was just the presentations, or the way it was delivered, was perhaps too long or not done, not in an incorrect way, but it just made it quite hard to concentrate and because we were saying there was such a long gap between doing things, it was hard to try and think back to what we'd done previously and how to apply it to that situation.

HC: Do you think then the three different workshops could have been brought back into a one day course, or something? Would that be better or actually was it better having it separate?

S: Yeah, a day might have been too intense, but I felt, was it the third workshop where we were in ITCS?

S: No, that was the second one.

S: The second one, I distinctly remember just that, I felt like I didn't achieve anything. I think it was just like filling out the care plan on the computer or something like that. It was largely based on what we'd already done in the first workshop, wasn't it?

General agreement.

S: So definitely maybe just two workshops might have been, condensed it and structured. I mean, I understand it was like the first time that they had done this so you know they were sort of you know what's going to happen kind of thing, so yeah it just needed to be like honed a bit more and more structure, yeah, I think.

S: I think the first workshop where we learned about System 1 was useful the trouble was it was off-site in Dereham so it made it seem like a much longer afternoon than it actually was.

S: I thought it was really arduous that day. And we only did one System 1 workshop, didn't we?

S: Yeah.

S: Yeah, but by the time, like you can't really learn how to use a system within like an afternoon really, it's quite complicated, isn't it? And then it was such a long gap between doing that and then having my actual consultation, I don't know if it was the same for everyone else, but I had no idea how to use it and I was just like, Sarah Mapes was and she was like click on this, and I was like, it was pointless having that workshop really.

S: It might be more useful to kind of have a sheet which kind of explains the key things that you've got to do. And then do it as you go along the first time you go into the .....

S: Yeah.

S: Or time it so you have that session right before your patient session.

General agreement to this point.

S: I think problem with these workshops was I think he did lose quite a few people from that first semester stuff whereas obviously once we got round to like being with the actors and the patients, we found out it was actually really, really good. I was so glad I didn't drop out, but they just need to make it a bit better at the start so you don't lose people.

Murmurs of agreement.

S: Maybe explain more of what you're going to be doing.

General agreement to this.

S: Like more objectives, because there wasn't really any clear direction of what we were going to be doing in that session and I went in there is it was bit like eh...

HC: Okay, so you had signed up for a study where you knew vaguely what you were going to do (over-talking).

S: Yeah, yeah, but then the sessions like what we were going to be doing in each session.

HC: Okay, so a bit more direction and objectives right from the start?

S: Yeah, but that might come with like just because this was a study, like you said, it might become with a bit knowing.

S: I think the issue was as well, we were all so busy in the first semester, we'd got so much other stuff to think about, I'm speaking for myself here, I felt that this kind of stuff went on the back burner while I was finishing doing course work, course tests, sorting all that stuff out up until Christmas, it was at the back of my mind and when a workshop was coming up I'd think oh, shit, I need to do it like the day before, I need to read over this stuff again rather than it being fresh in my mind all the time. Where I think it might have been a bit different if it was all in the second semester where we perhaps had more time because we'd just got projects, although they were a hassle, you've kind of got a little bit more time.

Murmurs of agreement.

HC: That's really interesting, actually that maybe the timing of it...

S: Having said that though I found that the organisation or just the constant emails and things like that helped me like keep it on my mind (agreement, over-talking) and just the general involvement by Rick (agreement) helped a lot.

S: Updating us... (agreement).

HC: Where did those emails come from? Were they from Rick?

Students: From Rick, yeah.

HC: Just keeping in touch with you?

S: Unclear.

S: And even just if there wasn't any new information just saying that they're sorting through some information or whatever, that it's still going on you know, we were still kept in the loop.

General agreement to this point.

HC: So it wasn't an annoyance?

General comments that this was a positive thing and was helpful.

S: The only other thing I'd say though about kind of moving it to later when it is project, I didn't feel all kind of maybe the staff in the department were kind of on board with it, because sometimes Rick would be like can you do this, can you arrange this with your project tutor and then you'd arrange it and they'd go well this is more important, you've got to make that choice and it's kind of a bit like when you're trying to do a study because you find it interesting but then you've got your kind of project tutor you know well this is your project, why aren't you focusing just on this, so maybe if all the staff, if it could be something where all the staff agree that time can be made for it, it would be better.

S: It's a time tabling issue then, isn't it?

HC: Did anyone else feel like that?

General agreement.

HC: Felt that you were a bit torn between what way your time should be spent, so perhaps a bit more support?

Murmurs of agreement.

S: Personally on my project we always had like Fridays off so if I ever needed to do anything I just would do it on that day if possible.

S: I think I was really lucky in that I had actually finished Rick's study by the end of semester one so I'd done everything, but I can imagine if I'd had to do like going out on semester two it would have been a real kind of like decision to make like I feel like I would have been more kind of felt like I had to drop out because of like the pressures of the project, my project, so.

S: Definitely in early semester two, I mean I was towards the end of semester two so at least it had calmed down a bit by then.

S: It was a really nice break from the project though, like (over-talking in agreement of this point)...

S: Yeah, because that's all you do, isn't it, it's kind of like you want something else.

S: Yeah, you're kind of stuck in lab start times thinking why am I doing this course and then you do something like consult with patients again and you go yeah, so personally I thought it was really good to do it.

S: I know it's difficult the get patients on board, the whole recruiting thing but it'd be really good to have more than just two patients or one patient just because I think it's something that is experience based learning and the more you do (murmurs of agreement) the more just sort of gets stored away.

HC: Okay, well that's great. I think it's given me a good flavour of how you found the study as well. We've talked a bit about the actual training you received and we went about that. What are your thoughts about the actual how prepared you were to then go and meet patients. So we've talked about



the structure of the training and how that all happened, the goods and the bads, but how prepared did you actually feel when you met real patients for the first time?

S: I felt that the session with the actors was the main session that prepared me because it was so realistic to what we were going to be doing, looking back in hindsight looking at when I was with my patient and then looking at the acting session before, it was a carbon copy, it was exactly what we were going to do so that was good. I don't think, personally I don't feel that the other sessions gave me anything more than what that session did, if you see what I mean, towards meeting them.

S: I suppose in a way that the other sessions were preparing for the actor session and then the actor session was then preparing, so personally I thought it followed a good route, but that's just how I felt.

S: I think the route was good but maybe if there'd been a bit more like follow on from each other because like we were saying having it the start of the year, because personally my patient sessions were right at the end of semester two so I think they would have been good preparation but I'd forgotten it all by then.

S: I felt my patient sessions were kind of different from my actors one because the actors ones had issues whereas the patients ones they didn't, I mean that's true to real life, it's not something that I was expecting maybe but yeah so.

HC: So, ?, you were saying specifically that the actor session was useful. Does anyone agree with that or disagree with that?

General agreement from all students.

S: Up until that point I was a bit like not really sure what I'm going to go in and talk to them about so it really helped.

HC: Why do you think it was so helpful? What were the skills and things that you learned from that?

S: I think when you normally do it with a student like we do in the workshop, obviously we're all in the same boat and I think we don't always mean to do it but I think students often prompt each other or you've generally got a script right in front of you and you're maybe just reading off your script. Whereas with the actor, it's somebody you've never met before, you don't know what they're going to say and you're having to like respond to their needs. I mean it was a little bit difficult with the actors because mine was supposed to be really obese and she was a really skinny lady but I forgot, I forgot she was an actor and I totally believed that she was the real patient and you do, you sort of learn to respond to their, and also to think on your feet as well a bit more when they ask you questions.

S: We were sort of observed as well by a member of like the pharmacy practice staff so and then they gave sort of feedback, you know you got feedback, did we get feedback?

General agreement from everyone that feedback was given.

S: We got feedback and yeah and there was a feedback session bit and I remember that being useful for like pointers of how you could improve and things like that. It was also reassuring when they said oh yeah you did well because you think okay maybe I can do this.

S: And you got feedback in between the two patients as well so I found that really useful because I did the first one completely wrong and then Debi said no this is what you need to do so then to then do the second one that was really useful.

S: And I think it was really good after we'd seen the actors that we got to see the GP afterwards who wasn't an actor, who was a GP, and so we got to kind of feedback what we would do in those situations and so that was good although I don't know that anybody got to feedback what they found to the real patients to a nurse or, I certainly didn't, I didn't see anybody after I'd seen my patients.

Various students hadn't seen anybody at the surgery after seeing the patients. Some had seen the nurse.

S: But our problem was she was the actual diabetic nurse so she knew everything already but it was still useful for her input.

S: I also remember that although if we didn't see them I think notes were made of some of the things they were going to bring up, so there was feedback we just didn't speak to them directly.

This point prompted a general memory in all students.

HC: How about, you had a chance to look at the patient medical records and sort of make a care plan for them before you met your real patients, did that help you? Did you feel a bit more prepared for what was going to...?

S: Yeah, it does prepare you, obviously that's when you've got to identify your issues but then again the gap was too big and I think that session was dragged out longer than it had to be, especially when it's like you have to write this down and it just seems realistically you could that in like 20 minutes, have a look at someone's records.

S: It was good to have like a background because then when you talked to them like it's you're not just like going in there blind, at least you've got some background of what the issues they might kind of pre-

empt you what they might bring up and things.

S: And it gives you an idea as to what you maybe want to bring up with them as well (murmurs of agreement), which is good.

S: I kind of disagree with that we could just do it in 20 minutes. I think because me and ? did it together which I was just going to say that I think doing it as a pair was really helpful as well because you weren't faced like all on your own, you'd find you could sort of like you could discuss it with each other, but I think we took quite a long time to get through (agreement from ?) because we have four patients to get through and we really did take almost up the full amount of time to get through the whole of the records.

S: And also it was a bit different in compared to what you do in the classroom. These patient all had other conditions and some of them we'd never heard of and it's trying to find out what they are and then deciding how that could affect their diabetes, so I think it just depends on how complex the patients you've got really.

S: I have to say I think I was the oddball in the whole group. Somehow the anonymisation with ? and I's patients got mixed up and I had somebody else's patient turn up on the day I was there so I had to very quickly look at a patient's records, I'm literally talking 10 minutes because she was in the waiting room, and try and find some issues to speak to her about. Obviously by that point system 1 was a complete, I don't, I couldn't remember how to use it so Rick had to help me, tell me what tabs to look on to look for things because I had to do it there and then because it was the wrong patient.

HC: You were thrown in at the deep end, really.

S: Yeah.

S: And had no one else, another partner to discuss (unclear – overtalking). No because I literally turned up to meet my patients that day and I got sort of all my notes ready, what I'd prepared, and when Rick looked and we'd checked date of birth and stuff and it didn't match at all, somehow things had got muddled, so I had to just...

HC: So when you met your patient, how well prepared did you feel?

S: For that patient, not very.

HC: And did you have a chance to have a to talk to another patient, did you have more than one?

S: Yeah, I had two patients, one was the right patient and the other one was I don't know whose patient it was meant to be and it did throw me. I mean fortunately she didn't have a lot of issues and she'd literally seen the diabetic nurse the week before so she didn't have any issues, but it was definitely very scary knowing that a patient was sat in the waiting room, waiting for me, and I hadn't got a clue about her background, I'd not had the two weeks to read over and make sure I knew what I was talking about and what I wanted to ask, so.

HC: And how about the rest of you (unclear)?

S: Yeah, a traumatic time.

HC: Did you feel that you had enough preparation before you met your patients? How well prepared do you think you were?

S: I felt prepared. I think for me it was partly I was really nervous because we've never done anything with a real patient before, so we've always been told kind of they'll talk on and on about something really irrelevant but you've never actually experienced that, you get there and it's really useful to have done it but I was really nervous. I think Rick helped because he ran through everything with me first because we were in the room where you can kind of bring it back and say that, I was nervous.

S: It's weird, I found like on the day when we had the actors that I was less nervous than when we do it in dispensary because the actor, or patient, doesn't know all the technical terms or I don't feel I was judged by my knowledge by the patient and I know that I need to simplify things whereas in dispensary if I get things wrong everyone knows (laughter). I found that more like a relief in a way. I found I was less nervous with the patients.

S: It's quite nice not having a marking scheme I think because like you can just kind of like you know it's just quite nice to just explore like different things with your patient rather than having to like follow a mark scheme and go through stuff so that was quite nice.

S: Yeah, it becomes quite rigid when you have the mark scheme (general agreement), you've got to get that to get more marks, etc, whereas with this it's just, it flows naturally (general agreement) it's just like I can talk...

S: Like, freedom...

S: ...yeah, yeah.

HC: ? you're agreeing with that. Did you feel that that was something that was a good experience?

S: Yeah, definitely. I think in the dispensary I like it's quite odd I just do it in any order and just cocked it

up (laughter), but yeah and then like oh I haven't said that but then with the patient you're like it doesn't matter because...

HC: So generally you felt a little nervous about going into that with the first patient. For those of you who had a chance to do it again with a second patient, did you feel that was then a bit better because you'd already got one under your belt, so the second one was a bit easier or was it not the case, was it all just a nerve-wracking experience?

S: No I think as ? said before you definitely felt a lot better just, I think it was so good to do this because you just feel more and more natural each time so I think next year I'm actually doing for real you just kind of get over that like really scary first ever time talking to a patient it does become a bit natural.

HC: Is there anything you feel that could have made you feel a bit more prepared for it? Maybe you feel as if you'd done everything you could it was just coming good on the day?

S: I think I might have felt more prepared if from going to the surgery and looking at the records and then doing your interview or your consultation with the patient had've been a shorter time, which I know that's hard because you had to go in when the patient was available, but I know for one of mine it was, when did we go and do our?

S: It was a big gap.

S: It was a massive gap, it was easily eight weeks in between and that seemed like such a long time I think when you're prepared to do something if you've got it all fresh in your mind and you go even two or three or a week after it's still fresh, it just felt like such a long time, and such a long time since we'd done the session with the actors, I don't know I think that's probably why I felt so nervous that I'd not done it just a few days before.

S: I think at least the notes that we saw wrote out was tailored so that we could look at it and then think you know this is the key things we need to ask them and then we had the clinical management plan as well so that sort of helped us to structure what we were going to say to them before, so I think that helped a lot.

HC: Would you agree with ?'s comments?

Several students agreed.

HC: We've talked a little bit about how you actually felt when you first met your first patient. What were your expectations before you met your first patient? Did you have a certain expectation?

S: I wanted to be able to answer like their questions and stuff but sometimes like they put quite like challenging questions and I found myself like Rick, help me. I wanted to be able to help them and like I wanted to be able to find something that I could kind of help them because I didn't want them coming all this way and then like them just be like know everything and it's a waste of my time. Because one of my patients she like she wasn't very pleased that there was nothing wrong (laughter). She said that like because she was, what do you call it when they're part of like a group that's like, oh I can't remember what it's called, but she said that because she got the letter saying she was like part of the group she thought that that was because she had issues, but like she didn't so I like felt really bad for her, but so yeah I really wanted to, I expected myself to be able to answer their questions and you know respond to anything, their needs and whatever needed changing, but yeah I felt really disappointed when I couldn't for her.

S: I think that's another thing we can gain from the study, the fact that every patient we see we're not going to be able to make a massive difference like obviously we want to, but it's something that we have to learn that we can't constantly be solving every problem and you know be a massive help, but we've still got to approach each patient in the same way so keeping that consistency is something, that's why it's good to have a lot of different patients if possible.

S: Yes, I think sometimes though looking at their like the lady who didn't have any problems like I think I could've told that, like said that from looking at her things because she's on hardly any drugs, got hardly any conditions. I think I could have probably of predicted that she wouldn't have any issues so I don't know whether it was worth like then having a consultation with her if there was you could have kind of predicted it, I don't know, you've just got to weigh it up.

S: I think with like one of my patients as well it wasn't so much that he'd got the issue, his wife had got the issue with him having diabetes and it's very hard when you've got no relationship or prior relationship with the patient, I didn't know his wife because obviously she hadn't come and it's very hard to make suggestions then without knowing the rest of the family situation or building up that relationship as a doctor or a normal pharmacist may have with a patient, so although I could make suggestions whether they were actually any use or not it's hard to know.

HC: Okay, that's interesting. So do you think it should have been open for them to bring a partner with them?

S: I mean possibly I mean it would be different in you know in practice because you would've built up that relationship with the patient and you might have known his like wife as well, it is hard as a student just going in on a one-off situation.

HC: Anyone else got anything to add to that?

S: I think like it is worth, even if you think from their records that they might not have any issues, is it still worth speaking to them because I had one of my patients he said something about, he was talking about when he took his doses of metformin it turned out he was taking them, what was he doing? Yeah, he was taking them before, yeah he was taking them before he'd had his food and you're meant to take them like with your meals or after and he didn't realise that so that wasn't recorded on his notes but when I actually spoke to him about it then that kind of came up and then I could say to him oh you know you're meant to take it with your meals because that's how the drug work kind of thing. So it is useful to actually speak to people because then they sort of say things but they might not be written down, so that was useful.

S: I think that's the other thing actually. I think quite often when we've done things in dispensary apart from maybe responding to symptoms, everything is about collecting information, it's not about using the information to make a change so it was quite nice to maybe collect things and then thing oh actually you could do this and give a kind of possible something they could do, but then it was also building up that confidence to the ideal of what they should do and actually say it rather than be like oh should they be on this? Shouldn't they be doing that? Because I think mine had like really bad constipation and he'd been on so many different things for it, but it turned out that it was actually something he was getting like over the counter that worked so we're like can we pass that on kind of, maybe we can get that prescribed for you, but actually thinking like oh let's actually make the change rather than have just collect the information and pass it on. That was quite good.

HC: So do you think you did perform well?

S: They told me I did (laughter), but I don't know if that was an actual like, I don't know. I can see, I can reflect on it and see how I could have done better kind of thing and you know there's Rick and the other lady who was sort of watching me do it, they said the good things that I did and then perhaps some of the things that I could improve on. Though I did feel that they were very nice like I felt that it should have been like more harsh (laughter), like more kind of constructive, I think they could say tell us...

HC: So you think more critical of your performance than perhaps they did?

S: Yeah, I think that's probably your way, is you're always more critical of your own performance because but yeah.

HC: Generally, do you feel you did well then?

S: I think it sounds really bad I think it sounds like you're blowing your own trumpet but...

HC: ...it's hard to do...(laughter)

S: ...I know, think I did okay because I think we are so hard, we're examined so hard in pharmacy practice to those damned marking schemes that like there is room to manoeuvre like you were saying to just flow with it and you don't have to stick to that particular sequence of how you should say things and so we managed to get the information across and got the information from the patient, it might not have been in the same order as what pharmacy practice would like in pharmacy practice you know dispensary sessions, but nevertheless the end of it is that we got the information that we needed and they received the information that they needed, so in that respect I think we did, you know I'm sure we're all very capable and we all did well.

HC: I see lots of people nodding (laughter and general agreement).

S: And it's good to gain confidence from it as well because I know I feel more confident talking to patients and stuff.

S: I'm not sure though when you when the patients mark like how well you did and stuff I feel like they thought it was a bit like that I was going to get, that something was going to happen to me if like and they were like oh don't worry, love, we'll mark you good (laughter) and I was like I don't mind like if you don't but I felt like they thought that something would happen to me if they marked me bad, so I don't think it

was like a true reflection.

S: I don't think they should have, they had to do it immediately after we'd finished talking and I had to fill out mine. I think they should have been sent it (some agreement to this) like you know in the post afterwards, maybe then you have the disadvantage of they're not going to send it back, or maybe just go out into the waiting room and fill it out...

S: ...yeah, they shouldn't be sat opposite you (over-talking in agreement)...

S: ...so I felt like they felt you know I don't know like maybe they did think it was great but I don't know.

HC: There was something I wanted to actually ask about so it's quite good that we've moved onto this. So you were talking about the questionnaires now and the patients had to mark you, what do you think about the scores you gave yourself first of all?

General murmuring.

S: I can't remember, but I think I would definitely have marked myself harsher maybe than what they gave us.

S: It's like ? said, you're always more critical of your own performance (general agreement to this).

HC: So how do you think the patients scored you?

S: They were just giving us all fives (laughter and agreement). Patients scored you really high and that they just thought it was a really nice thing for us all to come and have a chat with them, they just really enjoyed and said oh we'll give you five (laughter).

S: It's like a nice day out for them, isn't it? (Laughter.) It makes a change.

S: It's also that element that we were sat there when they were doing it and if they obviously thought it was kind of going to affect our marks somewhere, so maybe if they had gone out or been told that it didn't affect our kind of overall grade or something it might be a bit more realistic.

HC: They might have felt a bit responsible that you may fail your whole degree...

General agreement.

S: Yeah, because I think they saw it as though like really important coming in to talk to us as well, oh we're part of this, so...

HC: Do you think then the patients came in with a certain expectation of how you were going to do?

S: I didn't think they did really. I think they came in knowing they were going to talk about, well I guess, it was primarily about diabetes, but mine actually ended up not really talking much about their diabetic medicine. I think they just thought they'd have a bit of a check on their medicines and they're helping us more than anything.

S: I don't think all of them fully got why they were there, to be fair (general agreement to this), because I think they just turned up and like what are we doing today like yeah, so I think they need to be a little bit better informed, like you said she just turned up because she thought she had something wrong (unclear) if she thought she was okay she probably wouldn't have come (agreement to this) so we just kind of roped her into it (laughter and agreement). So I think that maybe, obviously I don't know what sort of communication was given to them from the beginning but I think (unclear) from this whole experience.

S: There were a lot of kind of you know slightly older patients that do that do like to come in for a chat as well (agreement and laughter) and I that was something I did find quite hard was just getting the information needed from them it's like one gentlemen I was like so tell me about your diet, he literally told me everything he ate and we were there for about 20 minutes (laughter) (unclear) a skill that is quite important for us to learn is how to get the information that you need...

S: ...yeah, really good at that just cutting them short a little bit like they've been talking for so long you think like just leave please (laughter).

S: Yeah, one of mine I was like oh do you eat any fruit and veg and he literally listed like every piece of fruit that he liked and which ones that he didn't like (laughter).

S: I kind of felt that my patients were a bit disappointed when they left in the fact that because they had no issues they were expecting to come and we were going to wave a magic wand, the diabetes would be gone and that was the end of the story kind of thing and because they had no issues and there was really nothing we could do, they were adhering to the medication and there was you know their blood glucose was being kept moderately low, well the hbacs were okay, we couldn't do anything, so then I think they felt a bit disappointed they were coming along to this thing and you know whether they thought there was going to be a new fabulous treatment or we were going to be able to tell them something that was going to radically change their lives and we didn't and so I think as much as they appreciate coming in and having a bit of a natter and maybe giving them some pointers, for my patients, it didn't make a difference to their lives...

S: ...anything picked up was so minor...

S: ...yeah, it didn't make a difference to their life. I think they perhaps their expectations were that that was what was going to happen in that session.

HC: Because really the purpose of the thing was for us to learn not really for us to do anything for them so whether they knew that, is that what you're saying?

S: Yeah.

S: I think there was a small element though of we were looking at things and I don't know I actually only saw one patient in the end but I did look at two records and on one of them I remember thinking why is that still on there this hasn't been changed in years, so maybe not so much with the patient but looking kind of more for the doctor for us to like oh have you not reviewed this patient, have you not thought about why they're on this drug, you know what should be done about it, so maybe it's more kind of behind the scenes stuff which the patient doesn't really get what we're doing (murmurs of agreement).

S: I think sometimes as well it is very dependent on the patient, how long they've had diabetes, because one of my patients has had diabetes for years and he'd become convinced he couldn't have any sugar of any kind at any time and so for him it was quite useful then to talk maybe a bit more about his diet which you might not have done with your GP, whereas but then I agree with my other patient, I don't think he really know why he was there and I think he'd of probably felt it was a bit of a waste of time so it probably is just very patient dependent.

HC: What do you feel that the patients did benefit from coming to see you or do you think it was more...

S: ...definitely more swayed towards us like learning and picking stuff up...

HC: ...they were coming to assist you rather than the patient coming for any sort of benefit on their part?

S: Yeah, the issues raised I don't think really warrant like a consultation at all.

S: I think a lot of the issues raised could have just been done without the patient being there, maybe us just talking to the doctor...

S: ...yeah, often you can't get the full story from the records and obviously they might have told the GP something and GP's changed it accordingly and we just don't know it because it's no one's labelled it, but yeah I don't think they need to come in for that necessarily.

S: The other thing I found with both of my patients is I don't know whether the doctors were aware that they were coming in and seeing us and what they were seeing us about, but both of them had their diabetes medication checked the week before I saw them, so what was the point? Do you see what I mean? And the changes that we'd picked up on in you know in the previous time when we went in and looked at the records, they'd already been sorted out because the doctor had seen them the week before.

S: But when we went in to do the care plan, wasn't a copy of that then given to the doctor?

S: The nurse.

S: I think a copy of what we'd come up with was given because when I went into my actual one I had a copy of it with her comments on it as to why things were...

S: See I never got a copy back of any of any of the stuff.

S: Did you not? Because maybe your copy was given and then that's why the nurse changed the meds oh we need to do something, but I did have something with comments on...

S: ...oh yeah, after your initial one?

S: ...yeah, trying to justify anything so I could bring it up if I still wanted to.

S: I think ideally the patients would be picked based upon maybe if they had any issues that we could sort out and if they hadn't had a consultation for a while but obviously this was quite dependent on Rick needed patients and it was kind of just I don't know if it was just whoever would do it really and maybe they were the ones that were more adherent because they're the ones that are more likely to come in and talk anyway.

S: I think maybe if we'd had a specific population group, so maybe newly diagnosed patients because then we maybe of checked what their adherence is like, how are they finding adapting to this new routine and maybe then they've had time to think of any questions.

S: Logistically that's a nightmare though (murmurs of agreement). Rick did his best to be fair, quite good.

S: Again for us it was so useful because we don't get like patient contact (general agreement) so you know it (over-talking) really helped us.

S: There were really good, useful consultations so...

S: Yeah, I mean there may not have been any issues but there's always the chance that there could have been issues (agreement) so it was still useful in a sense for them just as a sort of screening process you know just to see if there's any issues that, and even just to have a different person to speak rather than the doctor, because sometimes people don't relay certain information or think certain things are important so I think it was useful for them in that sense.

S: Maybe it was up to us a bit more to explain the purpose of the conversation and not kind of say we're here to sort everything out, we're kind of here to have a chat (unclear – over-talking).

HC: Do you think that had been said when that person was recruited or you don't know?

General agreement that they didn't know.

S: I think definitely with my first patient I probably didn't explain enough I suppose in a clear manner like why we were there. I think I definitely improved that with my second patient and I probably got more from him for that reason.

S: I think when you lay it out what you're going to do then they're not going to be disappointed when you do what you're going to do (laughter)...

S: ...Lower the expectations from the start (laughter).

HC: Do you think they might have been disappointed with the consultation?

General chatting from patients that they weren't sure and didn't feel they could generalise.

HC: Do you think they would come back again if you asked them?

S: If you did it as a follow up with a big enough gap, possibly yeah.

S: Yeah, you couldn't do it so soon...

S: ...Like next week, yeah...

S: ...so yeah, you had no problems then (laughter) do you want to come back and see if you've got problems now, but they seemed, well my patients were quite friendly so.

S: And like because we have placement at GP surgery you do see like how fast they just, like they wouldn't have time to discuss the stuff that we discussed like they can just put them on another drug or something like that but they don't really have the time to like talk about their condition, I guess sometimes they might just to kind of talk about it and maybe they just you know like someone to talk about it with and like it's good maybe for that from that perspective.

HC: So do you think that the patients that you spoke to had formed an opinion of what was going to happen in that consultation based on any other experiences? Do you think they'd spoken to a pharmacist or perhaps their diabetes nurse or GP?

S: I don't think they really knew what was going to happen.

S: Well they may have had pre-conceived notions of what might happen, yeah, but I think that they came in, I don't really think that they knew.

S: I think mine had forgotten anyway, he was only there because his wife had an appointment and Rick saw him out the window (laughter - unclear), so he just seemed really vague and wanted just to have a chat with me whilst he was waiting.

S: And quite a lot of people don't really know what pharmacists do anyway like they're a bit like aren't you meant to be given out the medicines (unclear – laughter).

S: Maybe because it was in a GP practice, they maybe didn't understand what the purpose of it was because they thought like it's not like a GP consultation was it?

HC: So you think maybe the environment might have changed?

S: Possibly.

S: I think going back to what ? said, I think a lot of patients maybe don't know that pharmacists have this kind of knowledge and so it's kind of a good process to raise awareness (laughter) that they can go to the pharmacist and talk about these things (general agreement) not just picking up issues in that one session and maybe they're opening up future conversations with the pharmacist, so there's always that.

S: Going off from ?'s point, one of my patients came in and told me she was on a load of these herbal tablets and chucked all these herbal tablets all over the, you know like dandelion flower and it was like are any of these going to interact and both Rick and I were like erm we'd have to look it up (laughter) we don't know, so in that respect, as a pharmacist, we were both like we don't know enough about herbal meds to know if they and equally we all know herbals meds are made of kinds of weird and wonderful things and so...

S: ...It's a good CPD point, isn't it? (Laughter)

S: ...and we're like we'll have to get back to you about that kind of thing, so in that respect we were a bit bowled over because I suppose you wouldn't, I don't know, you'd see a little old woman coming into a pharmacy to the desk and say is this going to interact with all my meds, so it's a good chance for her to, the doctor wouldn't know so she'd never ask the doctor, she'd never told the doctor she was taking any of these things so...

HC: But she obviously felt that it was okay to ask you?

S: ...it was an opportunity for her to come and ask about that so yeah that was good for her.

HC: You really were thrown in at the deep end weren't you? (Laughter) Okay, so just going back because

we started off talking about the questionnaires and the whole scoring system, do you think those scores that you got from the patients, and the scores that you gave yourself, were a real, a true reflection of your consultation?

S: It was only average (unclear) the best like marker to see how we've done and like you said we were probably a bit harsh on ourselves and they were probably a bit too lenient.

HC: So you under-marked yourself?

S: Yeah, yeah, need to find a happy medium between the two would be spot on I reckon.

HC: But was that, do you think it was a good thing to actually have the questionnaires or do you think that they are going to be so biased that the questionnaires...?

S: Maybe if we'd been marked by Rick and the other lady, it might have been more useful because I don't think I really took much notice of what I gave myself and what they gave me (some agreement), I couldn't tell you now how I really did I don't think.

S: Maybe the patients didn't know enough about this thing to give any criticism so it wouldn't be useful but like if Rick had marked us there would be like genuine pointers to improve on (some murmurs of agreement).

S: He gave us feedback, didn't he?

Murmurs of agreement.

S: Yeah, towards the end about it, yeah, that was good, that was helpful.

HC: The feedback was probably more useful then and what the patients said?

S: Oh yeah, it was really helpful for the OSCEs stuff as well I think just the whole process was incredibly helpful for that and yeah the feedback they'd given at practice sessions yeah.

S: I think, when we were with the actors, I think the actors' feedback was quite realistic because I mean they do it a lot more.

S: Yeah, they do it for all the medic students and stuff so they're quite clued up with this sort of stuff, yeah so that was good.

HC: Oh what you mean the actors scored you?

General agreement on this point.

S: My one got really moody at the end of the day though because like Dr Grassby said that she was wanting to go home so I don't know (unclear – laughter over).

HC: And I think ?, you mentioned about having the consultation in the GP practice, do you think that is the best place to hold that kind of consultation?

S: Maybe a pharmacy would be better because then they'd be like oh I'm going to the pharmacy, pharmacist in the pharmacy and so they'd like know where to go to like talk about that kind of thing so I think it wouldn't always be in a GPs, would it?

S: I don't know whether in a pharmacy though they'd like want to talk because like I remember when I was in Boots once and then there was this man and he was like oh would you like to talk about your medicines and he's like NO, he was like really annoyed, he was like I talk about it to my GP I'm not discussing it with anyone else and marched out, so I imagine you get that in pharmacy a bit because people think it's like a shop I don't want to talk in the middle of a shop just about anything, so maybe I don't know whether a pharmacy might be a bit like I don't know whether they'd come, I really don't know.

S: It's because the patient doesn't really have a sort of personal pharmacy whereas they have their own GP (general agreement) where their information is, where their trust is and then having them come to the GP earns a sort of level of trust I think, so that helped in that respect.

S: If it could become a regular thing that there was a pharmacist at the GP surgery then it would work, because I think the other thing is you get, because if I was to go to a pharmacist, even though I know what we can all do and I wanted to know about my drugs I wouldn't ask or expect to get out of it what we were giving kind of those patients in the doctor's surgery, I'd expect it to be much more this interacts with this, you should take this then, rather than discussing maybe what I should be on and am I still getting pain, is this actually kind of working, I think what we were kind of trying to give them in the doctor's surgery is quite different to what we would probably normally give in the pharmacy any way so it's getting kind of maybe that to be a regular thing in the doctor's surgery and people know that that's somewhere that they could go.

S: But then again, it's just about changing people's idea on where you can get this advice and where you can go and yeah people just don't realise that we can actually help them a little bit.

S: People just don't really know what pharmacists do (agreement to this).

S: I'm only a (unclear) (laughter).

HC: Okay, that's really interesting. I think you've really hit on some important points there as well that



hopefully will be good for Rick to hear too. Do you think that other students in a similar position to yourself should undertake some training like?

General agreement to this point.

HC: That's all pretty unanimous, isn't it?

S: There'd need to be some tweaks like that we've discussed but I think once that's kind of I think it would be really useful, yeah.

S: Any opportunity where you can practice communication skills, especially with real patients like I think you'd be mad not to do.

HC: Unanimous then?

Murmurs of agreement.

HC: The kind of the set up, the idea of the whole training, I know we've talked about the ways in which it could be tweaked maybe improving things that did and didn't work but that kind of set up would be a good way for other students to learn as well?

General agreement.

HC: Did you feel supported enough through that whole process?

Again, general agreement from students.

HC: That is something come up that you were really uncomfortable with, there would have been an opportunity for you to flag that up as well? (Murmurs of agreement.)

S: Rick's always been you know we joked about it just saying about coming out of the study but he's always said if you don't want to do it, just that's fine, he's always made that perfectly clear that we can drop out whenever we want if we're not comfortable or we can go to him if we've got a concern and I think that's been really re-assuring all the way through, and he's so jolly all the time you know you can't help but not if you've got a problem not go to him because you know he'd understand.

S: He was really nice like when we couldn't make sessions because of our projects and stuff and I'd always email him and say I'm so sorry, because I didn't like letting him because he's so nice, but he always just said look it's fine, we really appreciate you doing this and we know it's really hard so yeah it was really easy.

S: I think also that the fact that he did email us so much and kind of kept that constant contact made us feel supported because we always knew what was going on so that really helped as well.

S: Yeah, I remember when I was really late because my taxi wasn't there I just gave him a phone call on his mobile and he picked me up and took me there, I thought this is so cool (laughter).

HC: I think he's probably changed his number since then (laughter). Have I missed anything from my list?

SW: There is one thing, we were talking before about the motivations you all had for doing it, how far would you say those motivations were met at the end of it?

S: I think I got what I initially wanted out of it and I also got to put some stuff in my portfolio so that was always useful, but I was, I am really glad I did it (murmurs of agreement).

S: For me it was another experience, isn't it, we've gained proven the course which you can't really take away now so extra skills learned and it would have helped us all in the OSCE.

S: Yeah, I'm more confident for next year.

S: And I think it probably did give us kind of that advantage over people who didn't do the study because we'd just had that little bit more practice and that little bit more feedback from everyone.

S: I mean I think even before the study because we knew last, in our third year we were talking part in it, I mean I talked about it in my pre-reg interview and even from that point I think it set us apart maybe from other students, saying we're going to be doing this in our fourth year, or I've had this experience, it is just so unique.

HC: Yes, of course, because obviously you've all done this voluntarily, you've put yourself forward and done all this extra, if students didn't have that option, that it became part of the course you have to do, do you think the whole experience would be different?

S: Rick's actually said a little bit about this to me before and I think the way that, if it was part of the course it would be timetabled in so it'd be much easier rather than you'd have people saying oh no you've got to choose whether you go and do your project, it would just be part of it so it would be much easier.

S: You certainly wouldn't get the free lunch, would you? (Laughter)

S: But you'd still definitely get out of it what we've got out of it and it would probably just be that little bit easier for them to do.

S: I think they would get certain skills and stuff but I think I kind of like the fact that it was something that we were sort of volunteering for and it was something very new, it just felt like we were part of something...

S: ...yeah, like other people would ask like where you going and I'd say I'm going to my study (laughter) I liked that feeling.

S: I do think though that if, I don't think that if you'd have done it in a younger year we would have appreciated it as much as we have (general agreement) the experience. I think if we'd of done it in third or second year, we might one not have had the knowledge or the skills enough to do it but I don't think like we all say now we all really appreciated how much it helped us during OSCE and what we're going to take forward, it's still kind of fresh in our minds for when we're starting pre-reg and we'll be doing it for real. I think it was in a younger year, they haven't got the knowledge and skills to appreciate how important and how much of a great opportunity it is.

S: I think the key thing is doing it after third year (murmurs of agreement), when we gain most of our clinical knowledge and are able to utilise it in the consultation.

HC: And although it is hard work for you guys because you're trying to fit it in and it pressurised you in a way, you think it is well worth doing it?

Agreement from students.

S: And it was ideally timed (again agreement).

S: I think it scared us but we've probably got that little bit more confidence as well ready for next year, like it's kind of proved to us that we do have gained all this knowledge and we have got quite a lot out of it.

S: Because there's only a certain level that you can go up to when you're with an actor, it's like once you feel, I felt like I was kind of like pushing myself, well I felt like I just wanted to do for real because you don't really know how it feels like to do it for real, then it was good to actually be with a patient and do it.

HC: Okay, is there anything else that I haven't asked you about that you need to tell us about, that we've not discussed? Or are you happy? Is there anything I've forgotten, Steven?

SW: No.

HC: I think it sounds quite inspiring what you've told me and that you've got so much out of it, I think that's probably the great thing and thank you for being able to share that as well. Thank you for your time.

General thank yous from students.

## PCT Pharmacist Focus Group Questions

1. Can you tell me your general thoughts about the study where pharmacy students undertook medication reviews with patients.?

Follow on:

Expand.

Explain

How could that be improved?

Good idea or bad idea

2. If you were involved with the session where students met actors/patients do you have any thoughts on this?

Organisation

Location

Logistics

Time available for consultation

Time for feedback

What are your thoughts about using actors

Quantity of staff available that day.

Stress for students

Real or not

3. What are your thoughts about the sessions where students accessed medical records and made care plans?

Were they prepared.

Time

Location

Supervision

Was there any benefit? If so what and for whom?

Care plan – electronic or paper?

Knowledge

What are your thoughts on patient benefit from this exercise?

4. What are your thoughts about the session where students met patients for a consultation?

Student preparation

Patient acceptance

Any benefit?

The feedback session

5. What are your thoughts about the competence and/or confidence of the students when undertaking the consultation with a patient?

Suitably trained?

Did they need additional training

Communication

Location

6. Do you have thoughts on repeating the exercise?

Should it be repeated? If so change?

If not why not

Logistics.

Time

Pay for you.

7. Is there anything that you want to add to your previous comments? Are there any questions that I have not asked that you would like to raise?

Transcript of Interview with PCT Pharmacist on 30 July 2012

RA: The first question is a general one, so can you tell me your general thoughts about the study?

P: I thought it was very time consuming for what it managed to achieve.

RA: And time consuming for who?

P: For everybody. There was lot of travelling and waiting around for everybody.

RA: Could that have been avoided do you think?

P: No.

RA: And if there was a lot of time spent, do you think it was worth doing it?

P: That's what I'm not sure about, whether it would be worth doing it with the real patients in the practices. I felt that they learnt an awful lot more working with the actors.

RA: Okay, so we'll come on to that in a minute, then. There was a lot of waiting around, you said you thought it probably couldn't have been avoided.

P: No, it was just circumstances.

RA: What if we, for instance, had managed to get say, I don't know, a larger number, six or eight students, out to a practice at once, would that be of benefit or not?

P: A lot of the problems were because we only had small numbers of patients. I don't know whether the other practices had more and were more efficient, but because we only had small numbers of patients then we could only have a small number of students at any one time. But there was also several no shows, so you'd get an hour with a gap.

RA: Okay, so therefore, it's not so much a matter of, am I interpreting correctly? If we go through the different people that, the patients' time, is that okay?

P: The time spent with the patient?

RA: No, the amount of time spent by the patient.

P: Do you mean the length of time with the interview?

RA: Well, you were saying that a lot of people had to spend a lot of time, so do you think the patients had to spend too much time?

P: Ahh, no not really, I think it was quite efficient for the patients, there wasn't a lot of waiting around for them because if there was a bit of overlap we were lucky in that we had two pharmacists available so one went off to debrief and the second one took over.

RA: Okay, so really it's, okay let's work...

P: ...I thought it was inefficient for the pharmacists and the students, but not for the patients.

RA: Okay, fine. So therefore what is your opinion on do you think it's a good idea or a bad idea to undertake it?

P: I don't think the students got any more benefit from talking to a real patient than they did to an actor with a contrived situation.

RA: Okay then, so let's go on to that. So what are your general thoughts about the session with the actors?

P: I thought they were exceptionally good and I thought the students learnt an awful lot.

RA: Okay, so when you said they were exceptionally good, do you mean the actors?

P: Well, yes the actors were good. I just thought the whole thing was very profitable for the students.

RA: Was there anything in particular you thought was good about it then?

P: The efficiency of it, the way you'd constantly got it moving and there was a continuous stream. The only thing I would have said against it is that it was too efficient in that there should have been a bit more time for talking in between.

RA: I was going to ask about logistics and time scales in it, so what are your thoughts on the amount of time available?

P: With my student I found that I had to, after the first one or two students, I had to explain to the student what they were having to do because the first couple of students just thought they were coming in for data collection, so I needed to explain to them what they were then going to go on and do with the actor. I asked them all if they wanted feedback and each student, every student I asked, wanted individual feedback, there was no time for feedback and also, at the end, when I'd filled in the MRCF form, there's no explanations on the MRCF form, so I really felt the need to explain if I'd marked them low on a particular place, why I'd marked them low on that particular thing. Think of an example and it's time keeping, I needed to explain why I'd marked them down on the time keeping and because there was no time allowed specifically for debrief at the end and briefing at the beginning, I found that I was constantly chasing my tail trying desperately to keep up with the next student coming in.

RA: So, okay, there's several issues there. If I take the first one that you mentioned, the briefing for the students beforehand, should they have been given more briefings, is that what I understand from what you said?

P: They weren't aware that they were going to go through and do more than data collect, they weren't aware that they were going to have to give advice and if there were problems to try and sort the problems out. They just thought that they were coming in to collect the data off the computer and then collect more data from the patient, and write it down.

RA: Do you think there would be benefit from giving more information to the students in advance?

P: That would solve that one problem, yes. But I don't know whether it was given to them and they haven't actually registered it or whether they haven't been given it, but they didn't really appear to know it.

RA: The important issue is that they didn't know it, you know, for whatever reason. Okay the next thing then is the feedback. So let me ask, firstly about the feedback, do you, do I understand from what you said that you think feedback is useful?

P: Yes. Every student, that, at the beginning I was told that the students had been asked as a group whether they wanted feedback and the agreement was that they didn't want feedback. I personally, being a rebel, felt that it might be helpful, so I actually asked each one individually whether they wanted feedback or not. Every single student wanted feedback, individual feedback, so giving the feedback after the first session, after the first actor, invariably they were so much better on the second actor.

RA: And do you think there's a set amount of time that we need to put aside for feedback?

P: I can't remember what the exact timings were but we had a sort of a break of however long between the sessions for us to do things like go and fetch food or toilet breaks or whatever and I found that I was using that, but it was a rush, so we need a bit longer than that for the feedback, sorry I can't remember what the exact timings were, but if you could add an extra five minutes on to those times for feedback and then give us time for our own time as well.

RA: What about the amount of time available for the consultation with the actor?

P: That was about right, they fit that one in quite nicely. Some finished early and some were struggling to do it but it was about the right time.

RA: And you mentioned the MRCF, was it the right form to use or should we have used something else or was it of any value?

P: The MRCF form, it probably is the right form because it's an official form, it's a recognised document, got all the things on that you're looking for, but it's not self-explanatory, it's just tick boxes so if you just give that MRCF form to the student, they have no idea what they've done wrong, it doesn't give any explanations.

RA: Okay. What are your thoughts about, you've already mentioned the actors, what are your thoughts about the presentation by the actors?

P: They did a really good job. They were very believable.

RA: Okay, that was really almost going to be my next question. Did they come over as real patients?

P: They did, yes, they were really in the part.

RA: Okay...

P: Or certainly the ones that I had were.

RA: Fine, and do you think they had enough of a script or a like a life story?

P: Yes, they pulled it out at the right time as well, as a real patient would.

RA: Okay, so my interpretation of that is they were professionals?

P: Yes.

RA: Okay.

P: Probably better than a real patient, to be honest.

RA: Okay, in what way?

P: Well I suppose in that they had a story, whereas a real patient very often didn't have a story and there was nothing the student should be looking for really that was just a yeah okay, there's nothing there, whereas at least with the actors there was usually a string in there for the student to hang on to.

RA: Okay, that's an interesting comment because if you felt the real patients didn't have a story, should we have a good story for the actors?

P: If you want the students to learn anything, yes. A lot of real patients don't have problems, so you know you keep getting these no problems, no problems, no problems and the student isn't really learning anything from that.

RA: Okay. We've talked about the time available, were there enough staff on duty or available in the session do you think? Or were there too many?

P: Are you talking about at the university now or in the practices?

RA: No, this is still the session with the actors.

P: Still in the session, oh yes, there seemed to be enough staff on.

RA: Okay. One issue raised by some students was that they felt that the day was very stressful. Do you think it was unduly stressful?

P: It was a bit like an exam situation for the student. I think they felt that it was an exam situation rather than a learning situation.

RA: And is there a way that could be improved on?

P: Erm, I think it's steps into the unknown, so they're not going to be taking it comfortably, nobody likes going into the unknown. One possibility is if they haven't got their particular professors in charge who they're trying to impress, that might help but I wasn't aware of that at the time, it's only now that you ask the question, you know, possibly they're nervous because their tutor are there, whereas if they were complete strangers there then they might be less nervous. I don't know, I don't know what the relationship is with students and staff.

RA: Again, that's another interesting thought that, so do you think, well for example, people such as yourself, do you think that the students would have performed differently in front of say yourself rather than a lecturer or professor or...?

P: I think so, yes, because they're never going to see me again. It's like you tell strangers your life story but you wouldn't tell them to friends, so I think maybe, I would be less threatening than a staff member who they're going to see the following week.

RA: Do you have any other thoughts about the session with the actors?

P: Not that I can think of at the moment.

RA: Okay. If I move on then to the sessions at the GP practices where the students accessed the medical records and made care plans. Do you have any general thoughts about that?

P: They accessed the records and very often missed obvious things.

RA: Do you have any examples that you can remember?

P: Ahh, such that the diabetic patient wasn't on an ace(?), they hadn't noticed that a patient had just been into hospital and come out again on the records. Sort of really quite glaring things that would ring bells for me, but they didn't even notice. A person who was on huge numbers of ventelin(?) inhalers, it wasn't anything to do with the diabetes, but it was something that leapt out at me whereas they didn't even notice it.

RA: I can remember that patient, yes. So, thinking that through, is it a case of maybe that they weren't sufficiently prepared or that because they were in the real world they weren't tying together different skills or bits of information that they had or maybe even another reason?



P: I'm sure it was just lack of experience.

RA: Okay, no that's interesting. So...

P: And they need to do more of this to get more experience.

RA: Yes, okay. That was what I was wondering. I didn't want to ask you the question, but I didn't to lead you.

P: The more they did, the more experience they would get and the better at it they would get.

RA: Okay. Was the...

P: But doing it that way I don't think is beneficial because it's just too manpower intensive.

RA: Is there a better way of doing it, or is it just as we said earlier, just too time intensive?

P: I can't think of a better way.

RA: Okay. The amount of time that we allocated for each student to go through the records, do you think...?

P: That seemed to be about right.

RA: Okay. What about the location? Was it right to undertake this in the GP practice or should it have been elsewhere?

P: It's got to be in the GP practice for the access to the records, hasn't it?

RA: Although currently, I don't know what will happen in the future, but at the moment it could have been accessed at the PCT.

P: System 1 at Lakeside, yeah, I suppose if you could have practiced with System 1.

RA: But do you think there would have been any difference in the students learning or interest, whether it was in an office or at the GP practice?

P: Although, I mean Paston is the only one I can talk about, although it was at a GP practice, it was in the coffee room so it might just as easily have been in the PCT, but that then makes it more difficult for the patients to get there. The patient will quite easily go to their own surgery, but they're not going to be willing to go somewhere else.

RA: Okay. Maybe I'll ask about that in the next question. If I could ask about the supervision? Was the supervision, or the level of supervision available, about right, too much, too little?

P: It was, yeah, I don't know.

RA: That's okay, not a problem.

P: Yes, I would like to say it was enough that we needed that many but on several occasions we had two pharmacists there with just one student and that just isn't practical.

RA: No? Okay. Do you think there was any benefit from that particular session for anybody?

P: The students did learn things from it, but not enough to benefit all the man hours that were put in by the patient coming in and the two pharmacists who were there and the taxi fares to get them there.

RA: Okay. The care plan itself, originally we started with an electronic version and students seemed to like to work eventually, we found, with a paper version. Do you think we should have stuck with the electronic version or do you think the paper version is as good?

P: In real life we use electronic versions so I think it may have been a good idea to have encouraged those any way because in real life we're actually emailing them between technicians and pharmacists and you need to have it as an electronic version to that.

RA: Okay, so you think really sticking to the electronic version would be of value?

P: But having said that, if they've got the patient in front of them, they can't actually be typing into a care plan electronically, they really do need to do it by pencil while they're talking to the patient, because there's nothing ruder than just stilling typing while the patient's there in front of you.

RA: Fine. Thinking about again, still about the session where the students access the records, you've talked about their experience, what about their knowledge rather than skills?

P: I would have expected them to have a better standard of knowledge, sort of being a fourth, they were fourth year, weren't they?

RA: They were fourth year.

P: And they're virtually en route to becoming pharmacists. I would have expected them to have been a lot more knowledgeable than they were.

RA: Was this about, well simple things like, doses, interactions, adverse effects, that sort of thing?

P: Just about everything, really, they were at a pretty basic level of knowledge for everything.

RA: Okay. So if we move on then to the session where the students actually met the patients for the consultation. So they've already gone through the records and now they've gone to the session where they get to meet a patient, what are your general thoughts about that?

P: They were all really good with the patients. They all, as a generalisation, had a very good manner with the patients and...

RA: Okay, so in terms, you're saying, are you saying that...

P: ...a good bedside manner.

RA: Okay. So consultation skills, for want of a better word, or communication?

P: Generally, yes, was pretty good. It obviously needs a bit of honing and refining, but basically they were all pretty good.

RA: Okay. Do you think the patients. No I'll ask it a different way. How do you think the patients responded to them?

P: The patients who came in were obviously the ones who wanted to talk about themselves, which made it a lot easier for the students. I think they got to the end of the interview and were a bit confused about why they were there.

RA: Are you saying...

P: ...the patients...

RA: ...the patient is confused?

P: ...about why they were there, oh well is that it? Don't you want to tell me something?

RA: Okay. Do you think...

P: ...these are, again, generalisations from memory.

RA: No, no, well that's very useful. Do you think there was any benefit to any of the patients or not?

P: I can't actually remember any benefits to the patient. I think a lot of the sort of studies they have nowadays, they have you know the diabetes study that they're running and the sort of several of the longer term studies, health studies, the patients go in and they get tested for all sorts of things and they actually get things found out about them and they actually benefit from them and I think a lot of the patients were perhaps thinking that maybe they were going to benefit from these interviews, but there didn't seem to be an awful lot of benefit for the patient.

RA: Okay. Was there any benefit to the student, do you think?

P: There was benefit to the student to experience that, but I don't think any more benefit than if they were talking to an actor in an organised situation in the university.

RA: Okay.

P: Where it can be run a lot more efficiently.

RA: Now, at the end of the consultations there were two sorts of feedback. Firstly feedback by a pharmacist, do you think that was of value and also was the format okay?

P: Feedback to the student from the pharmacist, obviously being the pharmacist giving the feedback, I thought it was very useful. I pointed out several things and the student oh yes, of course, they hadn't thought of it so that is yet another learning experience for them, it gives them a clue as to what, you know that's something else that they need to look at next time they have an interview.

RA: And what about the feedback session with the practice nurse?

P: I didn't get involved in any of that.

RA: Okay, no that's fine, so we'll leave that. Now we've already talked a bit about this, what are your thoughts about the competence and/or confidence of the students within the consultation?

P: They appeared, a generalisation again, fairly confident. They had obviously practiced consultation skills quite a bit at university, you could see that they had got the basics of the consultation skills and confidence obviously varied.

RA: Okay, and earlier you said though that you felt their competence, or level of knowledge, was a bit lower...is that the right interpretation?

P: Yes.

RA: Okay.

P: I mean it could be that I'm expecting too much, but it's...

RA: No, the whole of point of this is to get your opinions and that's what's important. So, do they need additional training before they meet patients?

P: Well there isn't really an awful lot of time because they're at the end of the course any way, aren't they? So I don't know what other training they could be given, they need to learn what they've already been taught.

RA: Okay, interesting thought. I think we've talked through that quite fully. And again this other question has come up previously so, but I'll ask it as a blank question, what are your thoughts about repeating the exercise? Should we repeat it or not?

P: As I say, I don't think that the session that I had was of benefit, enough benefit, to warrant the large expenditure. The practice at the surgeries any way.

RA: Yeah. Is part of that to do with the logistics in terms of it was...

P: ...it's almost completely to do with logistics, yeah.

RA: So if that practice had been just down the road from the university, would that have changed your opinion?

P: I think it would and I think you'd need to have more than one room on the go as well. You'd need access to more computers and that just doesn't happen in doctors' practices, it's just not available.

RA: Okay, so and if you were to get more than one room, would it be, for instance, are you suggesting one pharmacist running more than one room or ...?

P: No, no, I suppose it has to be one pharmacist in each room because they've got to be supervising the data gathering and picking out problems that the students haven't seen in advance, so they've actually got to be able to look at the record at the same time and they've also got to be there to witness the consultation all the way through. They've also got to be there to give the feedback, as well, so you've got to have a pharmacist in a room all the while.

RA: Okay, and just on this topic, just an odd thought which has come up, it's been suggested elsewhere that medical students meet patients on a regular basis in practices and they simply ask for volunteers and patients come along, would there be any benefit or not in undertaking a similar type of session, or even joining in with a medical student session?

P: Yes, I think it would be, the students where I was working they only had very often one patient, whereas if you had a continual stream through the day, for each student, they would pick up so much more, you know after half a dozen patients they'd actually start learning what they were supposed to be looking and what they're supposed to be doing.

RA: Okay.

P: But I'm not sure how you'd logistically do it. I wouldn't want to be the person organising it.

RA: No. That's more or less brought me to the end, so at this point I usually ask firstly, is there anything that you want to add or you know you haven't really had a chance to say?

P: I think you've asked most of the questions.

RA: And that's almost my next question, is there a question that you think I should have asked but I haven't?

P: I can't think of another question.

RA: In which case, thank you very much and I shall end the tape.

Focus Group with PCT Pharmacists held on 6 September 2012

RA: Okay, first question, can you tell me your general thoughts about the study? And then I'll go on to specifics, I don't know if you've got any general thoughts.

Pha1: I think probably one thing, I enjoyed it because I'm not teaching at UEA any more so it's a nice chance to meet with the students and to do, to discuss some ideas with them and you can actually sort of talk to them, because it was one to one, you could talk to them on sort of a peer level so you could get their ideas as, you could draw a lot out. But I did wonder, it did take an awful lot of organising the placements so it was quite hard work I think for those who were having to book all the appointments and there was a lot of people perhaps let you down, whether it was surgeries or things like that, so quite intensive work in there.

Pha2: I think I agree that it was really worthwhile, a worthwhile study to do, worthwhile for both the students and the patients and surgeries and for us as teachers as well, I think it was really interesting to see how we could use that in future times as well to develop a new way of teaching rather than them just being in the ...

RA: Okay, you said worthwhile for lots of people...

Pha2: Yeah.

RA: Why is it worthwhile, let's say for the students?

Pha2: Right, students. Because they're learning with real people and they're not having to talk to their own peers and role play...

Pha3: ...it's a real situation for them...

Pha2: ...a real situation...

Pha3: ...and some of them obviously took to that and some of them were a bit worried because of that but it's good for them to see that rather than, role playing you never ever (unclear), no what a real patient requires because a real patient isn't like one of us doing a bit of role play, we can sort of spur you on so I thought that was really good for them I think as well, I think most of the learnt quite a bit as well.

Pha2: I think they did.

Pha3: Even if it was just their consultation skills and no clinical...

Pha2: ...how to approach people and how to carry themselves and how to (unclear)...

Pha3: ...and I think most of them, unless they were very good to start, actually improved on their second patient (unclear) from the feedback that was the you know that's why (unclear) they did make a difference for them, you could see the difference in them once they'd had the feedback if they didn't maybe do so well the first time.

Pha2: I think it settled their nervousness as well, (unclear) their thoughts about oh my goodness I'm going to be talking to a real patient, but to get that before they leave university, before their sort of mollycoddling almost is gone, I think to have that as an experience with somebody else to fall back on.

Pha1: I only did the data collection but that it was they all looked sort of outside just the diabetes and because you'd got plenty of time you could look up things or you could send them to look up things or

direct them where they could find other sources of information, and what's this? And looking at real figures and when they were imagining what someone would be like as well and the sort of problems they'd come across, the amount of time you have with them there's nothing like that in the university course, a chance to not feel silly because you're in front of a big group.

RA: So you think that being in a small group was better?

Pha1: Yeah, I think it would be very hard, and also if you'd had a big group the poor patient would (unclear – laugher)...

Pha2: ...would disappear under the table and not want to come out (unclear – over-talking).

Pha3: (Unclear) just one on one though weren't they? Did you do something different?

Pha1: Either one on one or twos.

Pha3: Oh, right, I only saw the one on one.

RA: So, oh sorry...

Pha2: I was going to say I think they went away with a completely different view of what consultations were about.

Pha1: And it was good CPD for us.

Pha3: It was very good for us, yeah, I brushed up on my diabetes before I went there.

Pha2: NICE guidelines and all sorts...

Pha3: ...just in case...

RA: Did you record it?

General agreement to this.

Pha3: But I think the patients actually got something out of it, all the ones that I saw definitely give them very high scores, even you know much higher so it was obviously better than they were expecting or a lot better than they were expecting for most of the patients.

RA: What do you think the patients did get from it?

Pha2: A different view of pharmacists and what we can actually do for them, not just give them a little packet of medicines over the counter, but there is a basis behind it more so I think than counting tablets, even just doing a medicines use review they don't get the full idea of what pharmacists do so for them see us in a different light with a more clinical head on (unclear) patients...

Pha1: ...how much time did the patients have?

Pha2: I think about 15, well between 20 minutes and half an hour.

Pha1: So that's more than they get with anything else which is quite nice to be felt valued and (unclear)...

Pha3: ...(unclear) issue as well weren't they if they had a specific issue or request or query they were listened to or any problems they felt they had as well...

Pha2: ...yeah, which I felt the students were empathetic with them so they wanted to tell them more and sort of probably be more honest than what they might be with the doctor as well, so I think they felt they'd achieved more.

RA: That's an interesting point.

Pha1: Particularly with perhaps the age and the fact they aren't qualified, again you can build trust quite quickly and perhaps they will tell you things that they wouldn't tell (unclear).

Pha3: They did though, didn't they, (unclear) tell them when they weren't taking medicines and things...

Pha2: ...and that they didn't exercise, or that they were still smoking or you know they were really honest.

RA: Would you think it was because they were seen as not a qualified healthcare professional?

Pha2: Or that they were more interested in the actual person rather than the all-round person, because the doctor you tend to go in with either an acute condition and you're just chat. chat. chat and then you're out the door or they just have a quick overview of your chronic condition and then you're out the door, whereas the students had time to delve a bit deeper and ask all the more important questions (unclear).

Pha3: And it's was a bit more personalised for them as well wasn't it, I mean your chronic disease management in most surgeries is tick, tick and you get asked to yes or no and you know people just say yes or no, whatever they think the answer should be. I felt that they were a bit more honest, like you say (unclear), I don't know if that's because we were there, I think that reassured them as well because quite a few times they did look over to say is this right what I'm hearing, you know.

RA: So, do you feel it's important to have a qualified person there?

Pha3: I think definitely.

Pha2: To give them that reassurance.

Pha2: Yes, safety net.

Pha1: Yeah, because you can't guarantee that they won't make something up, even if you've asked them not to, it's the sort of thing that comes from the back of their mind and I think you need to have someone (unclear)...

Pha3: ...and a couple of times something was needed to be said, whether because they didn't know and the patient was expecting it or just because they got to this part in the consultation where the patient had asked the question and the student didn't know...

Pha2: ...then they try and answer (unclear)...

Pha3: ...yeah, you know sometimes we did end it on some of the patients' questions (unclear).

RA: Was that a problem?

Pha3: No, because we revised first. We did our CPD, but it might have been (unclear).

RA: So, do you think, you said also there's benefit for the pharmacists, so do you think that was the benefit, it made you look things up?

Pha3: Yeah, it made me more aware of all the current guidance...

Pha1: ...yeah...

Pha2: ...definitely...

Pha3: ...and even you know doing MURs yourself you know it made me better at them as well because actually listening to lots of people with diabetes you don't often get that, you get one or two don't you but actually getting them in a block it made me pick out bits where I could see the patients had problems, because I know a lot of the patients have problems on gliclazide and now when I do MURs it's something that I focus on, so I always ask them about you know are they having hyperts, do they feel this way, do they feel kind of tingly, dizzy or anything, if they don't know it's a hypo so I picked up that from these consultations that's something I always ask them especially when they're elderly and I picked up a lot more on MURs because I ask the right questions, so you do learn things.

RA: I hadn't originally expected there'd be benefits for the pharmacists.

Pha2: Yeah, (unclear), well even like for me for the diploma, the MRCFs and running through all that and being on the other side of it listening to what they were saying and ticking off the boxes for them and thinking yeah I must remember to do that for me when it comes to my turn so for professional learning I definitely think it was worthwhile.

Pha3: Because it was all concentrated, wasn't it, in them few days which you don't normally see.

RA: That's an interesting one. And you also said it was worthwhile for the GP practice?

Pha2: Because it gave them I think some brownie points from their patients and then they'll go and tell everybody else what a good service they had, in my opinion, but that's maybe my warped Scottish thinking.

RA: Do you think they did get a good service?

Pha1: There's obviously some interventions that wouldn't have been picked up otherwise...

Pha3: ...there's certainly evidence on one of ours where the nurse got quite a lot of feedback, she came in and she got quite a lot of feedback and she said she was going to follow it through.

Pha2: One of the doctors in the Wymondham practice, she was really keen on following through on a lot of things as well from some of the feedback.

Pha1: Even raising awareness of what pharmacists can spot must be I mean that's going to be building relationships for the future, I would have thought.

Pha2: And it's (unclear) for them to think that they've got another resource to use, in the new climate where they're thinking well what can we do that we don't actually pay for but we might need somebody who can (unclear) expert medicines, so I think the practice found a lot more about what we can offer.

Pha3: I think the main downside was the organisation, wasn't it, it was just you know like how long have you got a room for and where is the room...



Pha2: ...you'd been promised a bit and then you've been let down because they can't give you the rooms, sort of that side of it probably (unclear).

(Unclear).

Pha1: And they get all these medicines reviews for nothing which can tick their (unclear).

RA: Okay, I'll go through (unclear) of these now, I'll come back to some of those things. So, if you were involved, some of you were involved with the session in November, if you can remember back that far, at the clinical trials unit with the role play actors...

Pha2: Oh yeah, I remember now, it's coming back to me...

RA: What are your thoughts about that session?

Pha2: That they weren't always the same, the actors, they were slightly different at each of the sessions. They became a slightly different person although they were meant to be the same one, I think they developed their characters as we went along so that each of the students didn't get the same type of person.

Pha1: But for something like that, would it matter, do you think? I mean it's quite nice to have it all the same but...

Pha2: ...yeah, but I think they were maybe giving more information (unclear) I felt they gave sometimes a bit more information so then maybe the student might not have had the same (unclear), it's real life.

Pha1: It's really, it's practicing your consultation skills so that's the most important bit and you do get some awkward ones, don't you, so I think it's quite important to do it before you go and meet the real patients because all the students were saying how much they developed, well putting everything into one session, you've got your drug history and everything else all in one go, that's something they'd never really done (unclear) useful, and you could see the students develop from the first one to the second.

(Unclear).

RA: Okay, what about the organisation of the day?

Pha2: I felt it ran okay for while I was there, but again I think when there was somebody didn't turn up that's when it seemed to be a bit more awkward trying to fill in the space (unclear), was it not one of the supervisors hadn't arrived either on time or was slightly late, I can't remember the complete scenario but I think that set the cat amongst the pigeons a wee bit, but generally where it was (unclear)...

Pha1: ...(unclear) and some of the OSCEs and things like that but it was about the right length, if you'd had more students, I think that was just right, if you ended up putting the whole year group through (laughter)...because you've got to concentrate...

RA: Do you think that's the maximum number we could do in one day?

Pha2: I wasn't there for the whole session so I don't know.

Pha1: I think just for the concentration because you start to think well did that student say that or was it the other one, oh bother, but then we were recording it so if it was in exam conditions you'd watch it

and as I say if it's really for practising skills I think they got an awful lot from it. But the capacity of the rooms as well, we haven't really got any more rooms either so it would be quite hard to do.

RA: What about the time available for the consultation?

Pha1: For most people, that was enough, wasn't it?

Pha2: I think it filled enough time, if they'd had any more they would have been struggling.

RA: Was there enough time for feedback?

Pha1: Most of them I gave feedback then and they then got the big feedback as well, didn't they?

Pha2: I didn't have time for much feedback at all really, so maybe a bit more. Whether it be generalistic feedback might be better.

RA: When you say generalistic?

Pha2: I don't know if you did that at the end, did you do a sort of (unclear) the feedback from like (unclear) as normal like the first years where we're giving them this general feedback from what we picked out of all the bits that were good and the bits that weren't so good, just like a general thing to all the students rather than like individual feedback?

Pha1: Yeah, that would be good.

RA: So, a formalised feedback? Interactive or...?

Pha3: Yeah and if you wrote in on piece of paper it would go in a file.

Pha2: Yeah, I think interactive is a good way of learning.

Pha1: Because you had the session getting the student to feedback to the professional or to the GP to say what interventions they'd like to make with the GP – recording ended.

RA: Okay, restart 6 September. Okay, so we were talking about the session where the students met the actors, so are there any other thoughts?

Pha1: We were just saying it would have been nice to do some general feedback on their consultation skills and I wondered whether that might be a place to fit it in is when they fed back to the GPs what they thought the interventions were because otherwise if they all went away you could do it as a big group session, but they might remember it when they do it straight away. I don't know how, would you bring them back another time?

Pha2: I think straight away after (unclear)...

Pha1: ...what, when it's fresh?

Pha2: Hmm.

Pha1: ...because you had three, three groups was it, or four over the day?

RA: I can't remember.

Pha1: No, I can't remember. You'd never get the whole lot in one go but that might be a place to put that in.

RA: Okay.

Pha1: I think it depends on who the marker was because if you were, if you were used to being at UEA and you're used to giving feedback after an OSPE session or in a workshop, the role play, then you probably did it automatically where I don't normally do so, you've perhaps haven't got the same amount of time if you went for UEA set up. I think you got all people who've done it before, didn't you?

RA: What about the stress for the students? Do you think that was an issue?

Pha1: One or two, but I think the fact it was actors, that helped a lot.

Pha2: I think they were very nervous for their first one but then they settled down more for the second one.

(Unclear).

Recording ended.

Pha3: Somebody that (unclear) about working in the pharmacy with me, they were the most stressed student I saw and I don't know whether that was then or whether because they knew me from somewhere else.

Pha1: I think as you went through the day sometimes the time got tighter because one group were coming in and the other one hadn't quite finished so they were a bit more rushed and you haven't perhaps got as much time to put them at their ease before the first patient came along but (unclear)...

Pha2: ...yeah, what maybe B's saying about the meeting them sort of informally just for five, ten minutes in the morning as they got there perhaps, not to discuss anything but just to see the faces and know that they're kind of normal beings as such and reassure them that it's not an exam it's just a simple chat, but a development of their skills.

RA: To meet who?

Pha2: The actors or just sort of general, just to see them a little bit so there's a bit more familiarity, potentially, I don't know, I don't know.

Pha1: And the students are all volunteers, aren't they, so it should be fun because otherwise it's...

Pha3: For a personal point of view it's being on the opposite end of this being a student, the most stressful thing is just doing it for the first time with somebody else observing and not knowing how you're going to do. I think once you've done it once or twice it's better.

Pha1: Or maybe to do it without the marking scheme for the clinical side, because you still need some feedback on the other points, but that might be quite nice to do.

Pha3: But would you expect them not to be stressed? Realistically?

Pha2: Adrenalin seems to make their brains work (unclear).

RA: Okay, so I'll move one. The session where the students went to the GP practice and accessed the records and made care plans.

Pha1: Sometimes it was like pulling teeth, but they'd actually got a lot of ideas and it was just getting them to write it down.

RA: When you say pulling teeth, was it difficult to get them to talk or to come up with ideas or what...?

Pha1: Well both but once you started asking them questions then they came up with all sorts of things and sometimes things that I'd not spotted, but actually writing it down on this carbon paper where if you wrote the wrong thing, you couldn't rub it out. I don't know whether it might be quite nice to just do it on normal paper that if they scribbled on or made a mess and then photocopy, I don't know, but the carbon paper really did worry them and particularly if they have (unclear)...

Pha3: ...they probably never seen it before though...

Pha1: ...no, because it's quite, it's not something that's used very often now. Or even now aren't they all going to have iPads or something soon? I know you can't put patient details...

Pha2: ...numbers and stuff...

Pha1: ...something like that might, because at least they can rub it, well not rub, delete and redo in the way they want to word it, because actually getting them to write things down was quite hard I thought, I don't know why.

Pha3: Sometimes the recommendations for the doctors and the nurses, they didn't really know how to word it (unclear)...

RA: Do you think they needed more preparation for that?

Pha3: Maybe some suggestions of how would you actually word this, how would you present this finding you know.

Pha2: That could come as part of that general feedback on the end of their practice session, some useful phrases or useful thoughts.

Pha1: Perhaps getting them to write it down rather than talk to the GP.

Pha3: To actually write it down is very different than saying it between your colleagues is quite easy because we all know what we're talking about, but actually writing it down for someone else where there's no ambiguity as well as to what you're actually meaning.

Pha1: Yeah, perhaps at the end of the practice sessions with the actors, to have to write that's there's so many actions...

Pha2: ...yeah, I think that would be good...

Pha1: ...that might be quite good because quite often they've forgotten by the time they went to see the GP all the points and it was because they were in a group they could say oh yes and we need to ask that, because they'd written on their forms but they had necessarily written (unclear)...

Pha2: ...whether they don't get taught about, I don't know whether medical students get taught that about note taking, but I think we can get taught how to verbalise and ask questions like MRCF ways and structure but I don't think they get the structure of note taking and then note giving, if you were putting something onto a record, what you would write. Would you write it in shorthand or would you write it in (unclear)...

Pha1: Because it's got to be clear for who was following up to know what they're going to do.

RA: Was there any benefit in any way from it? From this particular part of the exercise.

Pha1: I think that's where I did my CPD...

Pha2: ...yeah, in depth learning, I reckon. I reckon for us it was a of learning but for the students it was a lot of learning, because I think they're putting everything they've had taught to them into practice, real life situation.

Pha3: (Unclear) to know what they have to look up, didn't they, they had to you know exactly what they were trying find (unclear)...

Pha2: ...coming across the hurdle if it wasn't there, what did they do about it?

Pha1: And for me an opportunity although they are students to sort of discuss things and say what do you think about this and because we often off on our own and don't have anyone to talk to, so you just handle it, so it's quite nice to bounce ideas around and both them and us to know the issues you don't necessarily have to know everything once you're a pharmacist and we can still ask people (unclear)...

Pha2: ...that's good, because I think they saw us as the all-knowing, all-seeing (unclear), the reality check was that you know we don't know everything, but we might know where to find it or who to ask so I think it was a well worthwhile section.

RA: (Unclear)?

Pha1: Yes, but it was just getting them to write it down.

Pha2: And have the confidence to write it down and the confidence to think about it.

RA: Do you think they wrote any issues down that were inappropriate?

(Unclear).

Pha3: ...I think we talked a lot (unclear) they mainly discussed (unclear) before they went to the GP...

Pha2: ...like some of the issues they picked up were the kind of things I used to do before I first started with the PCT, would be thinking about oh you haven't checked this level and you haven't done that for a while, oh you know they're on (unclear) or the blood results, if there's not one there you ask to the doctor but that's how they were taught (unclear) at the University but in real life (unclear) don't want to know, like (unclear) level, when was the last time you to a (unclear) level...

Pha3: That's why it's important though, isn't it, for them to get some feedback doing that and how to actually present it to someone on paper (unclear) to look at it...

Pha3: And actually to prioritise their issues as well to make sure they actually in a real life situation if you were doing a review of someone you would actually prioritise it, wouldn't you, you know, you'd actually come in and say this is the most important thing that I want to talk about.

RA: Prioritisation is an important issue but it's interesting (unclear).

Pha1: And I think that was one of the things that stopped them writing things down because they wanted to put the most important points first and they were reluctant to start writing because they thought well I might write something less important and actually I want to put the important things.

Pha3: Can I just say something about the actual use of the computer, because obviously they'd been there a few weeks before, (unclear), I noticed a few of them have got all their records and everything from when they'd been before, but someone needs to tell them when they come back to the surgery you need to look at up to date (unclear) because obviously they've got their issues and that so we nearly all needed to be told oh just have a look and see what's happened, some of them were just ready to go with what they'd done three weeks ago, yeah. That might be something into the initial sort of training just to make sure you're up to date.

RA: That's interesting. And again, we've already talked about this to some extent so at the session where the student met the patient, are there any other issues, or any other comments?

Pha1: How long were the gaps between doing the data collection and seeing the patient?

Pha2: That varied, I think it varied, yeah, sometimes it was two weeks or three weeks because (unclear)...

Pha3: (Unclear) to have a look at the last few consultations, make sure that blood tests they were worried about had been done (unclear). I think one of the strange things I picked up when the students came was some of the students had two patients in a row and some of them had one at the beginning of it and then maybe they had to wait about two hours to see their second patient, I thought that was a bit odd, you know, just more regular timing would have been nice because some of the ones who had to wait, and if they didn't do particularly well the first time, I think they were just more worried by the time it all came around, whereas I think to actually see a patient, get your feedback and then if you have a little bit of time to think about that feedback, maybe even a gap and then go for it, that's (unclear).

RA: In effect they were randomised patients it was a matter of how we were able to book them, do you think we ought to do that differently?

Pha2: Only if you're able to. It's difficult to be able to run that how you want it because of the patients and their times, and when they can get there and where you said about the randomising of the trial you can't get it all like clockwork.

RA: Okay, well the question I was going to ask later, so I'll ask it now. If we were to repeat the exercise, and it wasn't a study, if it was actually part of the course, do you think we should do it any differently (unclear)? Maybe I'll ask a different question. Do you think it should be repeated or not?

Pha3: For everybody in the year group or just those who volunteer?

Pha2: As an ongoing thing?

RA: Yes.

Pha2: I think they should make it open to everybody.

Pha3: But you'd have to have a number of surgeries on board, wouldn't you?

Pha1: Would it be possible to do it so you booked an afternoon full of patients and then students do the data gathering in the morning and then see the patients in the afternoon so then they've just got one day out, so if it was a term, although it's quite intense, that might be, I don't know if it would be any easier for booking patients.

Pha2: Perhaps do it part of diabetic clinic within the GP surgery.

Pha1: But then you might know who's coming so you could then put (unclear)...

Pha2: ...maybe even (unclear) diabetic clinic, six months to a year in advance so you'd know what dates, maybe one or two people might pull out but at least you know you've got a cohort of ten diabetic patients on this day of this week and then ten the following week and ten so maybe some of those would be willing...

Pha3: I suppose if it was the same day in the same surgery over a weekly period, you're probably more likely to get them booked up as well, than just a random day when you're trying to get everyone in and then it's whichever patients can come on those days (unclear)...

Pha1: (Unclear) I've got this patient and this patient and one can come in on this day and one can come in that day, but if you knew well this day we've got these five patients, we've got these students, you could just put them one after the other.

Pha3: They must be able to book, if you gave them so many days like a Wednesday every week or whatever they must be able to book some many diabetic patients in because they do it for themselves for their review and I suppose if you said to them it's something so that they could tick a box with as well...

Pha2: ...well yeah, if they use that as part of their KORF(?) for that diabetics review then (unclear).

RA: So, my interpretation is that we should repeat it in one form or another?

General agreement.

Pha2: If I'd been given that opportunity, twenty years ago I would have thought it would have been brilliant, absolutely brilliant.

RA: We could possibly do it along the lines of booking via a clinic.

General agreement.

Pha2: ...because you would know where the timetable would fit for the students so then you would know where you need to be in say six months' time for x number of students, x number of patients (unclear).

Pha1: (Unclear) well at UEA at the moment I don't think you could (unclear) role playing skills and then clinical knowledge as well, it seems (unclear), they could get a lot out of it.

Pha3: (Unclear) situations, wasn't it.

RA: Okay. What did you think to the competence or confidence of the students?

Pha2: It varied, a lot.

Pha3: Obviously, I don't work at the UEA so I, it just varied an awful lot.

Pha2: I don't think they believe in themselves, I think...

Pha3: ...(unclear) either they're very good ones or the just weren't that confident, were they?

Pha2: No.

Pha1: One thing that sort of (unclear) through them was when they'd done their data collection, all the sheets were taken away and I think some of them were thinking actually before I come again I need look

up this, this and this and I don't how long before they saw the patients they had their sheets back, but that was something I could see them thinking oh yeah...

RA: So when should, I mean should they be allowed to keep that sheet or when should they get?

Pha1: Well they're anonymous, aren't they? They're anonymous so it shouldn't really matter as long as they bring them back again, but then you've got copies...

Pha2: I agree with that.

Pha1: ...or all do it on one day so they haven't got the worry that I might have forgotten about one of the things that I talked about this patient, because I think quite a few of them would think well I've forgotten what was the patient was that I did ten minutes ago (unclear) without having to wait two or three weeks before I look at these notes again, that's quite a long gap, so I don't think there's many things that they do where there's quite that much of a (unclear), if you do your preparation correctly you usually do it either on the day or (unclear).

Pha3: But it's like we said earlier though they probably needed to top up on their preparation when they got, didn't they, because it was so far in advance.

Pha1: Yeah, because it was so far, but you could get away with that bit if you did it on the same day (unclear).

Pha2: (Unclear) dual working with medics and the pharmacy students, the medics were really spot on with everything, their confidence was there but the pharmacy students were tending to be a bit mousey, and they didn't have a lot of confidence, so whether we need to expose them a bit earlier you know to something a bit more structured like that so that they're getting used to them, hello, come in, sit down, drugs, history, the whole nine yards and then by the time they get to the fourth year going out into their working lives that they are a lot more prepared.

RA: So you're suggesting that in maybe third year, or an earlier year, they actually have some patient contact?

Pha2: I think that might even be more beneficial but it's better to be (unclear)...

Pha3: ...(unclear)actors or anything, do they not do that already, then before?

Pha1: They do it with friends, people they're comfortable with.

Pha3: Yeah, that's not real, is it?

Pha2: They just don't have the same...

Pha3: ...it's not a real world, even an actor is better isn't it, you can still pretend...

Pha2: ...but I think this is where that's really valuable...

Pha3: ...but the medics team, they have patient contact...

Pha2: ...they do yeah, and everything's drummed into them all the time, this is how you do, this is how you do, and then they're just...



Pha3: ...and the other thing is with the medics they probably actually on placements see other doctors doing that whereas the pharmacy students on placements usually don't come into a consultation with a pharmacist.

Pha2: ...(unclear) curriculum, it's not part of the (unclear)...

(Unclear) – Pha1 and Pha3 talking over each other.

Pha1: ...they are not really ever seeing anybody else do it.

Pha3: I think pharmacists, because I've come across somebody who's just qualified this year and pre-reg tutor wouldn't let them go in with them, so she actually came to another pharmacy where I was working and a few other pharmacists she used work with, because she used to come as a summer student right, so she came into the pharmacy in her own time to come into the consultations with the pharmacists that she knew because her pre-reg tutor said oh well you don't need to come in with me.

Pha2: I think that's a confidence issue though from the pre-reg tutor.

Pha3: It is, isn't it? But if the pharmacists have a confidence issue, like you're saying, it's no wonder that students don't learn when they are on placement.

RA: So from that am I right...

Pha3: ...could it be part of their placement, that they can go in with a MUR or something or a consultation with a pharmacist? Because everyone's doing them, a NMS, so make it part of you know the day when I don't know second years go out to the community pharmacies but part of the day is they witness a consultation, that's the answer.

RA: And do you think that would help them (unclear)?

Pha3: I think it would help their confidence into seeing what people really do as opposed to what they perhaps perceive we do.

Pha2: Yeah.

Pha1: And seeing that we muck them up, and people clam up and you get the awkward patients who shout at you that would be...

Pha2: ...that would be really good idea, if you watched one and then there was a nice patient that came along that the pharmacist had a good rapport with they could say look would you mind just helping this student with like doing their confidence, let them actually tackle the MUR just with a little bit of tuition from the pharmacist to start with about this is what I want you to approach it, ask these questions, or (unclear)...get them to run it...

Pha3: ...I think pre-regs should be allowed...pre-reg...

Pha2: ...to get them to run it initially but then get the pharmacist to step in to do the actually MUR at the end of it, but give the student time to speak...

Pha3: ...on placements all they see is dispensing, they don't see any of the consultation skills whatsoever. I know on a personal level I watched a pharmaceutical study DVD, I think that was when MURs were first out around there, and I thought well I wonder what I'm supposed to do and I actually watched that and I thought is that it? (Laughter) So (unclear) that's fine I thought maybe (unclear) pharmacist or they had to look something up or they had to go away and come back and answer their

questions, which is how it really, that we don't know everything, that they're not expected to know everything, you know, and everyone's got their own, because one of the things the students had picked up on, because I work with the placements sometimes where there's about four pharmacists and pre-regs and all that coming (unclear) and the first thing they say is every pharmacist has their own style and they pick bits out what they like and what they don't like so much about but what they realise is they don't have to follow this set pattern and that they can be themselves and have their own personality, whilst asking the questions, they can still have their own style and the way they are, their own personality.

Pha1: Some of the students here really did (unclear) and you could tell the ones that were at their ease they got much more out of the patients than those who were nervous.

RA: There's a question that came out from the patients (unclear) was that we could ask them to come in and act as patients, if that makes sense, and they said oh we can take (unclear) be very grumpy or severe or very quiet, is that a good or bad idea?

Pha2: It would be difficult for the patient to be unnatural...

Pha1: ...I think it would depend how experienced they are, we have enough trouble with the ones that we have about OSCEs and things like that and to remember everything that's on their sheet and I think that's one of the biggest things, even the actors didn't remember everything on their sheet. If they'd like to, I mean the more volunteers you've got, the better.

Pha1: All just be themselves but have a variety of people.

Pha3: Were they keen to do that then were they?

RA: One or two were, yes.

Pha1: Because obviously they would have an idea what they would be expecting when they come to their review.

RA: Do you think that, am I interpreting correctly that you think if they do come they should be themselves rather than act a role?

General agreement.

Pha2: It's easier to be themselves because they're real people with real issues.

Pha3: That's why it's so much easier in a way with a proper patient than it is with somebody who's acting...

Pha2: ...because their story will always be the same...

Pha3: ...yeah...

Pha2: ...no matter how many students ask it...

Pha1: ...and any questions they get asked they'll have an answer, they won't have to think about the piece of paper they've got and if they're willing to put their medication around all those patients and all the students they've already said they'll do that as part of the study, but if (unclear).

Pha2: ...(unclear) it probably helps that the medical students regularly...

Pha3: (Unclear).

RA: I've almost got to the end. Is there anything that you wanted to say that you haven't had the chance to say?

General no's.

RA: Or are there any questions I should have asked and I didn't?

Pha2: I'm trying to think? Well done you for taking it on.

RA: Can I just ask a couple of practical things? In terms of yourselves, were the logistics and the pay and everything else suitable or were there problems other than the fact it took ages?

Pha2: I fact that I haven't been paid yet for my time, that not your fault.. I did it as part of my job anyway.

Pha1: Because we were flexible you could do that, but I think if we had been being pulled out of a community pharmacist...

Pha3: ...I work as a locum...

Pha1: ...no, but if you were like full time then you'd end up one day when you could do, but we could say well we can do pretty much any of these days, whereas if we'd cancelled and then (unclear) to do it then that would have been...

Pha3: That's why I didn't take part at the beginning, wasn't it? Because I wasn't able...

Pha1: I think because (unclear)...

RA: I think I've got some more questions. Thank you.

Recording ended.

Rick Adams  
Research Pharmacist  
School of Pharmacy  
UEA  
Norwich Research Park  
Norwich  
NR4 7TJ  
30.7.12

Dear

Thank you for returning the consent form and agreeing to attend a Focus Group to obtain views about the study when you met a Pharmacy student for a Medication Review.

I realise that some dates may not be suitable for everyone, so I am giving three and will choose the most popular. These are Monday 13<sup>th</sup> August, Wednesday 15<sup>th</sup> August, Thursday 23<sup>rd</sup> August. I will book a room at Barnham Broom Country Club and provide a buffet lunch at 12.30 after which we will undertake the focus group, which will take the form of a few questions to the group and take about 1 hour. I will be able to reimburse travel costs if you drive there, but if you have problems with transport please let me know and I will make arrangements.

Please complete the attached form and return in the stamped addressed envelope.

Thank you

Your Sincerely

Rick Adams

Focus Group Meeting  
Pharmacy Student Project

Please state your name.

.....

Please tick which dates you are able to attend. If you have a preferred date please write alongside the date. The meeting will be at 1230 at Barnham Broom.

Monday 13<sup>th</sup> August

Wednesday 15<sup>th</sup> August

Thursday 23<sup>rd</sup> August

I will require transport.

YES / NO

Please delete as applicable

Thank you

Rick Adams

07799131610

Please return in the enclosed stamped addressed envelope.

Intro for Patients' Focus Group

Presence of other people – who and what

Thank you for taking the time to come. Your views will be very useful in helping us to evaluate this study.

You have all signed a consent form to say that you are willing to be recorded.

Are you still willing for this to happen?

You will not be identifiable in any published work.

There is no right or wrong answer as far as you are concerned. We simply need your views/opinions.

There is no need to gain general agreement as the opinion of one person who disagrees with all the rest is just as important.

Please maintain confidentiality of other group members.

Please make sure that everyone gets the chance to put forward their views.

If you want to say something and have not had the chance please make a sign to me and I will ensure that you are included.

Please speak up when making a comment as the recorder is not sensitive.

Do not speak across each other. Courtesy and difficulty in interpreting recording.

Travel claims

## Patients Focus Group Questions

1. I would like to ask your views about the study which involved a consultation ( a medication review) with a final year pharmacy student.  
Before I ask specific questions do you have any general comments about the study?

Follow on:

Good

Bad

How to improve

2. What were your views/opinions about the consultation with the student?

Follow on:

Is it appropriate for a student to do this?

Was the student suitably prepared?

Was the student confident?

What was good?

What was bad?

**Was there any benefit to you directly? If so what?**

If we repeated this exercise what changes would you suggest?

Were there any travel issues?

Was the time allocated correct?

Location. GP Practice. Good or bad location

3. What are your thoughts about the recruitment process?

Follow on

What would have made you more/less likely to volunteer

What about the letter. From right person? Right wording

Timing

What was good

What was good?

What was bad?

If we repeated this exercise what changes would you suggest?

4. What are your views about the questionnaire that we asked you to complete at the beginning and end of the study?

Copies to pass round.

Too many questions or OK

Were the questions hard to answer?

5. Did you have any thoughts beforehand about how the student would perform?  
Did you expect them to perform well or not?  
Was this based on previous experience you had of meeting Pharmacists?  
Did you compare them to Nurses or Doctors?  
Has this study made it more or less likely that you will speak to a pharmacist to ask for information or advice.

5b. All patients were asked to complete a short questionnaire at the end of the consultation. What are your thoughts about the score that you gave?

Were you kind or was the student very good.  
Is it a true reflection of your feelings or opinions?  
Most scores were high. Is that correct?  
Did you have preconceived ideas about the benefit or otherwise and if so what prompted these views (e.g. an MUR) ?

6. What would your views be about repeating this exercise i.e. should final year pharmacy students meet patients for a consultation and medication review?

If yes – why?

If no – why?

Any changes? What about the way that Med students work?

7. Is there anything else that you wanted to say that you have not had a chance to say, or are there any questions that you think we should have asked?



**Transcription of Dereham and Wymondham Patients Focus Group held on 15 August 2012**

RA: Okay, the first question is a very general one, and I'd like your general views about the study. So this is the overall study where the students came and met you for a consultation. Has anyone got any views at about what we did?

P: Yeah, I was thinking about that this morning. There was two members of staff there and I think the student I had was inhibited by having them there, so I felt that she was very competent but I felt that she was not comfortable, I know it's an exam or that she's working for a degree but I just felt if it had been one to one she might have come across more comfortably. It just felt as if she was, especially with two members of staff there, I feel it was a little bit out of the boundary for her.

P: It's funny, that's the only thing I thought, it was a bit stage managed.

RA: When you say stage managed, in what way?

P: Because they would feel under some sort of pressure to give the right questions and the right answers. From our point of view it wouldn't matter what we said, but from their point of view they were being tested.

P: Yes (unclear) and I mean I'm basing mine on experience because in a previous life I interviewed an awful lot of Phd scientists and they were never comfortable when there was management in the room, and this was a similar scaled down version, that's why I raised it.

RA: So how do you think we could have got round that? What would you do?

P: One person initially and then, 10 minutes, a five minute slot with the student on their own. I know there's a problem because you've got to be politically correct, an old man in the room and all this kind thing...

P: There was a camera as well wasn't there.

P: Yeah, but they would have got used to working with a camera.

P: I found it oppressive for the student, not for me, I'm fairly relaxed kind of fella as it is.

RA: Can I just follow on from your point then that you mentioned you felt that after, well you said 10 minutes, that you'd be happy to then be alone with the student?

P: Yeah.

RA: And is that a general view...?

Unclear, over-talking.

P: I think the idea was extremely good because it gave them that one to one relationship with a potential patient which you can't learn through university.

P: I think they have got to be tested, you've got to see that they're doing it correctly. They do need some supervision or feedback.

P: They had to start thinking on their feet to give answers.

RA: And if they need testing, do you think that requires a qualified person present or ...?

P: Yes, I think so, personally I think so.

RA: Okay.

P: Unless they...

P: It's quite an important job.

P: Unless you recorded it.

P: There was only one staff member when I had mine. I felt I was probably the first person the student had seen as a first interview because she was exceptionally nervous at the start but having been used to lecturing and teaching most of my life I did my best to put her at her ease and I'm a bit larger than life as I would be normally and I think within about 10 minutes she was all right and I felt she put in a good performance and I think, I'm not, I don't think the member of staff there was inhibiting her at all, in fact I actually involved the member of staff because I asked a question that the girl wouldn't be able to answer, but I wanted the answer myself so I knew the staff member would have to and did and it was a bit of a three way discussion going on, I thought it came off very well.

P: Yeah, I had a similar experience, went through the interview, typical nervous student but not badly nervous but you could see the inexperience there really, and at the end asked one or two questions and she had the sense just to say I don't know and turned round to the expert who said well I don't really know either, which is fair enough.

P: But of course these students are going to meet difficult members of the public eventually aren't they, everybody isn't going to be understanding and nice and thoughtful, there are going to be some tricky people there.

RA: There are and how do you think we can teach that?

P: I don't know.

P: I was going to say I could've been nasty if you wanted me to but I'd have needed a bit of feeding time.

P: I would have thought somewhere in the course there should be an element of communication for students, the students and the outside world, because I've worked with students at the UEA on business things and they're very, very good once you get them to relax, but it takes time to get them to relax and then they come out and they usually come out with so much that I get lost.

P: It wasn't a criticism I felt for the student that she wasn't comfortable.

P: But it was an exam, wasn't it, it was part of an exam and you're not comfortable if you're meeting...

RA: ...it wasn't actually an exam it was more of a training exercise.

P: ...a training, well training and dealing with two other people who are teaching you, you know you're bound to feel nervous.

P: I don't know what preparation they had beforehand, but I think it would have been helpful to have some dummy sessions with their fellow students before meeting the public because that would have, they would have had more confidence and understanding of what they're doing. I mean there was that early nervousness I think could have been disastrous, I imagine some people you know not responding enough and it gets difficult you know and when you haven't got a co-operative person and they're going to have to meet people who are not co-operative.

RA: In fact, nervousness, timidness or whatever is something that has been raised by patients. Is that an issue?

P: I think it's inevitable at their stage, isn't it?

RA: But does that detract from the consultation?

P: No I don't think it detracts from their point of view, I think they absorb it and go off and see a teacher.

P: They obviously getting good out of it, they're just feeling uncomfortable while they're getting the goodness, like I am with my diet (laughter), but it's doing me good, but I'm not enjoying it.

P: But how do you feel then afterwards, having sat through that yourself, how do you feel the students have performed? Do you look back on this as well and say well she (unclear, over-talking)?

RA: Well we can reflect on it, but can I now turn that back to you and say how do you feel they performed?

P: I tried to make mine a bit humorous, actually, just to settle them down a little bit, and you know like one or two others I've done these sort of confrontations through television and people have been sitting in another room, maybe that's something you could do, sitting next door somewhere like that and leave the girl on their own, if it is a girl, but otherwise I felt it quite good actually, I enjoyed it, I must confess I enjoyed it.

P: Yes, after all, you have got a camera in there.

RA: Although the camera was there partly for us to be able to analyse the interview later. So can I then ask maybe what was very good or very bad about the whole exercise?

P: I think overall it was very good. It got them into a situation with other people, giving their opinions and using their knowledge and so on, I think it was good all over. The only thing I can think of is that, as I say, you had somebody who was really very awkward they could then use the timidity or whatever you want to call it to get right in and really make it uncomfortable for them and I wonder how they would hold up then.

RA: And in fact, the awkward patient, I am assuming that most people who volunteered were not of that nature, do you think there's a way round that?

Ps: Several yes's.

P: I'm sure you could get people together, I'm sure if you feed us this well I'd come to UEA and I can be a right sod if necessary.

P: Exactly.

RA: I'll remember that (laughter).

P: It's a bit of role play, isn't it?

Ps: General agreement.

P: I think some of the questions that the young student asked were rather good, actually because it gave a little bit more of an insight of what we've got. I mean I don't know a great deal about diabetic conditions at all, that never seemed to affect me much at all, I take my tablets daily and...

P: ...it's like you haven't got it...

P: ...exactly...

P: ...I do, I just carry on same as I normally do, it was nice of her to ask me questions, I felt oh well good question, you know.

RA: Any particular sort of questions or was it...?

P: Well how do you cope with it? I mean I cope with it fine because I still think that I haven't got it, you know, I'm taking the tablets daily, it honestly hasn't affected me one iota.

P: Which is type 2?

P: Yes, type 2, yeah, okay I'm on a diet as such and I don't put weight on, I'm sorry to say that...

P: ...you can hate people you know (laughter)...

P: You can't really find volunteers who are the real worriers and health fanatics, can you? You don't know how to, unless the doctors says why don't you invite Mrs so and so, you know you could do it that way, asking the doctors to recommend one of their worriers.

P: But it is real life, those young students are going to meet a whole variety of different situations and the more varied they are, the better, I mean some of them are going to be damned awkward for them and others are going to be a real dream you know. I mean the young chap who was interviewing me, he did actually say something quite useful because I seem to be taking far too many tablets and I tend to forget whether I have or not and he suggested doing you know splitting them up into separate containers, well I haven't actually done that but what I do is, every night now, I put the morning ones out by the kettle and the evening ones somewhere else and I think that's great.

P: I'm a real old person and I've got the pill box...

Ps: Ooohs and aaahs.

P: ...for two weeks and it's the only time I feel ill is when I fill up that pill box and I think you poor old soul (laughter).

P: I'm quite happy to have mine put in front of me, I just take mine two lunchtime ones that were put in the pill box for me (unclear), I'm spoilt to death, because I found the girl very competent and just felt that she was a little bit tense, and that's where we've gone right back to the beginning, but I thought the questions she asked and the one question I asked her, and I can't remember what it was, she was straight to one of the tutors and said, I don't know, could you help me with that and I like that, because she didn't try to give me any flannel, she could have flannelled me.

Ps: General murmurs of agreement.

P: Well thinking back to some of the things I got involved with in an earlier life, like marketing courses and so on where you had to do presentations, and in many cases there were cameras with a remote control outside somewhere and you'd be with a potential client and you were doing the sales presentation and then afterwards people in the other room would analyse what you've done and how good you were or bad. I did have one of the funniest experience though because it was after I'd given up smoking and the guy offered me a cigarette and I put it in the wrong way round, lit it (laughter) and I heard a load of hilarious screams from next door.

P: But I've seen people who are brilliant in every way, communication, intellectually and everything, the minute you put them in front of a camera...

P: ...yeah, fall apart...

P: ...they're like, they're absolutely, and it's psychological and I think my giving up smoking was psychological.

P: I was having problems at the time with my medication in that I was not exactly feeling ill but suffering from it because of an increase in the medication and I raised this and I didn't get, and probably didn't expect, an answer from a student that was I mean and then the supervisor got involved in this because the other student was out of her depth there, but even she wasn't helpful either and that went on and in fact only in the last three weeks I've solved the problem by changing my practice surgery, I've gone to one now which specialises, well has a speciality in diabetics and I'm going on to different medication. But having raised that with the girl, having raised it also with the diet clinic that I was attending and getting nowhere, I am suddenly now getting somewhere, but that was a problem that it's I think you can hardly expect the student to play it down the line as they've been taught, they're not in a position to think outside the box in a sense. And nor are his tutors in that case.

P: I think we could get over the problem of all this if there was a room set up with a hidden, or not very obvious, camera with just the student, us, as you say somebody in another room, let them get on with it basically.

P: What and be one to one?

P: Hmm, or as near as you can get, and if there were any problems, you would be there watching to pop back in again.

P: If I was going to do it, I would do it very much on a group like this, six of us, and then with the student or the students, however many there were, I don't know how many there were at Wymondham and then have the one to ones afterwards, when the students have had a chance to get to meet the patients to discuss, I know it's cost and I know all those that have been down that route, but you would get a lot better results in my book.

P: I mean it'd only take a ten minutes cup of coffee or tea...

RA: ...and are you saying the students all meet?

P: ...yeah, all the students, everybody together and then follow along.

P: So like we're in a friendly social atmosphere?

P: Yes, make them relax, because they will relax, I mean you're a teacher, if you're a teacher or a lecturer it's making the students relax, isn't it?

P: I was going to say, in my evil mind, I'd get them to do that and drop a right sod right in the middle that they wouldn't expect to see how they'd react.

P: There is another way of looking at it as well, of course, Peter. The students come in there and they'd probably pleased that you're there to support them, you know with saying they'd be better off without you, some of them may well think well I've got a bit of support here...

P: ...they're all individuals anyway...

P: ...well, yeah, absolutely, yeah.

RA: Do you think, and this is something that's coming up, do you think the students were suitably prepared, and I think there's two arms to this, one is their knowledge of drugs and one is their skills in terms of communication with the patients?

P: I mean were they advised on things like diabetes, I mean how far did their knowledge go in that respect?

RA: Well they obviously have been taught diabetes, there is a limit to what can be taught in that time. Is there a particular reason you ask that?

P: So far as I was concerned, the chappie I had it was very intelligent questioning and the answers were right as well, I felt I was the only one who was out of kilter with...

P: ...presumably they're prepared before anyway, are they not?

RA: They are, yes.

P: They got their 20 questions, or whatever.

RA: But it's a matter of whether you felt that the preparative training was suitable or sufficient?

P: I felt it was pretty good actually.

Ps: General agreement to this point.

P: I think the more one to one work they get with potential patients is the best way of moving forward because you can read up and learn as much as you like, but it's when you actually get in touch with people in real life situations that you start really learning.

P: I felt that the lad was very conventionally taught in the sense, as I understood it, from the student's questions and my interaction with the student.

RA: And when you say conventionally taught...?

P: Down one treatment road and not another, I mean there are different treatments for diabetes and different diets, very different, but I just, what I was getting was very much if you like the diabetics association, or whatever they're called, that type of thing, you know, keep off fats, well there is an alternative to that, just keep off carbohydrates, but the student was unaware of that.

RA: So it's depth and breadth of knowledge?

P: They probably don't do a lot on diet, they're pharmacologists so I'm being a bit unfair in that respect, but they are being let loose on patients.

RA: Well this is why I'm asking the questions, it's important.

P: But if I was to mark it out of ten, I would give my young lady eight out of ten for both and I take the two missing points from both things on inexperience because she is still learning.

P: My concern is how often does a patient have contact with the pharmacist? If I've got a problem, and this is what I said to my student, if I've got a problem I would go first of all to the diabetic nurse, who is absolutely wonderful as far as I'm concerned, and if she was concerned she would refer me to then to the doctor, but where would the pharmacist come in?

P: Well I can answer that for Wymondham because I had the same conversation because I'm taking a lot of drugs, not just diabetes because of what I have, and I said to Sam, who's my girl, I feel I'm taking too many pills and she said go and have a word with the, I can't remember his name now, the senior pharmacist in the chemist, it's Boots in Wymondham at the doctors and I saw him, private room there, which is always available, and he gave me half an hour and went through them and said stick with it, but it was (unclear).

RA: The reason we're looking at this training is not the current model, we're looking at a future model.

Ps: General agreement.

P: I found that most encouraging that I was actually referred to a pharmacist rather than the doctor (general agreement), because as much as I like my doctor, I don't always think that she's got all that knowledge that she (over-talking)...

P: ...did she bring down the little book?

P: It's when they go on the computer that I worry (laughter).

RA: Okay, so do you think it's appropriate that the student undertakes a consultation with a real patient?

Ps: General agreement.

P: And more so in fact. I would say more of it and more variation as well.

P: I would agree with you there, I mean mine had ten minutes, a half an hour would be better, wouldn't it?

P: I had nearly half an hour.

P: Did you, wow.

RA: We didn't actually restrict their time. Can I turn it the other way round, obviously we're looking at benefit for students, was there any benefit at all to yourselves?

P: In my case I have to say no because I've recently had a review by the doctors of my drugs so I have, like you, keep taking the tablets. Surprisingly, for the first time ever, I then went to pick up some tablets and the pharmacist offered to review them just two weeks later and then you came along, so (laughter) it all seemed to come at once, but I think it would be useful if the pharmacist was perhaps should I say a bit more up to date with the drugs perhaps than the doctor who may have been prescribing the same thing for a long time and there may be alternatives they could recommend.

P: Possibly.

P: I think at Wymondham we are rather lucky at the moment because there's plenty of staff there, the advice on diabetes is very good (general agreement to this). I'm put under pressure the whole time.

RA: Anybody else got any thoughts on this?

P: All I would say is that from the students' point of view real life situations are best they can get (agreement).

RA: If we repeated the exercise, should we change it?

P: I think you could give some guidelines to perhaps being occasionally a difficult patient (some agreement). I mean we all try very hard to put the student at ease and I think perhaps there is a case of occasionally just being a little bit harder.

P: From teaching practices, my first class I can still remember when teaching practice and you've got all the theory and stuff, it was a lovely class and I thought oh this is simple and then the next class and it all went pfft over there and everything you know...

P: ...and you had to think on your feet...

P: ...exactly, and the pressure of something coming at you that's not expected or difficult, or just outside expectation can completely wipe all your learning.

P: Yes, and I think also you could warn the students, look it may not always be easy, you may come across a difficult person, or a difficult questions. If they were warned that you know there could be something.

P: Well there's another thing of course, is that they learn not to flannel through an answer but to say well I don't know the answer to that, I'll find out, because that's important in every walk life.

RA: It is. Were there any travel issues?

P: Mine went to Theatre Royal in Norwich instead of the Theatre Royal Street in Dereham (laughter) – expensive taxi I think that was.

RA: And the location, we originally thought of having these at the UEA and after speaking to patients we changed it and arranged to have them at GP practices, was that the right decision?

Ps: General agreement.

P: The parking at the UEA is a right pain.

P: Oh it's impossible.

P: No but they will be in doctor's surgeries, won't they? And in the chemist, you know it's better for them to be, I think.

P: I don't agree.

P: I think it's, for me anyway, on these types of thing, I think it's better to get the student out of the academic institution.

RA: And what about yourself?

P: Grapes, six a week if you've got diabetes (laughter).

P: I just put the meringue on it (laughter).

RA: Okay, was the location suitable for yourselves?

Ps: General agreement.

RA: So, GP practice.

P: Yes, I think so.

P: You can walk to it.

RA: Sorry?

P: You can walk to it, you wouldn't need a car.

P: No, Barnham Broom at lunch time sounds a good idea (laughter).

Ps: General over-talking.

RA: And something else that's been alluded to, the time allocation, should we allow them an open amount of time or should we limit it?

P: Open.

P: Well time pays so they've got to get the idea eventually, I mean the more the time the more the cost to the service, but I mean if it's ten minutes, that struck me as a little bit short, but he may have felt he covered everything.

P: But then again if you get somebody who is a health fanatic and really worries about their health, it could be two hours.

P: I think as long as long as you draw a line somewhere (general agreement).

P: I don't think my student was itching to get away, I just think she felt she'd done what she needed to...

P: ...Yes, I felt that with mine too.

P: And most probably I didn't ask around the issue (unclear).

P: Do you teach them how to terminate these interviews politely, when somebody doesn't want to?

RA: We have given them some indicators (laughter). Okay, so moving on then, the recruitment process. So obviously this is a study and you were all recruited via your GP practices because ethics dictate what we do. Firstly, do you have any general thoughts about the recruitment process?

P: Well I personally like to volunteer for these things because now I've retired I think I can put something back in finally and I'd be quite happy to put my name on a list that you have, and not my GP had, provided you ask (unclear).

Ps: General agreement with the above comment.

RA: Is there anything that would have, if you had been wavering, is there anything that would have encouraged you more to volunteer?

P: Money (laughter).

P: I think it could possibly be an idea to have the meeting with you and volunteers and throw one or two ideas in that we might bring up with the student, a sort of preliminary you know be aware that you could ask these questions...

RA: So this is part of the process for...

P: ...the volunteers to be prepared as a patient.

P: I think the trouble with that is that, cross me out because I've (unclear) to say it's too much of my time. I'm happy to get the feedback and the lunch but you know in terms of I just think that's asking too much really.

RA: The letters and the information that we sent out to you about recruitment were they okay? Problems with them?

Ps: General agreement that information was okay and there were no problems with them.



P: Friendly and considerate letter.

P: You could ask for information which you put on database like what would you be prepared to do, you know come to UEA, come to the local hospital, etc, so if you wanted somebody who could attend the UEA at short notice to be a right lovely person, you could run through your database and pick them out.

P: Having talked about time, if I was dealing with more than one student, I would then be prepared. I mean I've got a very positive attitude towards students doing work which is you know involved in the community and in terms of their if you like their eventual patient market, if you dare call it market, so that just cut all that naivety out because they learn I think a tremendous amount. So if I'm a volunteer for more than one student, but you know in terms of other time, I then come in the introductory thing, because it's then an investment, isn't it? But in one student (unclear), it's pushing me personally a bit far.

P: What extra input someone like me could give, because I mean being a type II I don't even know I've got diabetes most of the time, you know, what other help could I give to a student? It's really a case of them asking me the questions and hoping to get the right answers.

RA: To be honest, the main issue was learning consultation skills. And diabetes was chosen as an example (unclear).

P: It's come to my mind now that we've all got diabetes and we were all picked for this because we've got diabetes. I've got other problems and had other problems, are you narrowing it down (unclear) or should the student think perhaps he isn't taking, he's taking what we'll say is metformin, but should he be taking brand B because he already he's taking this and this and this and this? We're all different, you may only be taking metformin and that's it.

P: There's also different types of type II.

P: Oh yes.

RA: So this is going to something I was going ask later, so that's fine, I'll raise it now since you've mentioned it. If we were to repeat in future, do you think we ought to just open it to any disease state or virtually any patient? Or should we restrict it?

P: I think it should be restricted, I think it's too wide to be assessed.

P: I think it would be a nightmare to do it with a whole range.

P: What you've got to bear in mind if some people of got lots, more than one thing wrong with them.

RA: And should the students restrict themselves to dealing with the diabetes or should they deal with the whole patient, i.e. (unclear) conditions the person has?

P: I think the whole patient, once you've got them in there.

P: Yeah, the whole patient, yeah.

P: Time, they'd need more time then.

P: I suppose when it gets to that point they're encroaching on the doctor's skills, aren't they?

P: Yeah, there is an overlap, isn't there, of quite a bit I should think.

P: Yeah, but you know, we're not cheap because we've got our own nurses, specialists in that, most probably the nurses we've got are more knowledgeable on diabetes than the doctor (over-talking, unclear).

P: I'm sure they are, I'm sure they are.

P: Oh, yes they certainly know more about diabetes than the doctors do.

P: That's why I said I would do it in that order, the diabetic nurse, then the doctor, then the pharmacist.

P: I couldn't agree with you more.

P: But there again we are lucky that we've got a good practice.

RA: So is it appropriate, I'll go back to something I mentioned earlier, is it appropriate for a student to be able to have a real consultation with a patient.

Ps: General agreement.

P: I think one thing they could do for instance, whilst I've got diabetes, I take pills for other things I don't think they interact with each other, but if we started at the diabetes and then we just check the other pills I was on the student might spot a potential interaction between them which she could throw up and...

P: ...I think that's very relevant that (general agreement). There are certain drugs I've had one reaction from one drug but it was the pharmacist that found it out, who suggested the change, not the doctor and not the nurse.

P: In one of my drugs luckily they said don't eat grapefruit...

P: ...oh that's statins...

P: ...statins...

P: ...otherwise I'd have gone quite happily munching through...

P: Don't eat strawberries.

P: I couldn't give up strawberries, there's one left, I wonder who wants it?

RA: Okay, we sent you all a questionnaire at the beginning and at the end, do you have any thoughts about the questionnaire?

P: (Unclear) thoughts.

P: Don't ask us what the questions were (laughter – unclear, over-talking).

RA: In terms of was it about the right length, did you find it difficult to complete?

P: I found a couple of questions wordy, that I struggled to answer and I can't remember what they were now, I'll be honest, where I wasn't sure whether they meant now or in the past or what, I didn't, I can't remember they were early on as well, because my wife sat there ticking the boxes and I said (unclear) and she got cross with me (laughter).

RA: (Unclear) I'll try and word it differently then. If we repeated the exercise do you think patients would have problems completing it? Should we change it?

P: No, no.

P: Most of the questions you can easily answer, I think there were a couple there I thought oh well which answer shall I give.

P: I think I found them why are you asking me that? Why are there so many options and I found a little bit irritating, no doubt each one was there for a specific purpose, but was it? And I think it felt that in some of (unclear) I can't remember, but they were you had all going down and down and down and I thought well I've answered that, maybe not in the way it was asked but it seemed to be the same issue. And the other one I had trouble with is where I think there was a table down the right hand side, you had to say...

P: ...question six...

P: ...was it? I can't remember what the question was even, but I thought maybe mine was 80 or something like that per cent or whatever it was. I thought well why is it? I've got no real basis for giving that evaluation, you know and I thought somehow I sort of like felt very well, well but something like that might have been more appropriate. I don't know how some people without any real statistical or mathematical background were coping with that.

P: Even with mathematical background you still can (unclear – laughter).

P: I think it was number six and I think it was also from seven to 23 I found all a little bit we weren't getting anywhere. We're answering questions for the sake of answering questions.

P: Do the students...

P: ...when you get to the point of oh god what should I put down for this one...

P: ...did the students make that up or (unclear).

RA: No, in fact these are nationally accredited questionnaires. We combined about four validated questionnaires into one.

P: That could be the problem (some agreement), I'd edit it if I was you.

P: I mean I did it well within the time, but I mean academics are notorious for being appalling form fillers (laughter).

P: Not only academics.

P: Well my wife started work in a building society and the manager always said that when there was problems with an application he'd say that's a school teacher and nine times out of ten it seemed to be. Arrogance, that's the problem, isn't it?

P: Possibly.

RA: Going back to the (unclear) student, did you have expectations of the students' performance beforehand? Did you think they would be good or bad?

P: No, no expectations before.

P: I expected them to be good, but that's built on past experience with the UEA.

P: I was completely open-minded.

RA: So a couple of open-minds?

P: Yeah, I thought they were fine.

P: They ought to be good at that stage because you primed them well, got them ready.

P: What, were they fourth year, were they?

P: I just thought they'd be competent.

P: Yeah, they should be quite keen.

RA: Had your experience of meeting pharmacists in practice given you any thoughts about what you'd find?

P: Well my experience with pharmacists only comes down to one who was an obnoxious little (laughter) because I'd gone and picked up some pills, I'd overlapped two prescriptions so I'd actually got two prescriptions in one and he was about to phone up the drug squad, he made one hell of a fuss, very publicly in the shop, and that's exceptional and I came back about a month later and he wasn't working for them anymore.

P: Usually if you get hold of the pharmacist at Wymondham, at the surgery, they're very, very helpful, aren't they?

P: Oh I've never come across anybody like this bloke before.

P: I've never come across anyone like the one we've got at the moment where he's been there (unclear), they put him in to sort Wymondham out didn't, by god he's sorted it out, but he's brilliant, he's the one who took me into the little room...

P: ...I don't like the system they've got for finding the prescriptions but...

P: I don't know if it's true, but someone told me that, it's come from two or three sources, perhaps you can answer it, that Wymondham is one of the largest practices (over-talking) for Boots in the country.

(Over-talking discussing the above point.)

P: Because I find that hard to believe that little old Wymondham is that big a practice that, there's an awful lot of staff in there though, isn't there? (General agreement.)

P: So how do you guys get to see your pharmacist, I never see mine?

P: (Unclear).

P: It would be nice to see him.

P: You go to the desk and ask to speak to the pharmacist.

P: Yeah, but if you're okay with the tablets you're taking, i.e. I am, I mean what's need for the consultation with the pharmacist?

P: If you need to take another tablet sometimes for something else.

P: Well my dietician nurse will tell me that, surely?

P: No she won't tell me...

P: She tells me.

P: ...for other drugs apart from...

P: ...metformin and sinfadol(?)?

P: Well I had occasion when I had a terribly inflamed throat, I went in there and I said I'll have some of those. Oh you're diabetic, aren't you? Because he serves me with the pills every month, you know, and he said no you'll have to see the pharmacist and he decided which ones I could take and which ones I couldn't.

P: I must admit, my wife went into Tesco, I wasn't with her and she'd had this virus that had been going around for about two going on three weeks, and the chemist asked the question about have you got high blood pressure, she said yes, so ah right and came up and the drugs she recommended, when we got home and read it, do not use if you've got high blood pressure (laughter).

P: And did they offer you two packets and you get one free as well? (Laughter)

P: No, from a pharmacist, allegedly in Boots, or maybe it was a shop assistant, whoever (unclear).

P: Maybe the just better move on then (laughter).

P: I've actually read through some of those bits of paper which say don't take it if and some of the ifs I've got but the doctor still recommends them.

RA: At the end of the consultation we asked you to complete a short questionnaire, a few questions about the student's performance. What are your thoughts about the score that you gave?

P: Well I think I gave fairly high scores because the questions were intelligent and designed to find out you know what they really wanted to know.

RA: Maybe I'll phrase it slightly differently. The scores were universally very high, do you think people were being kind or was it a true reflection?

P: I think from my point of view it was a fair reflection actually.

P: I think it was a bit of both.

P: Very true.

P: I think it must be relevant to trying to encourage the student as well (unclear, over-talking).

P: I think there was an element of what Carol said earlier, most probably this group here we're user friendly.

P: Because we've all done things like this before.

P: Yeah, we're all older, sorry (laughter) (over-talking), trying to help put the student at ease.

P: Yes.

P: As much as you could in such a short time any way.

(Unclear – over-talking.)

P: They were young weren't they? And they've studied for four years, yeah absolutely.

P: All the coppers look young too.

P: Everybody does.

P: (Unclear) cut my throat because he looked horribly young (laughter).

P: I thought god you've only just left school (laughter).

RA: Okay, one quick questions, has anybody seen their pharmacist for an MUR, which is a drugs review where, similar to what you said, you're taken into the consultation room and...?

P: Oh I think I did about three years ago, yeah.

P: No, I haven't.

P: I was offered one, but as I said I turned it down because the doctor had done it recently.

RA: So there's a couple of you have, fine. I've think we've talked about repeating the exercise and I think the universal feeling I got that the answer is yes (agreement) and I think we've talked about possible changes if we did repeat it. So really I've come around more to the end, so is there anything that anybody wanted to say at any point but they didn't really get the chance to say properly or do you think there are any questions that I should have asked you but I haven't?

P: I really think that it would be a good exercise if they had some difficult questions, or difficult patients. I think we've all been you know trying to help them...

P: ...we're all too nice, aren't we?

P: ...yes, and I do think they should have some experience of dealing with somebody who's not really kind and understanding.

P: (Unclear) I wouldn't be any good at that but I mean there are people who you could say would you go and be a little bit awful...

P: ...yes, I could do that, I could be awkward.

P: Could you?

P: Yeah (laughter).

P: Old people have to be don't they?

P: Absolutely (laughter) (unclear).

P: As long as they knew afterwards that we really sort of all right, I don't want them stoning me in the street (laughter) (unclear), but I do think there is a case that they should learn to cope with people who are a little bit difficult or really anxious, because people can become very anxious.

RA: And this is a theme that's come up a few times, but dealing with difficult or anxious patients (agreement).

P: Or somebody who's just gone in (unclear) to that and knew what the answer should have been.

P: Oh, absolutely, yes.

P: I find that terrifying.

P: Well I don't use computers.

P: Perhaps it's a generation thing but I mean I don't go on the internet (over-talking) to look at...

P: ...I have. I looked at the side effects of an anti-depressant that I used to take and it just kept on going (laughter) and I thought my god I'm lucky to be out of it.

P: My daughter's got a friend who is a hypochondriac and she spends half her time looking up what's the matter with her and actually there's nothing the matter with her.

P: Well my student asked whether I read the instructions inside the pill packet and I said no because it will say this pill may cause you constipation/diarrhoea and there's always the alternative so could affect you in any way so I don't read instructions in pills, that's what my doctor is paid to do, to make sure she gives me the right pills. And if I did feel ill, then I would go back, but I'd go to the doctor rather than a pharmacist.

P: It would be nice to put one of those little things in it to say it will make you feel really happy, full of energy (laughter)...

P: ...yeah, a happy pill...

P: ...a happy.

P: I've got a sister who keeps the private sector in funds, she gets a new disease every week (laughter).

P: Well I take one tablet and the other's an eye drop and, well I take others as well, but with these two I was taking them wrongly, but no one told me...

P: ...do you mean you were putting the tablets in your eye and the drops (laughter)...

P: ...no, no, it's a matter of putting your finger in and block the so it doesn't escape, because if you sniff or something you're going to bring that all the way down your throat. And the other one was this (unclear) tablet which I had so much trouble with and you know you're supposed to take it before food, but it wasn't, it may have been after I saw the student or the first questionnaire that actually did pull out the instructions and discovered that, but I had no advice from the surgery or on the pills as to whether you took them before, during or after food.

P: Yes, some of my tablets on the box it just says take as instructed by your doctor and I'm thinking that's three years ago, what did he say? Just swallow them (unclear).

P: I found those metformin things they tend to get a big sticky on the outside and get stuck just there.

P: You're supposed to take them with water.

P: Yeah.

P: You're supposed to take them with orange squash or lemon squash or something...

P: ...or double scotch (laughter), that's how I get it down.

P: If you take a double scotch you won't need the tablet (laughter).

P: We're into the realms of the unknown here, aren't we?

RA: Okay, is there anything else?

P: Thanks for the lunch.

P: I'd like to thank you for the excellent lunch you provided, it really was (general agreement).

RA: I think I owe you a greater debt of thanks for volunteering for this study and you have done a lot to help our students.

P: Well I hope so because I'm going to say this, you can do it on record, you hear people moaning and moaning about the national health service and I have reason over the last two years to be very grateful to the NHS (murmurs of agreement) and I have no problem with the NHS except one thing, there's too many bloody people walking around with clipboards who aren't doctors (loud noise, laughter).

(Unclear – over-talking.)

P: Well I think it's a brilliant service (general agreement) and if you can help them to help us it will be better.

P: It's a regional thing though, because we had an aunt who died recently but in the London area and her medical back up was absolutely atrocious.

P: Was it?

P: Yeah, but here, it's fantastic.

P: Well my son, unfortunately, it's ten years ago now, lived in America, he lives in America, but he lived in America then and his first wife died after she collapsed, she collapsed after a flight from New York to Seattle and she was rushed into hospital in a semi-coma and I had a phone call from my son saying dad can you help financially, they need £30,000 before they'll do anything for Anita(?). I thought...

P: And they resisted Obama's...

P: ...they pay insurance but it was not valid in Seattle, it was only valid in New Jersey and New York or (unclear)...

P: ...didn't he have (unclear) insurance?

P: Yes, you know, she died unfortunately within a week (end of tape).



Transcription of Roundwell, Paston and Hoveton Patient Focus Group held on 28 November 2012

RA: Okay, right, I'll start with a very general question. You all took part in the study where you met students, do you have any views on it, whether it was good, bad or indifferent or just a general view and then I'll ask more specific questions later?

P: I thought it was good, myself, I enjoy it actually.

P: Yeah, it was enjoyable.

P: I've been asking myself, this morning asking myself the question has it done me any good and I couldn't think of an answer, other than it didn't do me any harm.

P: That's what I was going to say, I was wondering whether the students had what they wanted, that they had requested it, were they happy with what they got back?

RA: Yes.

P: That's the main thing and did they know what to ask?

RA: The purpose of this is for them to learn.

P: They should ask as much as they can.

RA: I want it from your perspective, so you say you enjoyed it, why did you enjoy it?

P: Well, I mean it makes a change, doesn't it, (laughter) when you live a hum drum life as a retired person anything is better than nothing, change of scene, change of face, chance to talk to somebody, whatever.

P: Helping the students...

P: ...yes, I think it's the help.

RA: And you said it was good, what did you think was good?

P: Yes, well I thought I felt like I was doing some good in a way by giving my honest opinions on what they were asking you know and it seemed quite interesting.

RA: Anybody any other views?

P: Well, I used to be at the school of nursing when (unclear) I used to deal with student nurses and you used to have very strange conversations all about different ailments and illness you know and it's nice for them to have, talk to somebody who's actually got something rather than just a lecture, this is what happens, they're talking to somebody who's had that problem or got that problem and how they react and how they deal with that problem.

P: I think also it gives them the opportunity of telling me, kind of I go into the doctors, you sit there, you've got a five minute appointment and you're out the door, whereas here you know they were able to tell you a bit more about your medication, how it worked and why it worked, which the GP, nine times of ten, doesn't have the time to give you, so from that point of view when I came out I thought oh I didn't know that.

RA: So you actually learned something.

P: Yeah.

P: I think another good think about it was that, at least in my case, it seemed to be a bit open ended, there wasn't a time limit, I was quite surprised when I came out to find that I'd been in there quite as long as I had because I felt a little bit guilty then, I thought crikey am I taking up more time that I should have, but nobody seemed to be at all concerned so I don't I had, but you know it was good just not to have a sort of oh you've got ten minutes or you know and that's it, it was just a chatty sort of thing really you know.

RA: So following through that comment, if we were to repeat in the future, and we don't know if we will, would we be right to not time-limit it?

P: Yeah.

P: I think so, yeah.

P: It's hard thought, obviously, because somebody could be in there for five minutes when you've got another appointment for another hour, so people are just sitting around, I appreciate the problems that you've got with that, but I do think you know you're better off having it open ended so that if somebody wants to come and add their bit and then leave, that's one thing, but if they were to ask long questions (unclear).

RA: Okay. So if I can be a bit more specific then, the actual consultation with the student, was it appropriate for a student to undertake what they undertook?

General agreement from patients.

RA: Does anybody disagree?

P: (Unclear).

P: They didn't say a lot when I was there, no.

P: (Unclear) think of them more as free spirits (murmurs of agreement).

P: I thought there was one question that I was asked that was a bit intrusive or possibly asked a bit insensitively.

RA: Right. So that's down to, is it the way it was asked or the actual question? I won't ask because...

P: I just thought it was a little bit insensitive but I suspect that that's the sort of thing you'd learn not to do fairly quickly in practice, but I mean it was just a youngster learning her trade.

RA: Okay.

P: Well you were in my class, you were in my (unclear).

P: I find it helpful to have an exchange of ideas or you see you've got to say go to the doctors, the diabetic nurse, she's a lovely lady, but I live on my own and she nags me twice as much because I live on my own (laughter), so I go in there and I get about fifteen minutes of grief you see because I haven't done this and I haven't done that and I should be doing this you know, it's nice just to sit and talk about it without getting a load (unclear, over-talking) on the ladies but you know what I mean (laughter).

P: I've got a wife who does that (laughter).

P: Well I don't you see, that's why she does it (laughter).

RA: So do you feel the students were, or the student that you met, was suitably prepared?

P: I thought it was variable.

General agreement from other patients.

RA: Okay, you said variable...?

P: Variable, some were very well prepared, the very first ones I had but the second lot they were quite, they were fishing...

RA: ...you did say fishing?

P: Were quite sure how to start things off.

P: (Unclear) I think that's usual with the student, I think it was and she was a bit (unclear). She was a bit kind of trying to find something to grip onto whereas the first ones, they knew what they wanted to do.

P: I think I would kind of agree, I think the lady that I had, a very, very nice lady. I got at times that she wasn't very sure, I think that's the expression she used and I think I marked that down on my sheet, but I forgot at times she wasn't very sure, but then again what's the point of (unclear, over-talking) so...

P: ...we had a student, I had a student with a girl who seemed to know exactly what she was talking about and I said something to her because perhaps I'm not giving her a chance to say anything, ooh she said I'm listening and learning from the one who was doing the talk, so yeah, she was learning as well.

RA: So is the issue confidence or competent?

P: Yeah, confidence, I think.

(Unclear).

P: Confidence, I think.

P: I just thought it was lack of experience, something that perhaps she might have learnt from (murmurs of agreement).

RA: And do you think, then, that if they met more people such as yourselves that they would gain confidence from that?

General agreement from patients.

P: It's experience, isn't it?

P: I thought that was the point of the exercise.

RA: No, that's why I need your views to, think to see...is it worthwhile.

P: That's fine.

RA: So I think you mentioned possibly that there was some benefit, was there any benefit to yourselves or was it all benefit to the student?

P: I didn't learn anything that wasn't written at great length on the leaflet that comes in the packet and I imagine if someone hadn't read them then perhaps they might have learnt something, but it's all there.

RA: Anybody else?

P: Well I was, I'm a food technologist and I was a bit concerned that the students didn't know which (unclear) various foods (unclear) to recommend to their diabetic patients and I actually (unclear) recommend this book (unclear) and they hadn't heard of it, that's a very good book to learn what's got sugar in and what hasn't, it's been out for fifty years now.

RA: So you're saying that they need to know more about the content of food in order to give advice?

P: Exactly, exactly otherwise they can't (unclear).

P: I actually did learn something as in a technical thing, because I was talking about the effect of the metformin tablets and I didn't realise, because nobody had said, that you can in fact get something like a half strength metformin tablet instead of the one we get, so they're less of a...

P: ...tummy upset...

P: ...clearer thing, yeah.

(Unclear, over-talking).

P: That was what I was sort of saying and they did say to me you know you can ask for a half strength one and maybe that will help. I think the new, or newer thing, thing that I've been put on, this recently released drug thing that works earlier in the system or something, I think that's a better thing, I'm going to ask if I can you know, now I'm taking that, reduce the metformin dose.

P: What is it?

P: This new thing?

P: Hmm.

P: Can I just get up and get this thing out of the pocket (laughter).

RA: Okay, so one or two of you got a, you know learnt something but generally it wasn't much?

P: (Unclear) people that take the tablets. How many people actually read the bit of paper that comes inside the box?

P: I do...

P: And I do.

P: ...effects...

P: ...where you've got the side effects, yeah...

P: Yes!

P: ...because I was taking one tablet, occasionally I'd get an odd singing in my ear and I went to the doctors about it, old so and so, and there was nothing there, he said I'll give you some tablets and said just take

them when it's there and later on he said how're you getting on with that, I said that's the side effects of them tablets, I actually read the slip...

P: ...so you knew...

P: ...oh I'll change it for you, no so long as I know what's causing it...

P: ...exactly...

P: ...I'm happy you know, I just live with it you know, it's there.

RA: Okay, follow on from that would you want the student specifically to give you guidance about side effects?

P: Well if the students read what tablets we take and the bits of paper that go in the box, that help, you know (unclear, over-talking).

P: Isn't that a job for the doctor, I mean they're only students, you're putting a lot on them, aren't you?

P: Yeah, but it's nice to know what the side effects are...

P: ...yeah.

P: The interesting thing is, although I agree entirely, is that I was on (unclear) former medication, she asked me what I was on, I told her what I was on and all the time through the interview I kept coughing, if you remember, and she turned round and said what are you, well you know again what detail and I said I'm on propanelol(?) and she turned round and said I'll contact the doctor, or I'll write to the doctor and suggest that he changes because that is a side effect of propanelol(?), now that didn't happen, I don't think that happened because I landed up having to see the consultant because I suffer from asthma as well and you know and I'm sitting there cough, cough, cough I mean and it was incessant, day and night you know and even the consultant turned round and said to me what are you on so I told him and went, that's it, that's it, you know if she had followed that through then perhaps I wouldn't have suffered the next four, five months of (unclear), day and night, it was horrendous.

P: Now I've learnt something a few minutes ago, that gentleman says there, metformin gives you diarrhoea, I didn't realise that...

P: ...oh, it does, yeah...

P: ...oh, crumbs, I never knew that...

P: ...and wind.

P: If you, do you read all those things, because the pamphlet that I was just referring to is the thing called sexoglyptyn(?) and the thing that comes in with that, you know the piece of paper, is like war and peace (laughter), if I read the thing, I'd be there for hours...

P: ...take it to bed with you...

P: ...I'd almost want the next word, I don't think I'd get up because for most of the things I think I find that you know if I suffered any of these reactions, that is all thirty six of them, I'd be dead anyway.

RA: I might follow that on after the meeting, actually. I've got some thoughts on that. Okay. Can I ask, if we repeated this, would you want, no I'll ask it two ways. Is it something that we should repeat? And if we did, what changes, if anything, would you want?

P: I think you should repeat it, yeah.

Murmurs of agreement.

P: Well surely the question is was it of benefit for the students (agreement) because it's no benefit to us, it's for the students. If it's useful for them....

P: ...then it's got to be right...

P: ...then do it.

RA: We're concerned also unless it fits in with yourselves then people are not going to volunteer to come so that's why we're trying to find out.

P: It depends if you're away or not, that sort of thing.

P: As a suggestion, if you're going to repeat this sort of meeting, on your first letter if you could put the time of the start, because like I accepted and then I realised that I'd actually got a dentist appointment this morning and I was thinking oh sausage what time's it start and there was nothing on your letter to say the time of start, it was only your second one where you said that the buffet was at 12.30 or something.

RA: Okay, so if I go down to the practicalities then. The location, originally we were going to have the meeting, or meetings with the students at the UEA. We spoke to some patients and they said no, go to the GP practice. Is that the right place?

P: Oh, yes.

P: Yes.

P: I think so, yeah.

P: We all live near our doctors presumably, or relatively near.

General agreement to this point.

RA: So therefore, were there any travel issues?

P: No.

P: No.

RA: Okay. Recruitment, now because it was a research study we have to recruit in certain ways, was there anything about the recruitment that you think would have been more likely to have encouraged people, or less likely?

P: It was very low key.

RA: When you say low key...?

P: I mean it wasn't promoted, thing is you had to find out all about it.

P: There was a list in the surgery sort of thing but unless you're actually waiting and you're staring at that list, you didn't know.

RA: Well this one was the one where the practice wrote to you.

(Unclear, over-talking – general feeling of sudden realisation.)

P: (Unclear) lists up in the waiting room.

P: Ahhh.

P: Hmm.

P: Ahh, yes, no I got a letter, I think.

RA: That's medical students.

P: I got a letter, yeah.

RA: So we wrote to people and said would you be prepared to participate and then gave you some information, so looking at the information that was there, you all obviously volunteered. Is there anything we could have done to make it more likely that people volunteered?

P: I don't think so.

P: It's just nice to get a letter that wasn't inviting me to take our yet another bank card (laughter).

P: A bit more charity work.

P: Or the brown one with HM Customs & Excise on (laughter).

P: I think there are different types of people, I mean there those who are willing to do this sort of thing and really you could just ask them and turn round and say would you like to come and they'll say yes. There are other people who don't feel either that confident or don't want to and therefore even if you gave them fifteen pages of information, it wouldn't make any difference, you either want to do this sort of thing or you don't.

Murmuring throughout above.

RA: Okay. So really the information we gave you was about the right amount?

General agreement.

P: If you get too much information you're back to the (unclear, over-talking) what the hell is that, that goes in the bin.

P: (Unclear question).

RA: We sent you all a questionnaire to complete, what did you think about that questionnaire?

P: It was fine.

P: That was the thing we ticked, wasn't it?

P: Yeah.

RA: Was it about the right length, too long...

P: ...no, it was right...

P: ...no, wasn't too long, I think...

P: ...comprehensive...

P: ...whether there was enough questions on it, I don't know...

RA: Was it easy to understand or hard to understand?

General agreement that it was easy to understand.

P: I mean you could always turn around and say oh well I wouldn't have asked the question that way, I'd have asked it another way, but that's a natural way to think, as long as there is that box which says have you got any other comments you wish to add, which I did, you know, I found it quite...

P: ...it was easy to do, yeah.

P: Quite reasonable.

RA: Okay.

P: I do have a question about prescriptions, when they give you a prescription it says take one or two tablets a day, it doesn't tell you what it's for and when you take five or six different types of tablets and you don't know what they're for (unclear).

P: Can I say something there? I belong to Diabetic UK, you obviously know about it, you they tell all what tablets are for, why you're having them, very, very good. I learnt a lot from them.

P: Before I was a diabetic, they don't really tell you what those tablets are for, you see the doctor and he's prescribed them, told me about them though he's probably forgotten half of it anyway (unclear)...

RA: Is that something the student should have emphasised or not?

P: Yes.

P: I think so, yes.

P: I mean this is going back to what I said earlier that I learnt from that student because she was telling me things about the tablets that as I said that the doctor or the GP didn't have time to...

P: ...that's right...

P: ...if you stop taking the tablets you might find out what they're for (laughter).

General over-talking.

P: I think they can tell us or we can ask well what's this for, what's this one for.



P: And because of the environment you have a tendency to listen whereas in the doctor's surgery you're sitting there and all you really want to do is get out, you know, so even though they tell you things you don't necessarily sink in, whereas you know...

P: ...I take the wife along now...(laughter)

P: The student I had was quite sort of thorough in telling me what the different drugs were.

P: You should ask the lady over there, you go Diabetic, do you go to the lectures or the talks?

P: No.

P: They have them at Cromer.

P: What, in Diabetic UK? No, I haven't.

P: Cromer on a Thursday night about once a month. I have made a couple of visits there and one of them there was this lady, very interesting, but it was diabetes during pregnancy, now we're all of an age and 75% were male (laughter), you know, not relevant.

RA: So, before you met the student, did you have any expectations of how they'd perform? Did you think they would be really good? Or really bad? Or better or worse than they were?

P: I'll be honest, I thought mine would be better, to start with, you know, but that was whether that was a language problem as well because I think, was she Malaysian or Chinese, I can't really remember? But whether there was a language difficulty, do you know what I mean, whether that was the start of it, I wasn't terribly impressed to start off with, it actually warmed up and I was quite happy at the end, but when we started off, you know I found it a bit of a you know...

P: I have to say mine was I thought much better than I'd thought, I didn't think they would know anything about it, but they did.

P: I couldn't recall what year they were in, whether it was their first year or...

RA: ...fourth year.

P: ...fourth year? I see, well they know what they're doing by then...

P: ...they should do, yes (laughter).

RA: Does anyone else have any views of whether they were better or worse than expected?

P: Well I've dealt with nursing students of all different years, for about seven years, at the school of nursing and they're all much of a muchness. You'll get some that are really keen and knowledgeable and others that just sort of scrap through on things.

RA: But what about the student you met? Better or worse?

P: I think in the middle somewhere, yeah, I didn't (unclear, over-talking) ideas, you see, that's...

P: ...one thing you learn with a career in education is never to expect anything from any student (laughter), be prepared for anything.

RA: Okay.

P: (Unclear) any questions really, I had no preconceived ideas (unclear).

RA: So, did your experience of dealing with pharmacists in the local chemist have any impact on whether you, on your opinion of how you thought they would perform?

P: Our chemist is very good in Wroxham.

RA: But did that influence how you thought the student would be? Or not?

P: Well not really because he's qualified, isn't he, and they're not yet.

RA: No, that's fine, it's just something, this is a comment that we've have elsewhere.

P: Oh right.

P: I don't get anything from my pharmacist, I mean I know him, I taught him when he was a kid, I played cricket with him in the same team, but he doesn't say how are you getting on with your whats-er-names or do you like these or try some pink ones, it's just a bag of pills and away you go (unclear).

RA: And this is why we're trying to train them differently (general murmurs, laughter).

P: No I think my chemist is absolutely brilliant, you know, as soon as I go in there with something different he comes out and says now are you, you know what this will do, you know, you know where to find me if you've got any problems, you know what I mean.

P: That's nice.

P: Our chemist is very (unclear).

RA: But did that influence your expectation of how the student would perform? Or not?

General murmurs that it hadn't.

RA: Well that's fine, it was one comment that came up elsewhere and we just thought we'd follow it through. And just another odd comment that's been put to us, do you think that because they were pharmacy students, will this make it more or less likely or no effect in terms of whether you're likely to speak to a pharmacist in a chemist shop?

P: Well they like asking questions.

RA: But would this influence (unclear)...?

P: It wouldn't occur to me, it wouldn't occur to me at all.

P: I've got a pharmacist bloke, you know the one in the middle of North Walsham he sort of I don't know whether it's an annual thing or not but he sort of takes you into the little cubicle and just runs through the tablets that you're taking and says is there (unclear)...

P: ...is that in Boots in North Walsham?

P: ...yeah, well it used to be Boots, yeah.

P: That's why....

P: ...that's where I go as well.

P: ...and he'll say well have you got anything new, you go round there and they'll say right well so and so (unclear – over-talking).

P: Yeah, he sort of says you know how many do you take and what do you find them, that sort of thing you know, so he's sort of questioning if you like what is entirely different to what I thought and it is very different from what the students were like...

RA: Which is the best way?

P: Well I think that they're so entirely different that the one doesn't affect the other or any feeling that I had for the other you know...

P: It's more personal any way...

P: ...yeah, I mean with the student one I think we were concentrating on the what-it's-name, the diabetic thing, whereas the pharmacy one goes through, I have gout as well, I don't know if any of you suffer from gout, but it's the world's worst pain and (unclear)...

P: ...I was going to say...

P: ...but you know the pharmacist goes through all of them sort of thing so it's now really a comparable thing.

RA: Okay, so okay, fine I'll leave that one then. We asked you all at the end of the consultation to complete a questionnaire and in general the students marked themselves far lower than the patients marked them...

P: ...oh, that was nice...

RA: ...so what we're just wondering about is why, so was it a true reflection of how you thought the student performed or were you being kind or what?

P: I was honest where I thought it wasn't very good I did put it you know.

P: I tried to be helpful, but a cup of tea would have been useful to help them relax and perhaps keep them talking.

Unclear – general over-talking and laughter and the above point.

P: ...and the thing is that, perhaps the more relaxed the atmosphere of it you could say things a bit more...

P: ...yeah, that's true.

P: ...than before.

RA: I hadn't thought of that, so okay. What about anyone else?

P: I think that's a general tendency, actually, if you're filling a form in on how you perform you mark yourself down because you don't think you're as good as you are...

P: ...that's right...

P: ...oh, no, no, no...

P: ...and that's a human reaction you know, there are certain people that think that I'm god's gift and I'm here...

General muttering which unable to decipher.

P: ...well, actually, the average person in the street tends to mark themselves you know...

P: ...it does depend on what you're talking about. If you're talking about the annual appraisal form that you have to fill in and your bonus depends upon it, believe me you put yourself as box one. If there's no money involved then...

RA: In terms of how you marked the student, because the scores were very high and yes I would love the think that, but was it a true reflection, were you being kind or what?

General agreement that it was a true reflection and they weren't just being kind – too many speaking to clearly define comments.

P: I think it's true based on what we know. If I was a pharmacist I may well have been marking these a lot lower, but based on the information that I know, which is very pretty limited, you know I think to myself well that's very conscientious...

P: ...yeah, well that's fair comment...

P: I think the other thing that led it to be a true thing was that I don't want to upset you all but I filled mine in at home you know after the thing, if you're there sitting with the students and you're filling it in in front of them I can imagine that you're tempted to over mark if you like, but when you're back at home then you I think mark honestly.

P: Yes, it's not helpful otherwise, is it, really?

P: Do any of you who've got diabetes, suffer from cramp badly?

P: Yes, now and again.

P: You do?

P: I was told...

P: I have it very very badly.

P: Tonic water?

P: Yeah, I not had a doctor yet knows why you get cramp.

P: Did you hear us say tonic water?

P: Yes, I use tonic water.

P: I was told by my doctor to have that every night.

P: I mean I do take quinine every day right and I also take a (new era(?) unclear) tablet, I think it's got calcium in it and that seems to have made quite a difference, I take four in the morning and four at night, that seems to make a difference.

General murmuring about what people do about their cramp, not clear enough.

RA: So I think I've asked this, but I want to ask point blank, if we thought about repeating this, should we do it? Yes or no?

General yes's from patients.

RA: That's a definite yes.

P: If that's a benefit to them, yes.

RA: If we did it for a wider range of diseases or conditions, do you think people would volunteer?

General agreement to this.

P: As long as they weren't contagious.

RA: Now if we were to do it and it wasn't part of a research study, the recruitment would be different so I don't know if any of you have met medical students at the practice (a few yes's), but they simply put a list up and advertise and say if you've got one of these conditions, would you mind meeting a medical student. Do you think that is a suitable way or should we actually write to people individually?

P: I think writing is more reliable I mean I try only to go to the practice every six months to see the nurse, I know I do just occasionally get something wrong but you know I don't go there very often.

P: As I was saying before, you see that list in the surgery in the waiting room, if you go straight through or seen straight away, you don't see it (murmurs of agreement), so I think this way is a bit more personal.

RA: So I'm thinking we're saying, write to people?

General agreement to this.

RA: Is that right?

P: You'd get more response then. I think if you stick notices up on the door nine times out of ten people don't know the notices are there and the other part (unclear) you know I shalln't bother, whereas if you actually get a letter then you think oh yeah all right.

RA: One suggestion that we've had, and in fact something that we've seen has been done in America, is different professions working together so for instance one scenario we've seen is where a medical student a nursing student and a pharmacy student work together and meet patients and maybe focus on their own area. Would that be something you'd...

P: ...three to one you mean?

RA: Well either three together in the room or see each one separately on one occasion.

P: I think it's fine as long as the patients realise they're just students and they're not really the people to get advice from.

General agreement to this point.

RA: Okay, yeah that's the important thing to say.

P: Three to one, I'd take on three to one, yeah (laughter) – they'd all ask their own questions and you can focus on them.

P: Actually it should be a benefit for them as well because they're looking at the other persons, it's all very well them dishing out the tablets but what's the pharmacy say.

RA: You see when we look at it and think yes that would be a good way of teaching, but if you people think that's no good then we won't do it.

Several patients thought this was a good idea.

P: I'm sorry but I'm gonna have to run I'm afraid, I've got an appointment.

General noise of saying goodbye to patient leaving.

RA: I'm nearly there, okay. Is there anything anybody's wanting to say that they haven't had a chance? Or are there any questions you think I should have asked?

P: Diabetic and you've got sweets in the middle...

Unclear over-talking on this point.

RA: I couldn't see from this angle what was in there, yes you're absolutely right.

More general over-talking regarding sweets.

P: I think it would also be helpful if and when you have this sort of thing again is for you to have got the feedback from what the students (very garbled with over-talking) whether they...

RA: ...I've got feedback from students...

P: ...no I meant that you could relay to us if they turn round and say the students found (unclear).

RA: Okay, well I've asked all the questions that I want so if I say okay I'll go off line now, the students enjoyed it immensely. They were very often terrified... recording ended.

Start of new recording.

RA: Okay, if I can ask just one more question then, if we were to repeat, would there be any value in the student meeting the patient more than once, or would that be something patients would be willing to volunteer for?

General agreement that patients would be willing to do this.

P: I think it would be interesting because they would see what we were like in our first attempts and then we would see what they're like in their second, do you know what I mean? By the second time round we would be used to it and they would be used to it and perhaps there might be a slightly better (unclear)...

P: ...they probably wouldn't be so nervous the second time...

P: ...that's what I mean there'd be better communication between the two I think and we would know what to expect when we went in but I went in basically cold (unclear).

P: I did too.

P: I just went in with a list of tablets and that's my opinion.

RA: And can I follow that through, even if the students only see the patients once, would it therefore from what you've said be a benefit if we gave the patients, for want of a better word, a brief on what exactly was going to happen?

General agreement to that this would help.

P: The student would still be nervous for the first meeting.

P: I think you want people to be relaxed.

P: The trouble with briefing of course is that people go in there with pre-conceived ideas, probably.

P: If you've (unclear) and sit down you think, I was sitting there with a book when I went in there I thought to myself what the hell am I doing here you know and it was obviously before the student and the other people think what's he doing here you know what I mean. I think if you've got a briefing (unclear).

P: Going back to that gentleman's earlier comment, a cup of tea would break the ice.

P: Yes, there you go.

P: I should think if you were briefed too much that you'd go in there perhaps not being yourself.

RA: Okay, you're saying don't brief?

General agreement to this.

P: You need to break the ice.

RA: Okay, break the ice. So do you think that more than one meeting would be (unclear) (general agreement) – okay, I'll turn off again now.

# Appendix I: Publications

Age & Ageing (not related to this study)

Abstract presented as a poster at HSRPP Cork 2012, published in IJPP vol 20, supp S1, 2012

Abstract presented orally at RPS Birmingham 2012, published in IJPP vol 20, supp S2, September 2012

Abstract presented as a poster at ESCP Barcelona 2012, published in Int. J. Clin. Pharm. (2013) 25, p901

Abstracts presented as posters at RPS Birmingham 2013, published in IJPP vol 21, supp S2, August 2013



## Do older patients find multi-compartment medication devices easy to use and which are the easiest?

RICHARD ADAMS<sup>1</sup>, HELEN MAY<sup>2</sup>, LOUISE SWIFT<sup>3</sup>, DEBI BHATTACHARYA<sup>1</sup>

<sup>1</sup>School of Pharmacy, University of East Anglia, Norwich, Norfolk, UK

<sup>2</sup>Norfolk and Norwich University Hospitals NHS Foundation Trust, Medicines for Older People, Norwich, Norfolk, UK

<sup>3</sup>Norwich Medical School, University of East Anglia, Norwich, Norfolk, UK

Address correspondence to: D. Bhattacharya. Tel: +44(0)1603 593391; Fax: +44(0)1603 592003. Email: d.bhattacharya@uea.ac.uk

### Abstract

**Background:** multi-compartment medication devices (MMDs) are widely used, primarily by older people, to aid correct medication taking. Several MMD types are available yet little is known about the ease with which patients with varying functional ability use these devices and whether some types are easier than others. Such knowledge would assist healthcare practitioners in advising patients on a suitable choice of device.

**Objective:** this study investigates the ease with which patients with differing functional ability use three types of MMD.

**Method:** participants were recruited from an older person's medical ward. Demographic and medication information, cognitive function, visual acuity and manual dexterity were recorded. The Venalink<sup>®</sup>, Nomad Clear<sup>®</sup> and Dosett<sup>®</sup> MMDs were tested. Participants rated each MMD according to text readability, ease of opening, ease of medication removal, transportability and overall rating. These ratings were compared between MMDs for all patients and for subgroups with differing functional abilities.

**Results:** the MMDs were trialled by 50 patients; the majority rated text readability well but rated MMDs poorly according to the other criteria. Cognitively impaired participants may encounter difficulties in opening and removing medication from Venalink<sup>®</sup> and Nomad<sup>®</sup>. The Dosett<sup>®</sup> consistently rated better across all criteria. Transportability was the most influential criterion for overall MMD usability.

**Conclusion:** the poor patient rating of MMDs which are widely used in practice is of concern. Some MMDs may be difficult to open and access, especially for patients with cognitive impairment. This offers some guidance to health professionals in advising patients on MMD choice however, overall MMD rating appears dominated by transportability.

**Keywords:** compliance aid, adherence, functional ability, medication organiser, medication packaging, older people

### Introduction

An estimated 50% of patients do not adhere to their prescribed medication regimen [1], resulting in negative health and economic outcomes [2]. The population over 65 years have a higher prevalence of co-morbidities [3] and therefore are prescribed more medicines relative to younger patients [4]. Regimen complexity is negatively associated with medication adherence [5] and ability to self-manage declines with age [3].

Non-adherence arises from a lack of ability or willingness to take medication as intended by the prescriber and is often a combination of intentional and unintentional factors [6]. Despite little evidence of the impact of multi-compartment medication devices (MMDs), they are widely recommended

by healthcare professionals to address poor adherence with an estimated 100,000 patients using these devices across the UK [7]. MMDs are usually a variation on the design of a box or a blister pack, divided into days of the week with several compartments per day to allow for different dose timings. Numerous MMDs are available; varying in size and method of medication access from the device [8]. Medication packaging serves a number of roles including protecting the medication from the environment and access by children (Medication is removed from its original manufacturer packaging and dispensed into the MMD). However, these functions may inhibit access to people with impaired cognitive and/or physical function. Despite MMDs being largely targeted at older people, their manufacturers do not claim that

they have been tested with or are accessible to this population hence the need for independent research to evaluate their relative ease of use.

Patient ability to access medication from commercially produced packaging has been widely explored [9, 10]. In 1994 Atkin *et al.* reported that 41% of the older participants were unable to perform one or more of the tasks to gain access to varying forms of commercial packaging. The study included one MMD (Dosett<sup>®</sup>) and reported that poor vision and impaired cognitive function were predictors of inability [9]. There are no subsequent studies reporting the ease of using different types of MMD. Nor are there reports of the relative importance of MMD characteristics in influencing overall ease of use.

### Aims

To investigate the ease with which patients of differing functional ability use various types of MMD and whether some types are easier to use than others.

### Objectives

- Compare three types of MMD with respect to ease of use.
- Investigate whether a patient's functional ability is related to their ratings of ease of use.
- Determine the relative importance of aspects of ease of use in influencing overall patient rating.

### Method

Ethical and NHS research governance approval were obtained prior to study commencement at Medicine for Older Persons wards of a large UK teaching hospital. Eligible patients were regularly prescribed a minimum of one medicine and had a conversational level of English. Patients were excluded if not self-administering their medication, access was restricted to staff directly involved in their care or they were unable to provide informed consent.

Eligible patients were identified and approached by a hospital doctor; patients expressing an interest in participation were subsequently approached by a researcher for recruitment. Data collection was initiated by two researchers post-informed consent.

Based on 148 beds across four wards and an approximate mean turnover of 14 days, it was anticipated that an 8-week data collection period would provide 600 patients. Allowing for doctor and patient availability it was estimated that 25% (150) of these could be identified and approached by a hospital doctor. If a third of these consented and completed the tests, the resulting sample of 50 would be sufficient to detect an effect size of 0.5 between two matched MMDs with 89% power assuming 0.05 significance and a worst case asymptotic relative efficiency of 0.864.

### 2

### Participant characteristics

Medical records were accessed to obtain age, gender, living arrangements pre-admission and number of regularly prescribed medicines. Participants reported via questionnaire completion whether they had any prior experience of using an MMD or any previous problems with accessing medication from packaging.

### Functional ability tests

Validated tests presenting the least burden to participants with acceptable sensitivity were selected. Cognitive function was assessed using the Mini-Cog test which produces binary data of impaired or unimpaired cognitive function [11]. Visual acuity was assessed using the Vocational-Near-Vision Test Type [12], and the Grooved Pegboard was used to assess manual dexterity [13]. The mean time per pin was calculated for all patients who attempted the task.

### Participant rating of MMDs

Three MMDs were selected for rating: Venalink<sup>®</sup>, Nomad Clear<sup>®</sup> and Dosett<sup>®</sup> as collectively they account for >60% of the UK market share [14] (and data on file) and represent varying sizes and methods of medication access from the device. Figure 1 illustrates the three MMDs; the Venalink<sup>®</sup> is a cold-sealed blister pack which is also similar to most commercially available heat-sealed devices. The Nomad Clear<sup>®</sup> represents the monitored dosage systems and the Dosett<sup>®</sup> is similar to most MMDs sold within community pharmacies for self-filling or filling by lay carers [15].

Participants were presented with the three MMDs each containing seven days of placebo tablets. For each MMD, participants were asked to read the text indicating the days of the week and times of the day (comprehension was not assessed), remove a placebo tablet and then rate the MMD on a 10-point VAS (ability to open the MMD and remove a tablet was not independently assessed). A score of '1' indicated easy/convenient/very positive rating and '10' difficult/inconvenient/very negative rating. Participants rated each MMD against five criteria

- (i) ease of reading the text on the MMD;
- (ii) ease of opening the MMD in order to access placebo medication;
- (iii) ease of placebo medication removal from MMD;
- (iv) perceived convenience of transporting MMD;
- (v) overall rating.

Additionally, for each criterion, space was provided for participant comments.

### Analysis

Descriptive statistics were calculated for the sample. The scores for the three functional ability tests and participant ratings of MMDs were summarised. Median ratings were compared between MMDs using the Friedman test. For each




The Dosett®	The Nomad Clear®	The Venalink®
		
15cm Width x 10cm Height x 2cm Diameter	22cm Width x 17cm Height x 3cm Diameter	16.5cm Width x 24.7cm Height x 2.5cm Diameter
Font size 16 for days of the week and 10 for times of the day (each compartment is also numbered with a font size of 15)	Font size 20 for days of the week and times of the day	Font size 14 for days of the week and 12 for times of the day

Figure 1. Multi-compartment medication devices (MMDs) tested.

MMD the frequency of participants allocating it their highest overall rating was calculated.

For the Vocational-Near-Vision Test Type results, the proportion of participants unable to read font size 12 or smaller was calculated as this is the minimum font size for literature recommended by a national organisation for blind and partially sighted people [16].

Bivariate analyses were performed between the criteria ratings of each MMD and functional ability variables using Mann-Whitney U (for cognitive impairment) or Spearman's correlation. Regression with a random effect for participant was used to investigate which of the four criteria for ease of use and whether participant characteristics and functional abilities predict overall rating. While a nominal significance level of 0.05 was taken, conservative interpretation accounted for simultaneous multiple testing. All statistical work was executed using SPSS versions 14–18.

Participant comments were analysed for common themes using a thematic approach by AM. Not all participants have been referenced in the results; however, every effort was made to give a spread of opinions. The final quotes used were checked against original questionnaire comments by a second researcher (DB) to ensure they were representative of the group.

## Results

Of 120 eligible patients identified, 50 (42%) consented. The sample was primarily female with 12 (24%) male participants. Ages ranged from 77 to 98 years (median of 85 years). Pre-admission, nearly all participants lived in their own home; 26 (52%) were living independently and 18 (36%) with a carer. A further five (10%) lived in a retirement home and one (2%) in a care home with nursing. Participants were prescribed between 1 and 15 medications (median 5) and 11 (22%) had prior experience of using an MMD. Previous problems with accessing medication from its packaging were reported by 27 (54%) participants.

## Functional ability tests

The Mini-Cog identified 20 (40%) participants as having impaired cognitive function. Visual acuity ranged from a point size of 5 to 48; median (IQR) of 9 (8, 12), with 11 (22%) participants being unable to read font size 12 or smaller.

The Grooved-Pegboard test was refused by 22 (44%) participants; all cited feeling too tired. A further 15 (30%) did not complete the test. For the 28 participants attempting the test (13 completed), the time per pin ranged from 3.2 to 57.5 s, median (quartiles) of 10.75 (6.43, 18.17) s.

## MMD rating

Table 1 summarises participant ratings of the three MMDs. The distributions were bimodal and ratings of 1 or 2 were categorised as easy/convenient, ratings >7 as difficult/inconvenient. For 'text readability' there was no significant difference between median ratings for the three MMDs; the majority of participants reported the text easy to read. The clarity of text on the Venalink® was, however, cited as a problem:

'light shines off reflective cover, can be difficult to read'

'clear but would be better on black background'

Similarly, with the Nomad® it was suggested that:

a 'different colour would be better'

The days of the week on the Nomad® were easy to read but the timings were considered too small and the font on the Dosett® was generally considered too small.

The Venalink® was particularly difficult to open; reportedly requiring too much pressure to open the blister, being 'too small' and 'too flexible'. Despite scoring well, some participants reported that the Nomad® was 'stiff and hard', 'indistinct. Not easy to contrast between grey and blue' and that the Dosett® was 'awkward' and 'stiff'.

Table 1. Participant rating of MMDs

Criterion	Measure	MMD rating			Friedman ( <i>P</i> )
		Venalink <sup>®</sup>	Nomad <sup>®</sup>	Dosett <sup>®</sup>	
Text readability	Median	2	2	2	0.395
	<i>n</i> (%) rating 1 or 2	30 (60%)	31 (62%)	31 (62%)	
	<i>n</i> (%) rating 7 or higher	7 (14%)	8 (16%)	7 (14%)	
Ease of opening	Median	8	2	3	<0.001
	<i>n</i> (%) rating 1 or 2	14 (28%)	24 (48%)	19 (38%)	
	<i>n</i> (%) rating 7 or higher	30 (60%)	9 (18%)	11 (22%)	
Ease of removal	Median	5	5	3	0.005
	<i>n</i> (%) rating 1 or 2	15 (30%)	17 (34%)	23 (46%)	
	<i>n</i> (%) rating 7 or higher	24 (48%)	20 (40%)	12 (24%)	
Transportability	Median	5	6	3	<0.001
	<i>n</i> (%) rating 1 or 2	9 (18%)	7 (14%)	16 (32%)	
	<i>n</i> (%) rating 7 or higher	18 (36%)	22 (44%)	7 (14%)	
Overall rating	Median	5	5	4	<0.001
	<i>n</i> (%) rating 1 or 2	9 (18%)	8 (16%)	19 (38%)	
	<i>n</i> (%) rating 7 or higher	17 (34%)	18 (36%)	9 (18%)	

Both Venalink<sup>®</sup> and Nomad<sup>®</sup> were more difficult than the Dosett<sup>®</sup> for removing medication and less transportable. No comments were provided about the Venalink<sup>®</sup> but for the Nomad<sup>®</sup> it was reported that the flap hindered medication removal. The Dosett<sup>®</sup> was reported to be 'stiff to slide' and that 'tablets would easily spill everywhere'.

Only 18 and 14% of participants reported the Venalink<sup>®</sup> and Nomad<sup>®</sup>, respectively, to be convenient to transport; the repeated theme was that they are too large. Conversely, 32% of participants reported the Dosett<sup>®</sup> easy to transport.

The Dosett<sup>®</sup> was allocated their best overall rating by 27 (54%) participants followed by the Venalink<sup>®</sup>, which was rated most highly by 7 (14%) participants and the Nomad<sup>®</sup> by 5 (10%). The remaining participants allocated multiple MMDs their best overall rating.

Tables 2–4 summarise the bivariate analyses between the ratings and each functional ability test. Cognitively impaired participants reported even more difficulty in opening the Venalink<sup>®</sup> and removing medication from the Nomad<sup>®</sup> than non-impaired participants. However, as five similar tests were conducted for each MMD, the results should be interpreted with caution. No significant associations were identified between the Grooved-Pegboard results and ability to open or remove medication from MMDs. Highly significant positive correlations were identified between the Vocational-Near-Vision Test Type score and text readability of all three MMDs.

A regression to determine which of the four criteria ratings of ease of use were predictors of overall rating identified only transportability as significant, explaining 46.2% ( $R^2 = 0.462$ ) of the total variance (coefficient 0.62,  $P < 0.001$ , 95% CI: 0.49–0.75).

For models investigating the contribution of functional abilities and patient characteristics to overall MMD rating, time per pin was included as low ( $\leq 10$  s), high ( $> 10$  s) or missing to address missing Pegboard results. The bivariate associations differed for each MMD suggesting that separate models should be fitted. A mixed-effect linear model including the interactions

of functional abilities and patient characteristics with type of MMD confirmed existence of significant interactions.

The multiple regression exploring impact of functional ability and patient characteristics on MMD rating identified for the Venalink<sup>®</sup> that living independently predicted a higher rating (more difficult to use) (2.41, 95% CI = 0.90–3.94,  $P = 0.003$ ) as did the number of prescribed medications (0.389, 95% CI: 0.11–0.67,  $P = 0.007$ ). Previous MMD experience made it easier (–2.03, 95% CI: –3.94–0.13,  $P = 0.038$ ). For the Nomad<sup>®</sup>, those living independently predicted a higher rating (1.64, 95% CI: 0.06–3.23,  $P = 0.043$ ), whereas those previously experiencing problems with accessing medication predicted a lower rating (easier to use) (–1.56, 95% CI: –3.11, –0.1,  $P = 0.049$ ). For the Dosett<sup>®</sup>, those reporting previous access problems had higher scores although this was not significant (1.54, 95% CI: –0.12, 3.20,  $P = 0.068$ ). No other predictors were significant.

As a sensitivity analysis, variants of the models were fitted with time per pin in seconds; broadly similar coefficients, but higher  $P$ -values were obtained.

## Discussion

The reasonable consent rate which is similar to other MMD studies [7] and sample demographics reflecting the characteristics of the population primarily using MMDs [7, 17] afford some confidence in the generalisability of the results. The magnitude of impaired cognitive function and visual acuity was also similar to other studies [18, 19]. The Grooved-Pegboard test despite being simpler to complete than the 'gold-standard' Purdue Pegboard test [20], proved too onerous as a manual dexterity assessment and therefore an alternative measure is necessary for any subsequent study.

The results suggest that a large proportion of patients provided with MMDs may be unable to access their medication with ease. All three MMDs performed reasonably well

## Are multi-compartment medication devices easy to use?

**Table 2.** The relationship between MMD ratings and participant functional ability, relationship between MMD rating and Mini-Cog Test score ( $n = 50$ )

Criterion	Venalink <sup>®</sup>		Nomad <sup>®</sup> clear		Dosec <sup>®</sup>	
	Impaired	Unimpaired	Impaired	Unimpaired	Impaired	Unimpaired
Text readability MMD rating [median (quartiles)]	1.5 (1, 6.25)	2 (1, 4.25)	1.5 (1, 7)	2 (1, 4)	2 (1, 7.5)	1.5 (1, 4.5)
Mann-Whitney U ( <i>P</i> )	0.983		0.760		0.514	
Ease of opening MMD rating [median (quartiles)]	9 (3.5, 10)	7 (2, 8.25)	3 (2, 7.75)	2 (1, 4.25)	4 (2, 9)	3 (1.75, 5)
Mann-Whitney U ( <i>P</i> )	0.042		0.050		0.210	
Ease of removal MMD rating [median (quartiles)]	8 (3, 10)	5 (1.75, 8.25)	6.5 (3, 9.75)	4.5 (1.75, 8)	3 (2, 8)	2.5 (2, 5.25)
Mann-Whitney U ( <i>P</i> )	0.094		0.027		0.408	
Transportability MMD rating [median (quartiles)]	5 (4.25, 8)	5 (3.75, 8)	4.5 (3, 8)	6 (3.75, 8)	3 (2, 5)	3.5 (2, 6)
Mann-Whitney U ( <i>P</i> )	0.714		0.530		0.810	
Overall rating MMD rating [median (quartiles)]	5 (3.5, 7)	5 (4, 7.25)	5 (4, 7)	5.5 (2.75, 8)	4 (2, 6)	4 (2, 5.25)
Mann-Whitney U ( <i>P</i> )	0.841		0.992		0.802	

Cognitively impaired ( $n = 20$ ) and unimpaired ( $n = 30$ ).

**Table 3.** Relationship between MMD rating and Vocational Near Vision Test Type score ( $n = 50$ )

Criterion	Venalink <sup>®</sup>		Nomad <sup>®</sup> Clear		Dosec <sup>®</sup>	
	High	Low	High	Low	High	Low
Text readability MMD rating [median (quartiles)]	3.5 (1.25, 8.5)	1 (1, 3)	2 (1, 7.75)	1 (1, 3.25)	4.5 (1.25, 8.5)	1 (1, 2.5)
Spearman correlation ( <i>P</i> )	0.491 (0.0003)		0.383 (0.006)		0.571 (0.00002)	
Ease of opening MMD rating [median (quartiles)]	8 (2, 9.75)	7.5 (2, 9)	3 (1, 7)	2 (1.75, 4.25)	3 (2, 9)	3 (1, 5.25)
Spearman correlation ( <i>P</i> )	0.075 (0.604)		0.100 (0.490)		0.240 (0.093)	
Ease of removal MMD rating [median (quartiles)]	8 (2, 10)	5 (2, 9.25)	6.5 (2, 9)	4 (2, 8)	3.5 (2, 7.75)	2 (2, 5.25)
Spearman correlation	0.121 (0.402)		0.260 (0.067)		0.247 (0.084)	
Transportability MMD rating [median (quartiles)]	5 (4, 7.75)	5 (3.75, 8)	5.5 (3, 8)	6 (3, 8)	3.5 (2.25, 5.75)	3 (2, 6)
Spearman correlation ( <i>P</i> )	0.022 (0.881)		0.011 (0.941)		0.042 (0.774)	
Overall rating MMD rating [median (quartiles)]	5 (3.75, 7)	5 (4, 7.75)	5 (4, 7.75)	5.5 (3, 7.25)	4 (2, 8)	4 (2, 5.25)
Spearman correlation ( <i>P</i> )	-0.105 (0.466)		0.017 (0.905)		0.095 (0.512)	

High ( $>9$ ) Near Vision Test Type score ( $n = 30$ ) and low ( $\leq 9$ ) Near Vision Test Type score ( $n = 20$ ).

**Table 4.** Relationship between MMD rating and Grooved-Pegboard test score ( $n = 28$ )

Criterion	Venalink <sup>®</sup>		Nomad <sup>®</sup> Clear		Dosec <sup>®</sup>	
	High	Low	High	Low	High	Low
Text readability MMD rating [median (quartiles)]	1 (1, 3)	2 (1, 4)	1 (1, 2)	2 (1, 5)	1 (1, 4)	2 (1, 2.5)
Spearman correlation ( <i>P</i> )	-0.250 (0.199)		-0.455 (0.015)		-0.248 (0.203)	
Ease of opening MMD rating [median (quartiles)]	5 (2, 8)	7 (1, 9)	2 (1, 5)	2 (1, 3.5)	3 (1, 6)	2 (1, 3)
Spearman correlation ( <i>P</i> )	0.166 (0.399)		-0.47 (0.811)		0.277 (0.154)	
Ease of removal MMD rating [median (quartiles)]	5 (1.5, 9)	3 (2, 5)	3 (1.5, 6.5)	2 (2, 7)	2 (1.5, 2.5)	3 (1, 6)
Spearman correlation ( <i>P</i> )	-0.118 (0.549)		-0.136 (0.489)		0.320 (0.097)	
Transportability MMD rating [median (quartiles)]	5 (2, 8)	5 (3.5, 8)	5 (3, 8)	7 (3, 8.5)	5 (3, 6)	3 (1.5, 6)
Spearman correlation ( <i>P</i> )	-0.231 (0.237)		-0.376 (0.049)		-0.041 (0.837)	
Overall rating MMD rating [median (quartiles)]	5 (4, 6)	6 (4.2, 8.5)	6 (4, 8)	5 (2, 7.5)	5 (2, 6)	4 (1.5, 5.5)
Spearman correlation ( <i>P</i> )	-0.266 (0.172)		-0.157 (0.425)		0.018 (0.926)	

High ( $>10$  s) mean time per pin ( $n = 13$ ) and low ( $\leq 10$  s) mean time per pin ( $n = 15$ ).

in terms of readability although manufacturers may wish to consider the materials and colours used due to negative remarks about text clarity.

The Nomad<sup>®</sup> and Dosec<sup>®</sup> were better rated than the Venalink<sup>®</sup> in terms of ease of opening and removing medication. The Venalink<sup>®</sup> was rated particularly badly by participants with impaired cognitive function which is in accordance with

previous study findings that cognitive function is associated with ease of medication access from packaging. [9] Participant reported problems were contradictory to these findings as they related to the force and dexterity necessary to manipulate the MMD. There may therefore be an element of participants being reluctant to report MMD complexity as a barrier to use. This requires further exploration but introduces the notion that

healthcare professionals may need to be aware of such sensitivities when involving a patient in decision-making.

Given that the Dosett<sup>®</sup> is smaller than the other two MMDs, it is unsurprising that it was considered most convenient to transport. All of the MMDs, however, performed poorly in this category with participants expressing a clear desire for smaller devices. The Dosett<sup>®</sup> was most frequently given the best overall rating; while performing well for all criteria, the key factor predicting overall rating was transportability. There is some indication that the Venalink<sup>®</sup> and Nomad<sup>®</sup> were more difficult to use for those living independently which may be related to them being less transportable.

Inter-participant variation in MMD rating indicates that selection should be made from a range of MMDs and that it is not a case of 'one size fits all'. The results provide some guidance for health professionals in advising their patients; <50% of the variability in overall rating could be accounted for by the four criteria of ease of use, suggesting that other factors may play a part in patient preference. Hence, it seems appropriate that patients should be involved in the decision-making despite evidence that this is not currently widely adopted [7].

### Key points

- Older people find some commercially available MMDs are easier to use than others.
- Cognitively impaired patients may experience more difficulty than others in opening and accessing medicines from some MMDs.
- Patient rating of MMDs is dominated by ease of transportability.

### Acknowledgements

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### Conflicts of interest

None declared.

### Funding

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**Title: Stakeholder focus groups as part of the development phase of a pilot study of pharmacy student led medication reviews for patients with diabetes in primary care**

Adams R, Bhattacharya D, Eddy G, Grassby P, Holland R, Howe A, Norris N, Sach T, Symms C, Wood J, Wright D.  
University of East Anglia, Norwich. U.K. NR4 7TJ, Email: richard.adams@uea.ac.uk

**Background**

A need for greater patient exposure for U.K. pharmacy students has been identified.<sup>1</sup> Research in Australia<sup>2</sup> and America<sup>3</sup> has shown that student provided medication review to patients enhances patient care and improves student performance through experiential learning. For UK pharmacy students to increase their exposure to patients in a similar manner, evidence is required to demonstrate both patient safety and patient benefit and the pilot study is a randomised controlled trial of how such a student service should be implemented in the UK. The aim of this piece of research was to determine stakeholder opinions on the design and implementation of the RCT.

**Method**

Focus groups of five to eight members, each representing one of the stakeholder groups: final year pharmacy students, patients with type 2 diabetes and Primary Care Trust Pharmacists, were undertaken. Separate groups were held to ensure that clearer views were obtained through the synergy of group interaction. The General Practitioner/Specialist Nurse focus group is planned for October. Five or six group specific pre-prepared questions formulated to check the design of the intervention phase of the study were answered by each group. Topics included overall study objectives, student preparation training, documentation, intervention delivery and data analysis. Framework analysis of recordings and transcripts with independent validation was undertaken.

Full ethical approval was granted by Cambridgeshire 3 REC in January 2011

**Results**

All groups were positive about the concept of student led medication reviews; however, a number of additional common themes arose:

- Importance of student preparation prior to meeting patients is essential to provide mutual confidence, with consultation skills being important in addition to drug and disease knowledge.
- The service should be provided in a familiar easily accessible surrounding for the patients i.e. the G.P. practice and not at the university
- Consultations should be structured by protocols and care plans, whilst interventions made when required by a Pharmacist or Doctor to prevent students giving erroneous advice are essential.

In addition important issues were raised by single groups

- 'Control' patients need easily understood explanation of the importance of their role to encourage continued participation (Patient group).
- Travel to GP Practices in a rural location for placements is difficult and of concern (Student group)

The opinions of doctors and nurses will enrich the data further, and as group meetings have proved difficult to arrange, one-to-one interviews have been arranged at individual Practices.

**Discussion**

The positive attitude of both patients and practitioners to pharmacy students delivering supervised clinical services is encouraging. The need for the pre-intervention focus groups was demonstrated by the common themes which arose. Issues raised reinforce the need to ensure that practical and logistical issues (e.g. travel, supervision, protocols, location) are well planned to maximise recruitment<sup>4</sup> and clarity of results

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**Title:**

Patient and student opinions on student provided medication reviews for patients with type II diabetes in primary care

**Abstract:** (Please refer to instructions to authors and example abstract)

**Focal points**

- The project aim was to obtain patient and student opinions on final year pharmacy student provided medication review (MR) to patients with type 2 diabetes (T2DM).
- Within a pilot randomised controlled trial 57 patients in the intervention arm and 30 final year pharmacy students provided opinions on the appropriateness and effectiveness of the service
- Patients and students were very positive about the experience, although students were generally more self critical

**Introduction**

UK pharmacy degree accreditation criteria<sup>1</sup> require students to gain meaningful patient contact. Evidence from Australia<sup>2</sup> and USA has shown that pharmacy students undertaking medication review (MR) is both educationally effective and beneficial to patients. The School of Pharmacy at the University East Anglia obtained research funding to pilot the provision of MR to patients with T2DM. This paper investigates student and patient opinions.

**Method**

Patients with T2DM were recruited from five medical practices within one PCT and randomised to intervention (to receive a MR from a final year pharmacy student) or control (standard care). Third year pharmacy students were recruited into the study with the intention to review 2 patient's care, and given additional training to enable them to perform both an initial paper based review and a subsequent face to face consultation (MR) with the patient, within their final year. A brief questionnaire was developed, based on previously published work<sup>2</sup> and consisting of five point Likert scales to be completed by patients and students immediately post-consultation to determine initial student and patient opinions on the ability and appropriateness of pharmacy students undertaking MR and the perceived value of the service. The mean (sd) score for responses to each question was calculated with 5 representing strong agreement. Independent samples t-test was used for comparisons. NHS ethical approval was obtained.

**Results**

The study aim was for each student to undertake a MR with each of two patients, however, recruitment rates meant that three students undertook a MR for only one patient. 54 patients receiving the service completed post-intervention questionnaires (PIQ) whilst 3 declined. All 30 pharmacy students completed PIQs relating to 54 of 57 patients. Table 1 provides comparison of student and patient scores.

**Table 1 Comparison of patient and student opinions.**

Question	Patients (n=57)	Students (n=30)	p
Student communicated well	4.84 (0.4)	3.8 (0.7)	<0.001
Student was confident	4.7 (0.6)	3.6 (0.8)	<0.001
Student was appropriate person to perform medication review	4.7 (0.6)	3.8 (0.6)	<0.001
Patient learned something useful	4.2 (1)	3.5 (0.9)	<0.001
Medication review was important to patient's health	4.6 (0.7)	4 (0.8)	0.001
Would recommend this medication review to another patient	4.9 (0.3)	4 (0.9)	<0.001

**Discussion**

Patients were very positive regarding pharmacy students' ability and appropriateness for the role and would almost unanimously recommend the review to others. Students were less positive and reasons for this require further exploration. Patient outcome data (obtained 3 months post intervention) will determine whether opinions on the importance to health are substantiated.

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## Abstract Submission for ESCP 2012 Symposium

Community Pharmacy - Clinical education

ESCP12-1064

### Student participants' opinions of a novel consultation skills training programme

R. P. Adams<sup>1</sup>, D. Bhattacharya<sup>1</sup>, P. Grassby<sup>1</sup>, A. Howe<sup>2</sup>, N. Norris<sup>3</sup>, D. Wright<sup>1</sup>

<sup>1</sup>School of Pharmacy, <sup>2</sup>Norwich Medical School, <sup>3</sup>School of Education and Life-Long Learning, University of East Anglia, Norwich, United Kingdom

Is this work original?: Yes

Please choose in which of the following ways you would prefer to present your work, if the abstract is accepted: :

As an oral communication

**Keywords:** Clinical education, Primary care

### Background

UK evidence supporting pharmacist led medication reviews (MRs) is lacking<sup>1,2</sup>, possibly due to insufficient training. USA<sup>3</sup> and Australian studies demonstrate pharmacy students learning whilst benefiting patients during MR consultations. The UEA School of Pharmacy obtained research funding and NHS ethical approval for pharmacy students to deliver MR consultations to patients with type 2 diabetes (PWT2DM).

### Method

Recruited PWT2DM were randomised to student-led MR or usual care. Volunteer final year pharmacy students participated in a consultation skills training programme (CSP) comprising 3 podcasts, 3 workshops, consultations with professional role-play actors, then MR consultation with 2 patients at their medical practice. Two on-line surveys (1.main CSP, 2.role-play session) using Likert scales plus free text options were developed regarding each training element of the CSP to capture all student participants' views, including any failing to complete the CSP.

### Main outcome measures

CSP acceptability and effectiveness.

### Results

48 students were recruited with 31 completing the CSP, including undertaking MR with 57 of the 137 PWT2DM recruited. Of 24 students replying (survey 1), 75.9% agreed the CSP enhanced consultation communication skills and 100% would recommend the CSP to another student. Of 17 students replying (survey 2) 93.7% agreed this role-play is an ideal way to learn consultation skills, however, two students found this too challenging and left the CSP.

Students reported enjoying consulting and helping real patients, whilst increasing self-confidence and professionalism. They requested more of the realistic consultations with actors in consultation rooms but 'patient history' provided earlier, and consultation skills demonstrations, not generic skills, in workshops with all preparation immediately prior to consultations. More training with patients from year three of undergraduate training was requested. Most frequently reported clinical skills learned were diabetes, cardiovascular and medical record utilisation.

### Conclusions

Students want more patient contact whilst undertaking real tasks, earlier in the course.

Practical preparation is preferred, just before consultations, including more use of professional actors (with more 'patient' information provided to students earlier).

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**Title:**

"It's the Traffic Warden's hat": Patient views on designing a feasibility study to evaluate a student led medication review service

**Abstract:** (Please refer to instructions to authors and example abstract)

**Focal points**

- The study aimed to obtain from focus groups, the views of patients with diabetes about how best to deliver a feasibility study of final year undergraduate pharmacy students providing medication review.
- Patients wanted reassurance that students would be supervised and working to protocols.
- It is important to reassure patients that usual care will not be taken away and that they are important to the research process.

**Introduction:**

Medication reviews<sup>1</sup> are designed to reach an agreement with the patient about treatment in order to optimise the impact of medicines, minimise the number of medication-related problems and reduce waste. To effectively deliver a patient-centred medication review it is important for pharmacists to not only have appropriate clinical knowledge but also necessary consultation skills and these should start to be developed within the undergraduate degree. Whilst USA and Australia<sup>2</sup> regularly report students providing medication review services to patients as part of their undergraduate training, this is not the case in the UK. Before undertaking trials to demonstrate costs and effects of such services it is recommended that feasibility and pilot studies are performed and that the design of these are stakeholder informed. The study aim was to determine the views of patients with Type 2 Diabetes Mellitus (T2DM) on how best to design a feasibility study to evaluate an undergraduate student led medication review service.

**Method**

People with T2DM were invited, via a local diabetes advice group and advertisement amongst university staff, to attend a one hour focus group designed to gain views about the proposed pilot study design. One researcher facilitated the meeting using a topic guide consisting of open questions about recruitment, documentation and questionnaires, plus study design and implementation. No incentives were offered although lunch was provided. Focus groups were transcribed verbatim and analysed thematically. NHS ethical approval was obtained.

**Results**

Of six volunteers five were able to attend the focus group (4 male, 1 female- 2 university staff and 3 members of the advice group. Age 40 to 65yrs).

Major themes identified included:

Patients wanted reassurance that students would follow clear protocols and practice in the presence of a trained supervisor to ensure safety and validity of recommendations.

Participant recommendations to improve recruitment included:

Provide a short précis of information to encourage patients to read entire documents.

Reassure patients to make them certain that 'usual care' will not be taken away.

Avoid abbreviations; a strong dislike was expressed regarding their use.

The terms intervention and control should not be used in documentation for patients. Instead describe roles e.g. "medication review group" or "group not meeting the student".

Inform control group patients clearly and simply the importance of their role.

Make it clear that you cannot manage without the patients; stress the importance of the patient. "It's the traffic warden's hat. It makes him feel important."

**Discussion**

Participants provided useful clarification for patient information leaflets which was subsequently incorporated into the study. Student-provided patient services are novel; therefore unsurprisingly, patients wanted reassurance before involvement in any trial that the students would follow a protocol and be closely supervised. No concerns regarding pharmacy students providing care were identified but researchers must reassure patients of their importance to the trial process, particularly if in the control group, whilst patients want confirmation that any new service would not result in removal of usual care. This study, though limited by small numbers of self-selected participants, showed the importance of obtaining stakeholder views before delivering and evaluating any new service. Future studies involving patients should utilise focus groups when finalising documentation as many only employ the views of one or two patient representatives.

**Reference**

1. Taskforce.on.Medicines.Partnership, National.Collaborative, Medicines.Mangement.Services.Programme. A guide to medication review: the agenda for patients, practitioners and managers, 2002.
2. Boyatzis.M. Domiciliary medication reviews by fourth year pharmacy students in Western Australia *International Journal of Pharmacy Practice*. 12(2):73-81. Jun 2004 2004;12(2):73-81.

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**Title:**

"I must confess – I enjoyed it": Patient views after participating in a student led medication review service

**Abstract:** (Please refer to instructions to authors and example abstract)

**Focal points**

- The study aimed to obtain from focus groups, the views of patients with type 2 diabetes (T2DM) about a study where final year undergraduate pharmacy students had provided them with a medication review.
- Participants found students initially nervous, more relaxed as consultations progressed and competent in most areas, providing patient benefit in some cases.
- Participants expressed views on the method for a subsequent, larger student-led medication review study including location, time allocation, student preparation, supervision and medication review content.

**Introduction:**

Studies have demonstrated pharmacists failing to effectively undertake medication review for a number of reasons including lack of effective training such as consultation skills<sup>1</sup>. As medication review is designed to reach patient agreement about treatment, consultation skills are essential to ensure effectiveness, as a patient centred approach with good communication has been shown to be more effective<sup>2</sup>. Whilst some countries regularly report student-led medication review services to patients as part of experiential undergraduate teaching of consultation skills, this is not the case in the UK and evidence is required to demonstrate effectiveness. The study aim was to determine views about study design and acceptance by patients with T2DM who had received a student-led medication review.

**Method**

3 months after reviews for logistical reasons, 53 people with T2DM who received a student-led medication review as part of a study, were invited by letter to attend a focus group to gain views to enable evaluation of design of a pilot study and student performance within it. One researcher facilitated meetings using a topic guide consisting of open questions about recruitment, patient benefit, student performance plus study design and implementation, however, this abstract focusses on implementation plans, patient benefit and student performance. No incentives were offered, although lunch was provided. Focus groups were transcribed verbatim and analysed thematically. NHS ethical approval was obtained.

**Results**

14 volunteers each attended one of two 1 hour focus groups.

Patients' consensus showed undergraduate pharmacy student-led medication review is a good idea.
The training should be repeated and patients were willing to participate again.
Patients valued the extra time and information provided.
Students displaying competence but were nervous, however, gaining confidence when meeting their second patient. Some patients found nervousness a problem.
Specific commendation was made because students "did not flannel" i.e admitted when they did not know.
Some patients stated enjoying the session and learned useful information previously unknown by them about their medicines or diabetes. One student identified a previously undiagnosed significant drug:disease interaction.
Negative comments included poor food content knowledge with 'insensitive' alcohol intake questioning in one case.
Patients described supervision as essential for student-led medication review; however, some patients stated that supervisors inhibit students and should observe via video link.
Student led medication review should be undertaken at patients' GP Practices and not time limited in contrast to short GP appointments.

**Discussion**

Study limitations were patients being volunteers and therefore self-selecting, thus potentially more positive whilst 3 months after reviews data may have been lost. Student provision of patient services is novel and demonstrated good patient acceptance with patients reporting 'enjoying' the student's discussion about health without time limits. It is valuable to know that patients are willing to participate again, whilst stating that student experience of this training is essential. Pharmacy students' main contribution was provision of information under supervision. A full-scale study of this training is supported by results. Some students demonstrated nervousness, however, this is the first time they have met patients for a consultation and improving confidence demonstrates the need for more preparative training. The information gained shows the value of determining participants' views when reviewing studies.

**Reference**

1. Salter, C. Compliance and concordance during domiciliary medication review involving pharmacists and older people. *Sociology of Health & Illness* 2009;32(1):21-36.
2. Little P, Everitt H, Williamson I, Warner G, Moore M, Gould C, et al. Preferences of patients for patient centred approach to consultation in primary care: observational study *BMJ* 2001;322:468 Date accessed, 5 April 2013 at <http://www.bmi.com/content/322/7284/468#alternate>

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