A practitioner behaviour change intervention for deprescribing in the hospital setting

Sion Ieuan Scott

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School of Pharmacy

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Abstract

Background

Half of older people in hospital have a pre-admission medicine prescribed that is potentially inappropriate. Deprescribing research has historically focused on the primary care setting. The aim of this thesis was to develop a practitioner behaviour change intervention for enhancing deprescribing in the hospital setting.

Methods

Underpinned by behavioural science, the research programme comprised four empirical studies: evaluation of existing hospital deprescribing activity; survey of patients' and carers' attitudes towards deprescribing; focus groups with geriatricians and pharmacists to identify key barriers and enablers to address in an intervention; expert panel consensus study to select Behaviour Change techniques (BCTs) for the intervention.

Results

Deprescribing in hospital occurred for 0.6% of pre-admission medicines, of which 84.1% was reactive in response to harm and 15.9% proactive to prevent harm.

Deprescribing in hospital was acceptable to patients and carers: 97.4% and 76.3% respectively were willing to accept a doctor's deprescribing proposition.

Geriatricians and pharmacists described several existing deprescribing enablers in hospital including alignment with their generalist role/knowledge and routine patient monitoring.

Key barriers to deprescribing were a misconception of patients' and carers' resistance to deprescribing, pharmacists' perception that deprescribing is riskier than continuing to prescribe, pharmacists' working patterns limiting capacity to support deprescribing and it being a low hospital priority. Introduction of incentives to deprescribe was an enabler.

Six BCTs were selected and characterised to address the key barriers and enabler: social comparison (two distinct characterisations); salience of consequences; pros and cons; restructure the physical environment; action planning.

Conclusion

There is significant scope to increase deprescribing in hospital and this is acceptable to patients and carers. The behavioural intervention to enhance geriatrician and pharmacist led deprescribing requires modelling to determine the optimal configuration of BCTs. Subsequent testing of the intervention is necessary to determine efficacy at enhancing deprescribing and impact on patient outcomes.

Table of contents

List of tables

List of figures

List of appendices

List of abbreviations

ADE	Adverse Drug Event
ADWE	Adverse Drug Withdrawal Event
APEASE	Affordability, Practicability, Effectiveness/cost-effectiveness, Acceptability, Safety and Equity
BCI	Behaviour Change Intervention
BCT	Behaviour Change Technique
BCTTv1	Behaviour Change Technique Taxonomy version 1
CI	Confidence Interval
COREQ	COnsolidated cRiteria for rEporting Qualitative research
EMPOWER	Eliminating Medications through Patient OWnership of End Results (brochure)
FORTA	Fit fOR The Aged
GP	General Practitioner
hDIF	hospital Deprescribing Implementation Framework
IMPPP	Improving Medicines use in People with Polypharmacy in Primary Care
IQ	Interquartile
κ	Cohen's Kappa
LESS-CHRON	List of Evidence-Based Deprescribing for Chronic Patients
MOST	Multiphase Optimization Strategy
MRC	Medical Research Council
NGT	Nominal Group Technique
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NNUH	Norfolk and Norwich University Hospitals NHS Foundation Trust
NPT	Normalization Process Theory
OPM	Older People's Medicine
OR	Odds Ratio
PATD	Patients' Attitudes Towards Deprescribing (questionnaire)
PIL	Participant Information Leaflet
PIM	Potentially Inappropriate Medicine
RCT	Randomised Controlled Trial
rPATD	revised Patients' Attitudes Towards Deprescribing (questionnaire)

STOPP	Screening Tool of Older Persons' potentially inappropriate Prescriptions
STOPPFrail	Screening Tool of Older Persons Prescriptions in Frail adults with limited life expectancy
TDF	Theoretical Domains Framework
UEA	University of East Anglia
UK	United Kingdom
USA	United States of America

Initials

AC	Allan Clark
AD	Alex Dima
CF	Carol Farrow
DB	Debi Bhattacharya
DJW	David John Wright
HM	Helen May
JG	Janette Guymer
JT	Jo Taylor
MJT	Michael James Twigg
MP	Martyn Patel
NN	Noreen Neal
SS	Sion Scott

Publications and presentations

Thesis related publications

1. **Scott S**, Clark A, Farrow C, May H, Patel M, Twigg MJ, Wright DJ, Bhattacharya D. Deprescribing admission medication at a UK teaching hospital; a report on quantity and nature of activity. International journal of clinical pharmacy. 2018 Oct 1;40(5):991-6.

2. **Scott S**, Clark A, Farrow C, May H, Patel M, Twigg MJ, Wright DJ, Bhattacharya D. Attitudinal predictors of older peoples' and carers' desire to deprescribe in hospital. BMC geriatrics. 2019 Dec;19(1):108.

3. **Scott, S**., Twigg, M. J., Farrow, C., May, H., Patel, M., Taylor, J., … Bhattacharya, D. (2019). Development of a hospital Deprescribing Implementation Framework: A focus group study with geriatricians and pharmacists. Age and Ageing, accepted in press.

4. Wright D, Bhattacharya D, **Scott S**. Deprescribing: Routine pharmacy practice or an exciting research opportunity?. International Journal of Pharmacy Practice. 2019.

Thesis related conference oral presentations

1. Health Services Research and Pharmacy practice conference 2018: Deprescribing practice at a UK teaching hospital: reactive or proactive?

2. 14th UK Society for Behavioural Medicine Annual Scientific Meeting 2018: Barriers and enablers affecting pharmacists' deprescribing of inappropriate medication in hospital: A focus group study using the Theoretical Domains Framework

Non-thesis related publications

1. **Scott S**, Clark A, May H, Bhattacharya D. Validation and Feasibility of the Medication Acceptability Questionnaire to Investigate Tablet and Liquid Alendronic Acid with Older Hospital Patients. Pharmacy. 2018 Sep;6(3):84.

2. Al-Jabr H, Twigg MJ, **Scott S**, Desborough JA. Patient feedback questionnaires to enhance consultation skills of healthcare professionals: a systematic review. Patient education and counseling. 2018 Sep 1;101(9):1538-48.

3. Prajapati AR, Dima A, Clark AB, Gant C, Gibbons C, Gorrod R, Mosa G, **Scott S**, Song F, Teague B, Twigg MJ. Mapping of modifiable barriers and facilitators of medication adherence in bipolar disorder to the Theoretical Domains Framework: a systematic review protocol. BMJ open. 2019 Feb 1;9(2):e026980.

4. Shenoy R, **Scott S**, Bhattacharya D. Quantifying and characterising Multi-compartment compliance aid provision; a national survey of community pharmacies in England. Research in Social and Administrative Pharmacy. 2019 Jul 27.

5. Wright DJ, **Scott S**, Buck J, Bhattacharya D. Role of nurses in supporting proactive deprescribing. Nursing Standard. doi. 2019 Mar 1;10.

Formal training

University of East Anglia Personal and Professional Development modules

- Introduction to research methods
- A Comparison of Qualitative Methods
- Analysing Qualitative Data
- Further qualitative research methods
- How to conduct focus groups
- Basic Principles of Correlational Research
- An Introduction to NVivo
- Introduction to Ethics in Health Research
- The process and regulations for submitting ethics for clinical trials
- Using Statistical Package for the Social Sciences (SPSS) for advanced data analysis
- Word processing a long document e.g. a thesis
- The Literature Review
- Survey design
- How to Write for Publication: Qualitative
- Pilot and feasibility studies
- Sample size and statistical power of a research study
- Development of behaviour change interventions
- Evaluation of behaviour change interventions

University College London Centre for Behaviour Change Summer School

- Behaviour Change - Principles and Practice
- Process Evaluations and Implementation of Behaviour Change Interventions (advanced summer school)

Cochrane Interactive Learning

- Conducting an intervention review

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Diolch o galon.

Siôn

Chapter 1 Background

1.1 Ageing

Advances in healthcare and improvements in living conditions have contributed to populations in Western countries living longer(1), with average life expectancy being 80 years, relative to 50 years in the early 1900s(2). This trend is set to continue, with a rise in the proportion of people aged ≥80 years being the primary factor contributing to the United Kingdom's (UK) 15% projected population increase over the next 25 years(3). This rise in people living into old age represents a significant achievement in Western medicine, but has evoked a substantial change in population health needs.

The mainstay of current health problems in Western countries are non-communicable, long-term conditions that are associated with ageing. Approximately 15 million people in England are living with at least one long-term condition and a further 1.9 million are living with several, which is termed multi-morbidity(4).

This increase in patients with multi-morbidity imposes significant resource and economic costs on health systems. UK survey data captured in 2009 reported people living with long term conditions accounted for 50% of general practitioner (GP) consultations, 64% of outpatient appointments and 70% of hospital bed days(4). Similar data have been reported in the United States of America (USA), which associated the number of morbidities a patient has with the degree of healthcare recourse utilisation(5). Unsurprisingly given the acknowledged population trends, substantial increases in demand on health systems for treating long-term conditions are predicted(2,6).

Management of the majority of long-term conditions requires pharmacological treatment in order to alleviate symptoms and/or halt disease progression(7,8). It is therefore unsurprising that older people are the population in receipt of the largest number of prescribed medicines(9). The total number of prescription items dispensed in England in 2016 was 1,104.2 million, equating to an average of 20.0 items per head of population(10). The majority (61%) of medicines in England are prescribed for people aged 60 and over.

1.2 Polypharmacy

Polypharmacy is most frequently defined in terms of a numerical threshold for the number of prescribed medicines. Five or more medicines is the most widely reported threshold(9), however, there is variation in how it is applied with some

studies defining it as the use of at least three medicines, while others have reported it as a minimum of 10 prescribed medicines(11,12).

An evaluation of prescribing indicates that the proportion of patients receiving polypharmacy, defined as ≥5 medicines, increased by almost 50% between 1995 and 2010 to 20% of adults(13). Moreover, the proportion of patients prescribed ≥10 medicines increased from 1.9% to 5.8%. Proportions are larger for institutionalised patients such as those living in care homes, with a cross-sectional study reporting that one third of nursing home residents are in receipt of ≥10 prescribed medicines (14).

Continuing trends in population ageing are predicted to result in both an increase in the proportion of patients receiving polypharmacy and in the number of medicines prescribed per patient. Polypharmacy has been described as both a positive for it's contribution to healthy ageing, and a potentially serious problem arising from the risks associated with concomitant use of medication(9,15). A report commissioned by the King's Fund determined that polypharmacy was a "*necessary evil, that for many patients is required to improve clinical outcomes*"(9). This view accords with associations between polypharmacy and a reduction in some adverse outcomes such as hospitalisation described in the literature for patients with multi-morbidity(16). There is a place for polypharmacy in instances where the benefits outweigh the risks and it is deemed appropriate. However, there is also a need to acknowledge and distinguish between appropriate and inappropriate polypharmacy, where the risks of concomitant medication use outweigh the intended benefits.

1.2.1 Appropriate Polypharmacy

Polypharmacy is 'appropriate' when prescribing of several medications is indicated and collectively, the intended benefits of each medication outweigh the risks. Prescribing should therefore be underpinned by evidence of benefits, achieve improvements in health status and sustain or improve quality of life(11,17). For example, the national body which publishes health and social care guidance in England recommends prescribing five medicines for secondary prevention of cardiovascular events following a myocardial infarction(18). Patients who were previously medication naïve are therefore prescribed a polypharmacy regimen post-implementation of these recommendations. However, this regimen is appropriate and is underpinned by evidence demonstrating significant health benefits.

Appropriate polypharmacy requires ongoing monitoring to identify any changes in circumstances that indicate that some or all of the prescribed medicines are no longer appropriate. For example, development of a new condition such as age associated renal impairment should trigger a medication review(19).

1.2.2 Inappropriate polypharmacy

The intended benefits and risks offered by a medication are important considerations at initial prescribing and subsequent medication reviews(20,21). Medicines that offer an individual patient more risks than benefits, including those without an evidence-based indication, are inappropriate. This determination is specific to a patient's individual circumstances, and considers factors such as multi-morbidity, suitability of concomitant medication prescribing and quality of life. Additionally, any prescribing of more medicines than are clinically necessary is considered inappropriate polypharmacy, given that each additional unnecessary medicine brings additional risks in the absence of any additional benefits(22).

Inappropriate polypharmacy increases the risk of iatrogenic harm, which is harm resulting from a healthcare intervention(23). Harms associated with inappropriate polypharmacy are well documented and include adverse drug events (ADEs) such as side effects which can lead to adverse outcomes including morbidity, hospitalisation and mortality(24,25). Resultant harms may also contribute to intentional medication non-adherence, for example a patient may choose to take less medication than prescribed in order to limit exposure(26). Patients may not be able to identify the problematic medication, and may therefore decide not to take some or all of their medications as prescribed, including those that are appropriate, which may directly lead to adverse outcomes.

ADEs are an established and frequently preventable cause of hospitalisation. A prospective analysis at two UK hospitals over six months in 2011/12 evaluated 18,820 admissions to determine the causes(27). ADEs accounted for 6.5% of all unplanned admissions, representing an annual cost of £466m to the National Health Service (NHS) in England. The average age of patients admitted with ADEs was 76 years and significantly higher than the 66 years for patients admitted for other reasons. Almost three quarters of ADE admissions were categorised as possibly or definitely avoidable(27). Similarly, a prospective multi-centre study in the Netherlands reported that 5.6% of all admissions were medication related(28), of which 7.2% required treatment in an intensive care unit, representing significant

clinical and economic implications. Gastrointestinal bleeding, constipation and diarrhoea were the most frequently reported ADEs leading to the admission(28). The economic costs of preventable ADE related admissions to hospital are motivating factors for this healthcare setting contributing to the development and implementation of strategies to address inappropriate polypharmacy(29).

1.2.2.1 Potentially inappropriate medicines

Quantifying the prevalence of inappropriate medication prescribing in large-scale studies is challenging due to the individualised nature of a medicine being inappropriate for a given patient. Validated screening tools such as the Beers' Criteria(30) and Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP)(31), are therefore frequently used to identify potentially inappropriate medicines (PIMs) in observational studies. These tools define PIMs based on the assumption that on the balance of probabilities, a medicine is more likely to be inappropriate than appropriate, usually in the older people population(32). However, these decisions are based on evidence of medicines interacting with each other or a disease state, which frequently do not represent all patients. Moreover, these tools are based on the assumption that the medicine is being used for a licensed indication, which is frequently not the case. Accordingly, the tools apply black and white criteria to a population of complex patients, and may under or over emphasise the scale of inappropriate prescribing. PIMs therefore need to be reviewed in the context of the individual patient to determine whether or not the medication is 'actually' inappropriate(33).

A prospective analysis of the admission medication for patients ≥65 years across six European hospitals using the STOPP tool reported an overall PIM prevalence of 53.3%, ranging from 34.7% to 77.3%(34). The odds of being prescribed a PIM were more than doubled for those prescribed six to ten medicines relative to those prescribed less ($p<0.001$). For those prescribed more than 10 medications, the odds of being prescribed a PIM were more than seven times greater ($p<0.001$). Being prescribed a larger number of medications was found to independently predict being prescribed a PIM (odds ratio (OR) for 6–10 medications: 2.31, 95% confidence interval (95% CI); 1.68–3.18, $p<0.001$; OR for>10 medications: 7.22, 95% CI 4.30–12.12, $p<0.001$). Older people, as the population receiving the largest number of prescribed medication, are most likely to be prescribed a PIM(25,35,36). The aforementioned study did not measure PIM prevalence at discharge, therefore it is

unclear whether PIMs are reviewed for appropriate discontinuation during hospital admissions. A longitudinal study in an Irish primary care setting included 38,229 patients ≥65 years and reported a PIM prevalence of 51.0%(37). A sub-group analysis revealed that an admission to hospital was associated with a 72% increase in the risk of being prescribed a PIM. Accordingly, older patients in hospital are at greater risk of being prescribed a PIM relative to non-hospitalised older patients, which has led to renewed calls for hospitals to prioritise addressing PIMs(38).

1.2.2.2 Factors contributing to inappropriate medication use and resultant harms

Several factors may contribute to a medication being inappropriate for a given patient; these are often age associated and progressive, and are discussed hereafter.

1.2.2.2.1 Physiological changes with age

Ageing is associated with reduced physiological reserve, leading to a reduction in the body's pharmacokinetic and pharmacodynamic medication processing capacity and, through the subsequent accumulation of active compounds, a predisposition to ADEs(39). The main physiological changes that impact medication processing are summarised in table 1.

Table 1 Summary of age associated physiological changes that impact medication processing (reproduced from ElDesoky(40))

Body system affected	Age associated changes
Liver	Reduced organ mass, blood flow, albumin synthesis
Kidney	Reduced glomerular filtration rate, tubular function
Gastrointestinal tract	Decreased gastric acid production, gastric emptying rate, gut transit time, intestinal blood flow, absorption surface area, intestinal metabolism
Circulatory	Decreased cardiac output, altered tissue perfusion, decreased plasma protein binding
General	Reduced total body mass, basal metabolic rate, lower water composition, increased body fat

Two of the body systems outlined in table 1 relate to the body's main methods for processing medication; the liver and kidneys. The liver is the predominant site for drug metabolism, which may involve activation of therapeutic metabolites, detoxification of harmful intermediates and production of species for elimination from the body(40,41). Age associated changes resulting in a decline in the liver's metabolic capacity lead to incomplete activation of metabolites, limiting the potential benefits afforded by medication. Additionally, a reduction in capacity to produce eliminable metabolites increases the risks of retaining harmful intermediates, leading to ADEs.

The kidneys are the predominant site for drug elimination. The number of glomeruli, which are the kidney's filtration units, declines by 60% between the ages of 30 and 90 years, leading to a substantial reduction in the kidneys' capacity to eliminate drugs. Older people are therefore at increased risks of retaining harmful metabolites via this mechanism(19,42).

Other age-associated changes effecting the efficacy of medication include reduced drug absorption across the gastrointestinal tract, reduced tissue blood perfusion and a change in the distribution and regulation of target receptors(41). Non-organ specific changes associated with age such as reduced body mass and basal metabolic rate render older people more sensitive to the effects of medication relative to younger people, and are a predisposition to ADEs such as side effects(40).

Physiological changes with age lead to a net reduction in older people's capacity to process medication, obtain intended benefits and avoid harms. Accordingly, as the trajectory of physiological decline progresses with age, a medication previously appropriate may become inappropriate several years later.

1.2.2.2.2 Exclusion of older people from clinical trials

Variation in medication processing between older and younger people is also an important consideration when interpreting data derived from clinical trials. Historically, upper age limits have been applied to trial participant recruitment, which has led to underrepresentation of older people. A retrospective analysis of oncology trial demographics revealed that people ≥65 years accounted for only 32% of study populations, however this demographic represents 61% of patients treated with anti-

cancer medication(43). Similarly, a health technology assessment reporting on the socio-demographic exclusions from clinical trials found that people ≥65 years represented only one-fifth of statin trial participants, but form two-thirds of the treatment population(44). Consequently, medications approved and frequently prescribed for older people may not have been adequately tested for safety and efficacy in this population. This practice has been challenged by clinicians and there has been a call for trial participant populations to better reflect treatment populations(45).

1.2.2.2.3 The prescribing cascade

A retrospective cohort study of patients in the ambulatory care setting in the USA reported an ADE incidence of 50.1 per 1000 person-years(46). Distinguishing between ADEs and manifestations of organic disease can be challenging to both patients and practitioner, and there is a risk of the former being mistaken for the latter. ADEs that are incorrectly diagnosed as a symptom of organic disease may result in prescribing a new medication, leading to the 'prescribing cascade'(47). For example, hyperuricaemia is a side effect of thiazide diuretics, which can lead to developing the painful inflammatory arthritis condition gout(48). Failure to associate developing gout with the prescribing of a thiazide diuretic may lead to inappropriate prescribing of anti-gout therapy, rather than substituting for an alternative diuretic(49).

The prescribing cascade has been identified as a significant driver for inappropriate medication use(47). Whilst in certain circumstances prescribers may intentionally prescribe a medication to manage the side effect of another where no alternative exists, it is widely accepted that this should be done so as a last resort(47).

1.2.2.2.4 Treatment guidelines

Prescribing is frequently informed by treatment guidelines, which are designed to ensure that prescribing is underpinned by quality scientific evidence(50). Treatment guidelines are clearly beneficial in facilitating evidence-based prescribing within therapeutic areas, however their utility in prescribing for older people with multi-morbidity has been questioned(50). Treatment guidelines are largely disease specific and offer little direction for practitioners regarding prescribing in the presence of multi-morbidity(51). A recent review applied treatment guidelines by the

national body which publishes health and social care guidance in England to a hypothetical older patient with multi-morbidity(52). The review found that the majority of guidelines recommended initiating several medications, increasing medication regimen complexity. None of the guidelines discussed when dose reduction or medication discontinuation was likely to be necessary, nor the approaches to safely implement them. A study examining nine of the most frequently utilised treatment guidelines in the USA reported similar findings(50). Whilst four treatment guidelines did consider prescribing in the presence of multi-morbidity, two of these were morbidities very closely related to the treatment guideline's therapeutic area, such as diabetes and cardiovascular disease(50).

1.3 Medicines optimisation

Rising financial pressures and limited health system resources have led to calls to maximise resource utilisation through minimising avoidable expenditure such as inappropriate medication use and resultant harms(53). 'Medicines optimisation' guidance was developed by the Royal Pharmaceutical Society in 2013 in collaboration with NHS England, the Royal College of General Practitioners, the Royal College of Nursing, the Association of British Pharmaceutical Industry and the Academy of Medical Royal Colleges(7). Medicines optimisation was defined as "*ensuring that the right patients get the right choice of medicine, at the right time*" to "*improve their outcomes; take their medicines correctly; avoid taking unnecessary medicines; reduce wastage of medicines; and improve medicines safety*" (7). Medicines optimisation acknowledges the value of the safe use of medication whilst indicating a need to develop strategies to identify and minimise unsafe use. Emphasis is placed on evaluating the appropriateness of prescribed medication over time to identify circumstances indicating that discontinuation is necessary. The four principles of patient-centred medicines optimisation are provided in figure 1(7).

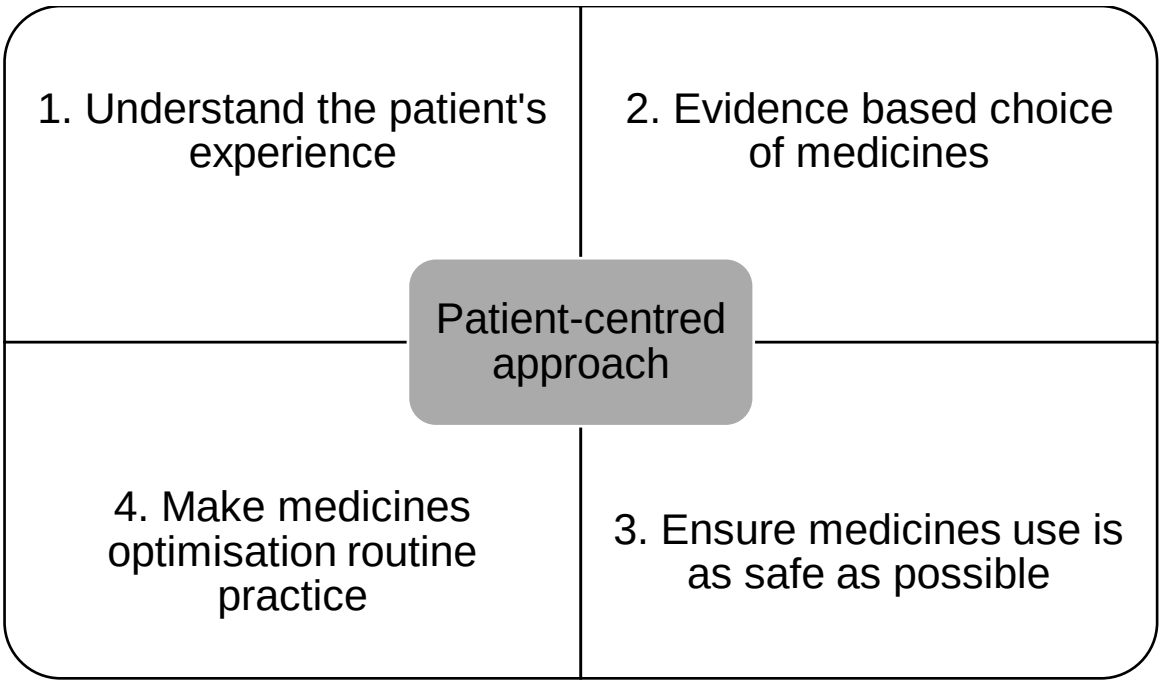

Figure 1 Summary of the four principles of medicines optimisation (adapted from the Royal Pharmaceutical Society's Medicines Optimisation guidance(7))

The need to address inappropriate medication use aligns with all four principles. The use of a medication may be unjustified if a patient experiences side effects that have a serious impact on their quality of life (principle 1), information regarding the efficacy and safety of a medication may be unavailable for the given patient population (principles 2 and 3). As the risks and potential benefits of medication change with time, healthcare practitioners should routinely review the appropriateness of medication regimens (principle 4). Moreover, principle 4 recognises that medicines optimisation is not yet embedded into routine practices, and that strategies for successful and sustained implementation are required.

Strategies to support adoption of medicines optimisation have been developed, which promote individualised and patient-centred prescribing of medication. Practitioners are encouraged to explore patients' health goals and priorities to inform decision making(11,54,55). In 2016, the national body which publishes health and social care guidance in England produced guidance for treating patients with co-morbidities. This guidance encourages practitioners to consider multi-morbidity when tailoring care, including prescribing and reviewing medication(56).

In the context of high PIM prevalence for older people and the resultant harms and financial implications, the medicines optimisation initiative endeavours to ensure that medication use is safe, provides benefits that outweigh risks and is aligned with

patients' wishes. A key component of medicines optimisation is identifying medications that are inappropriate and developing strategies for appropriate discontinuation.

1.4 Deprescribing

The term 'deprescribing' refers to the process of discontinuing inappropriate medication to prevent harm and improve health outcomes(25). Deprescribing was first defined by Woodward in 2003 as "*reviewing all current medications, identifying medications to be ceased, substituted or reduced, planning a deprescribing regimen in partnership with the patient and frequently reviewing and supporting the patient*"(25). Woodward suggested that deprescribing could prevent ADEs and medication related hospitalisations and, improve patients' adherence to remaining medication. Woodward acknowledged that evidence to support these predictions was sparse and therefore called for empirical deprescribing research(25).

Since Woodward first introduced the term, several further deprescribing definitions have emerged, which has led to calls for an agreed definition, to facilitate transferability and synthesis of research findings(57). A 2015 systematic review by Reeve *et al.* included 89 articles, of which 37 provided a unique definition for deprescribing. The following eight characteristics themes were synthesised from the 37 definitions(57):

- Use of the term stop/cease/discontinue/withdraw/remove or other synonyms.
- A description of the type of medication to be ceased (e.g. long term, inappropriate medications).
- Uses the term 'process' or 'structured'.
- Withdrawal is planned/ supervised/judicious.
- Describes deprescribing as involving multiple steps.
- Includes dose reduction and/or substitution.
- Definition includes a goal or desired outcome of deprescribing.
- Uses the term 'taper'.

The following definition, which incorporates five of the eight characteristics was proposed by Reeve *et al*.(57):

"*Deprescribing is the process of withdrawal of an inappropriate medication, supervised by a health care professional with the goal of managing polypharmacy and improving outcomes.*"

The included characteristics define deprescribing as a multi-step process and the primary goal is to reduce the risks of iatrogenic medication harm. The 'dose reduction and/or substitution' characteristic was excluded as the authors felt this was more strongly associated with 'optimal prescribing', whilst deprescribing was thought to be the complete withdrawal of a medicine. Excluding the 'taper' characteristic was considered necessary because medication discontinuation does not always require gradual withdrawal. It was deemed unnecessary to include the 'involving multiple steps' characteristic, since this concept was already captured by including the 'process' characteristic(57). Limitations of the study and resultant definition were noted, including later publication of further relevant articles and inclusion of research published by the authors themselves. Nonetheless, the definition proposed by Reeve *et al.* is the first and only deprescribing definition underpinned by the existing literature.

Subsequent to Reeve *et al.*'s synthesised definition, Scott *et al.* later defined deprescribing as the "*…systematic process of identifying and discontinuing drugs in instances in which existing or potential harms outweigh existing or potential benefits within the context of an individual patient's care goals, current level of functioning, life expectancy, values, and preferences*"(58). The important element of this sentence is the separation between 'existing and potential harms'. Deprescribing may therefore be 'reactive' in response to an existing harm, or 'proactive' where the risk of harm may no longer be outweighed by the potential benefits.

Whilst deprescribing is a relatively novel term, advocating identification and discontinuation of inappropriate medication has long been a component of good prescribing practice. The principles of prescribing and discontinuing medication are analogous and both are underpinned by an assessment of risks and potential benefits(59). The professional body for medical practitioners in the UK mandates doctors to monitor and review medication and consider the needs of individual patients and the risks posed by their medication. Regular review should be undertaken to establish whether a medication is required, effective and tolerated(20). Accordingly, whilst there is an expectation that deprescribing should form part of current prescribing practice, the aforementioned high PIM prevalence suggest that there may be scope to increase this activity in the hospital setting(34).

1.4.1 A model for deprescribing

Reeve *et al.* sought to develop a model for deprescribing, underpinned by the existing literature, which would break the process down into individual stages. A literature search identified 10 articles characterising deprescribing processes, which informed the development of a model comprising of five sequential deprescribing activities (figure 2).

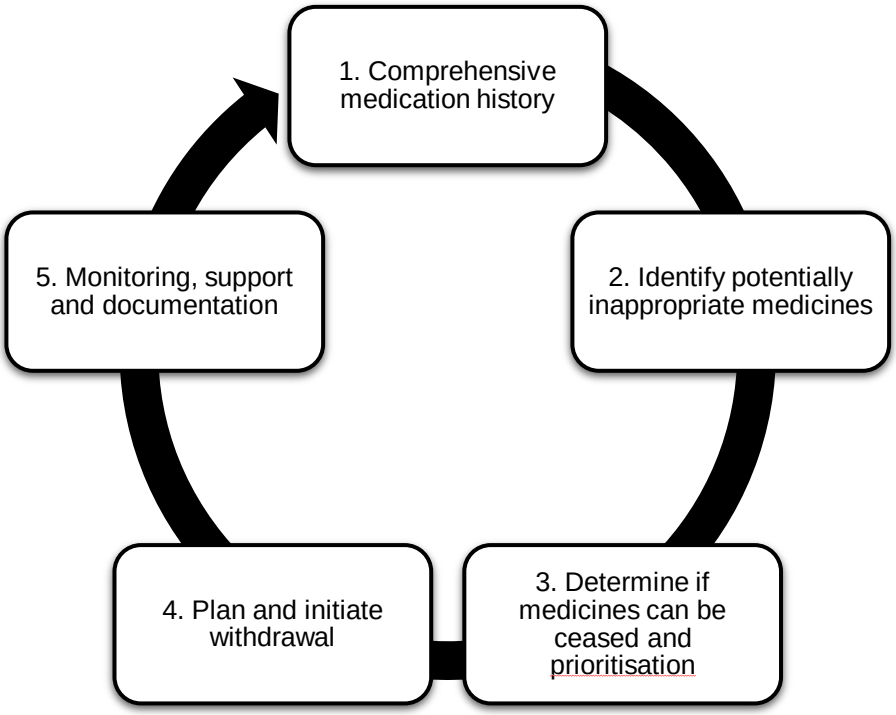

Figure 2 Deprescribing model (adapted from Reeve *et al*.(60))

Given that inappropriate medication use is prevalent across the primary care, care home and hospital settings, deprescribing opportunities should be acted on when they present across all healthcare settings. The challenges and potential solutions to routine deprescribing across these settings will vary according to contextual factors, such as resource availability and practitioners' knowledge and skills.

1.4.2 Deprescribing priorities

Determining which medications require deprescribing depends on individual patient circumstances. A 'one size fits all' list of medications to deprescribe is therefore

neither feasible nor helpful. However, clear therapeutic areas have been identified as appropriate foci for deprescribing because they are thought to be associated with most medication-related harms, and are not routinely deprescribed. In 2015, an expert panel of pharmacists, medical practitioners, nurses and social scientists participated in a modified Delphi process to specify which medication classes should be prioritised for deprescribing in older people(61). The group prioritised and ranked 14 commonly prescribed medicines and medication classes for deprescribing (table 2). Medication to treat mental health, cardiovascular, gastrointestinal and neurological conditions were most strongly represented in the ranking, however the 14 medicines/medication classes span the majority of therapeutic areas, suggesting generalist knowledge and skills may be required to provide holistic deprescribing for older people.

Table 2 Ranked medication classes prioritised for deprescribing for older people (reproduced from Farrell *et al.*(61))

Rank	Medication class
1	Benzodiazepines
2	Atypical antipsychotics
3	Statins
4	Tricyclic antidepressants
5	Proton-pump inhibitors
6	Urinary anticholinergics
7	Typical antipsychotics
8	Cholinesterase inhibitors
9	Opioids
10	Selective serotonin reuptake inhibitors
11	Bisphosphonates
12	Anticonvulsants
13	Beta-blockers
14	Antiplatelets

1.4.3 Resources developed to support deprescribing

Given the relative novelty of deprescribing as a research and practice priority and the complex nature of evaluating the risks and benefits of medication in older people, it is unsurprising that several resources to support practitioners to deprescribe have emerged.

1.4.3.1 Deprescribing tools

Tools to support practitioners to identify PIMs and thus potential deprescribing opportunities were briefly discussed earlier in this chapter. These tools therefore support point two of Reeve *et al.*'s deprescribing model(60): identify potentially inappropriate medicines.

A 2018 systematic review identified 15 tools to support identification of deprescribing opportunities in frail older people(62). Reporting of how tools were developed was found to be inconsistent and generally poor. However, the majority of tools were lists of medication which were thought to be PIMs based on the expert opinion of doctors, pharmacists and researchers. Only four tools had been tested in the trial environment in prospective studies and none had been tested in definitive high-quality trials such as a randomised controlled trial (RCT). The majority of tools (n=9) list medicines which are considered PIMs if patients fall into certain categories such as confounding morbidity. Examples of these tools include the Screening Tool of Older Persons Prescriptions in Frail adults with limited life expectancy (STOPPFrail)(63) and, the List of Evidence-Based Deprescribing for Chronic Patients (LESS-CHRON)(64). Four medication specific tools were identified which provide practitioners with criteria and guidance on how to deprescribe certain classes of medicines such as antihyperglycemic agents(65) and proton pump inhibitors(66). A further two tools were identified which provide guiding principles for practitioners to follow when reviewing medication for opportunities to deprescribe. One model developed by Holmes *et al.* proposes four considerations when determining whether to deprescribe; remaining life expectancy; likely duration until intended benefits; goals of care; and treatment targets(67).

The systematic review focussed on deprescribing for frail older people and therefore did not capture tools that may be available for deprescribing for older people who are not frail. Several other medication lists are available that have been extensively utilised in high quality RCTs(68), which were not captured including the Fit fOR The Aged (FORTA)(69) criteria and the aforementioned Beers criteria(30) and STOPP tool(31). A narrative review published in 2015 identified a further seven deprescribing models(70); 'Geriatric medication evaluation algorithm', 'The good palliative-geriatric algorithm', 'Prescribing optimisation method', 'Assess, review, minimise, optimise, reassess', 'Geriatric Risk Assessment MedGuide', 'Medication algorithms for reducing polypharmacy in mental health', and 'Confirm, estimate, assess, sort, eliminate'. These tools are similar in format and content to the aforementioned for frail older people(62).

Similar to deprescribing guidelines, these tools focus on providing information regarding what practitioners should do, such as deprescribe a certain medication for a certain group of patients. However, they do not support routine implementation in practice by addressing the range of likely barriers and enablers to deprescribing.

1.4.3.2 Deprescribing guidelines

Several evidence-based guidelines have been developed targeting some of the medication classes prioritised for deprescribing in older people(61). The guidelines provide practitioners with useful information and decision support regarding when and how to deprescribe these medicines. Initial work has focussed on the medication classes which were deemed of highest priority, including benzodiazepines(71), antipsychotics(72) and proton pump inhibitors(66). These guidelines support point four of Reeve *et al.*'s deprescribing model(60): plan and initiate withdrawal.

An evaluation of the impact of the three deprescribing guidelines on practitioners' deprescribing behaviour was undertaken using a self-efficacy survey. Overall self-efficacy scores significantly increased for antipsychotic deprescribing ($p=0.04$) but not for proton pump inhibitors and benzodiazepines, suggesting guidelines providing knowledge regarding when and how to deprescribe do not address all challenges faced by practitioners. This is an important consideration given that the deprescribing guidelines take eight months and a year to develop at a cost of C$80,000 and C$100,000(73).

1.4.4 Risks of deprescribing

There is potential for deprescribing to lead to significant improvements in health outcomes by preventing harms associated with inappropriate medication. However, deprescribing itself is not free from theoretical potential harm, and it is important to consider the potential adverse outcomes(74). Both practitioners and patients will need to consider the risks and potential benefits of deprescribing within the wider clinical context at points three and five of Reeve *et al*.'s deprescribing model(60): determine if medicines can be ceased and prioritisation and monitor, support and documentation respectively.

1.4.4.1 Adverse drug withdrawal events

A harmful physiological response to medication withdrawal is termed an adverse drug withdrawal event (ADWE) and may present as a return of disease, symptom or both. Deprescribing may precipitate ADWEs and this can be difficult to predict and mitigate. A retrospective analysis of medication withdrawal in domiciliary older people in the USA reported a 26% incidence of ADWEs, and the majority were exacerbation of an underlying condition(75). Approximately a third of ADWEs resulted in increased healthcare utilisation such as hospitalisation. Similar ADWE incidences have been reported from retrospective analyses of medication withdrawals in care homes(75).

Whilst it appears that in most instances medication withdrawal is safe, vigilance is required to manage the risks of ADWE precipitation. The aforementioned analyses of medication withdrawal and associated ADWEs did not actively seek to include medication withdrawal resulting from structured, patient-centred deprescribing as has been characterised in this thesis(60). Accordingly, analyses of deprescribing trials may produce different findings and are discussed later in this chapter.

1.4.4.2 Pharmacokinetic and pharmacodynamic changes

Medication withdrawal may alter the pharmacokinetic and pharmacodynamic processing of remaining medication in a patient's regimen. A prospective analysis of hospitalised patients concomitantly prescribed potassium sparing and potassium decreasing medications evaluated the effect of discontinuing of one of these medicines(76). Withdrawal of potassium sparing medication resulted in a decrease in serum potassium in 70% of patients, and withdrawal of potassium decreasing medication resulted in an increase in serum potassium for 59% of patients. Only a small minority of cases represented a change in serum potassium that was deemed clinically significant, with 17% of patients developing hypokalaemia and 3.2% hyperkalaemia respectively.

Akin to managing ADWEs, careful planning of deprescribing to manage the risks of adverse pharmacokinetic and pharmacodynamic changes is necessary. Hospital provides a conducive environment to managing these risks, given that physiological and biochemical monitoring is routine practice in this setting.

1.4.4.3 Medical condition relapse

The absence of symptoms indicates that either a medication is working as intended or the condition may have resolved. Therefore, a trial of medication withdrawal in a controlled and monitored environment is necessary to monitor for symptom relapse. A systematic review of medication-specific withdrawal trials included people ≥65 years and found variation in incidences of condition relapse(39). Only a small number of medication classes were represented, primarily anti-hypertensives, benzodiazepines and psychotropic medicines. Up to 85% of patients who had anti-hypertensive medication withdrawn were normotensive for between six months and five years with no increase in mortality. Whilst there is some evidence to suggest that certain classes of medication can be withdrawn in the majority of older people without condition relapse, evidence is lacking for the majority of medicine classes. Accordingly, there is a need to monitor closely for a return of the medical condition and agree a strategy for represcribing where necessary.

Deprescribing of preventative medication may be more challenging than for medication prescribed to treat a condition because there are no short-term symptoms for which to monitor after medication withdrawal, however a long-term increase in mortality post-deprescribing is a possibility. It is therefore important for practitioners, patients and carers to work together to identify medication offering greater risks than potential benefits and, agree whether or not to agree to deprescribe(74). A preventative medication may on the balance of probabilities prolong life, however if it adversely affects quality of life, a collaborative decision to deprescribe may be taken.

1.4.5 Safety and efficacy of deprescribing

Prior to implementing any new practice, there is a need to ensure that the potential benefits outweigh the risks of iatrogenic harm(77). The primary potential benefit of deprescribing is avoidance of harm associated with inappropriate medication, such as a reduction in ADEs and thus improvement in quality of life(25,58,78,79). Deprescribing may also reduce medication burden, which is more than simply the number of medicines in a patient's regimen, and in addition to ADEs, also encompasses other medication-related factors burdening patients such as(80):

- Practical challenges of taking medication (e.g. opening packaging).
- Social burden associated with stigmatisation of being prescribed medication.

- Medication taking activities interfering with day-to-day life (e.g. multiple daily dosing).
- Receipt of conflicting information and information overload regarding medication.
- Medication being a constant reminder of a patient's ill health.

Validated tools are available to measure medication burden such as the Living with Medicines Questionnaire (LMQ), which may be useful in the trial setting to evaluate the effect of deprescribing on medication burden(81).

The potential benefits of deprescribing must however be weighed up against the risks. There is a need to review the existing literature to evaluate the likely safety of deprescribing, and identify any evidence supporting the potential benefits that have been widely proposed(82).

A 2016 systematic review and meta-analysis evaluated the effects of interventions to deprescribe long-term medications for older people on mortality across healthcare settings(83). One hundred and sixteen studies including 17,428 participants were identified, across 56 RCTs, 22 non-randomised controlled trials and 37 uncontrolled trials. The mean participant age was 74 years and 51.8% were male. One hundred and three studies were undertaken in primary care setting and 14 were based in hospitals. Deprescribing interventions had no effect on mortality across all RCTs. However, a subgroup analysis showed that patient-specific interventions, which were those where investigators identified target medications to deprescribe and presented these to the healthcare team, resulted in a significant decrease in mortality (p=0.007) compared practitioner education interventions. In the non-randomised studies, a significant decrease in mortality was identified. Reassuringly, deprescribing did not produce a significant increase in ADWE incidence across all study types. No difference in quality of life or risk of falling was identified between the intervention and control groups, however people who did fall experienced significantly fewer falls in total. Unsurprisingly, the largest outcome effect observed was on the medication regime, with both a significant reduction in both the number of prescribed medicines (mean difference: -0.99, 95% CI: -0.183--0.14) and the number of PIMs (mean difference -0.49, 95% CI: -0.70—0.28).

A more recent 2018 systematic review of RCTs of interventions to deprescribe PIMs for older people, specifically in the hospital setting, reported variation in the

magnitude of deprescribing achieved(84). Study samples were relatively small, varying from 114 to 409 participants. Of the nine studies included, seven favoured the deprescribing intervention and the remainder found no significant difference between the intervention and usual care. Of the seven studies favouring the intervention, six reported an average PIM reduction of ≤1 between admission and discharge.

Given that over half of older patients admitted to hospital are prescribed at least one PIM and over a quarter are prescribed several PIMs(34,85), deprescribing on average less than 1 PIM is unlikely to be of clinical relevance(84). The remaining study was an 11 month RCT (n=172 patients) testing the effects of a pharmacist-led medication review intervention using an adapted version of the STOPP(31) criteria on geriatric wards at a large teaching hospital in Belgium. Pharmacists then provided deprescribing opportunities to doctors, who used their discretion to accept or reject the recommendations. A median additional discontinuation of one PIM was reported in the intervention arm between admission and discharge compared with the control(86). However, limitations included over half of patients refusing participation or being ineligible, limited follow-up of patients after discharge to explore whether deprescribing was sustained and other important outcomes such as readmission rates were not measured.

Secondary clinical outcomes were also captured in the systematic review(84). For all clinical outcomes, the deprescribing intervention was either comparable to or more favourable than the control. Two studies compared the incidence of ADEs between the intervention and control group, with one reporting no difference(87) and one reporting a significant reduction in ADEs in the intervention group(88). Health-related quality of life was assessed in two studies, with one reporting no difference between groups at six months(89) and one reporting a statistically significant improvement in the intervention group(86). Deprescribing interventions were not associated with a difference in mortality in the three studies reporting this outcome(86,90,91). Similarly, all four studies comparing readmission rates between intervention and control groups reported no difference(86,90–92). Of the four studies reporting the incidence of falls(86,91,93,94), deprescribing was associated with a statistically significant reduction in falls in one study(93). Functional status captured using the Barthel index, a validated measure of disability(95), was assessed in two studies(93,94), with a significant improvement in function reported at discharge in the deprescribing intervention group(94).

There is some evidence to suggest that the process of deprescribing in hospital may be feasible and that it has not been associated with negative clinical outcomes, and in certain circumstances an association with positive clinical outcomes has been reported(84). Caution should be applied when interpreting these results given the small sample sizes concerned, and studies were not powered to evaluate the impact of deprescribing interventions on secondary clinical outcomes. Moreover, the trials and participation within them provided the incentive to deprescribe, it is therefore not known whether any increase in deprescribing behaviour by practitioners was maintained post trial discontinuation or what the long-term effects were.

Designing interventions that sustainably change behaviour requires an understanding of the barriers and enablers to the behaviour within the usual, non-trial environment(96,97). There has been no comprehensive consideration of the barriers and enablers to deprescribing in hospital reported for the development of interventions(84). Failure to design interventions to overcome the barriers and enablers to deprescribing from the perspective of key stakeholders may provide some explanation for the limited efficacy reported within evidence syntheses(83,84).

1.4.6 Patient and carers views on deprescribing

Analogous to prescribing, deprescribing is a patient-centred process(60). A 2013 systematic review by Reeve *et al.* synthesised patients' barriers and enablers to deprescribing(98). Of the 21 studies identified, 13 were qualitative, seven mixed-methods and one study was a quantitative survey. All but one study focused on patients' views regarding the withdrawal of single medications or medication classes, such as hypnotics or antidepressants. However, a more recent qualitative study explored patients' views towards deprescribing of non-medication specific polypharmacy and reported views indicative of those captured in Reeve *et al.*'s systematic review (table 3)(99). Accordingly, the barriers and enablers from the patient perspective are similar regardless of the medication that is being deprescribed. Further research on this topic is not therefore a priority as there is already a large body of literature with findings transferable to the context of deprescribing in polypharmacy.

Table 3 Summary of patient barriers and enablers to deprescribing (adapted from Reeve *et al.*(98))

Barriers	Enablers
Beliefs regarding future benefits associated with continuation of a medicine	Lack of perceived ongoing need for the medicines
Scepticism about the reasons for deprescribing	Lack of perceived effectiveness of the medicines
Lack of confidence in the prescriber's knowledge of how to deprescribe	Experience of side effects
Concerns about insufficient guidance on how to discontinue medicines	Practitioner initiated the discussion
Fear of withdrawal reactions	Fear of addiction
Fear of relapse	Discontinuation trial to test the medicine's ongoing effectiveness
	Provision to enable return to the original medicine if the discontinuation trial is unsuccessful
	Dislike of taking medicines
	Inconvenience associated with taking medicines

1.4.6.1 Patient barriers to deprescribing

Disagreement with the appropriateness of deprescribing may relate to patients perceiving that the medication concerned is necessary and will provide future benefits(98). Interestingly, fear of missing out on future benefits has been expressed by patients despite acknowledging no tangible benefits. Similar reports from carers such as family members have also been captured. For example, in one qualitative study carers expressed resistance to deprescribing of medication intended to treat the symptoms of dementia, despite acknowledging that the medication had not yielded benefits for several years(100). Furthermore, some patients report feeling psychological benefits from the act of taking several medication, perceiving this as a health promoting behaviour(101,102). Patients have also provided their perspectives on the appropriateness of different healthcare practitioners' roles in deprescribing. A qualitative study reported patients' lack of confidence in GPs to deprescribe certain specialist medication such as antiepileptic agents(103). This is supported by another qualitative study which found patients' prefer specialists to deprescribe medication if the initial prescribing was by a specialist(104).

Patient barriers to the process of deprescribing related primarily to the perception that practitioners have limited time available to support them(98). Several studies report patients describing the time allocated in consultations to review medication as

insufficient and, there being anxiety regarding inadequate time invested in ongoing monitoring and support.

A further barrier expressed by patients is feeling compelled to adhere to medication taking by carers and practitioners, which negatively influenced any attempts to proactively propose deprescribing of suspected inappropriate mediation(98). This has been confounded by practitioners' continued issuing of repeat medication prescription endorsing these expectations.

Unsurprisingly, a previous negative experience following medication withdrawal has been associated with discontent to consider future deprescribing propositions. A qualitative study exploring patient experiences of discontinuing antidepressant medication cited experiences of withdrawal events are likely to heavily influence future decisions(105). Similarly, an awareness of the potentially negative consequences of deprescribing is reported in most studies and principally relates to a fear of worsening or return of symptoms(98,105).

1.4.6.2 Patient enablers to deprescribing

A key patient reported enabler to deprescribing is that they agree with a healthcare practitioner decide that a medicine is no longer appropriate by recognising that the risks of continuing to prescribe outweigh the intended benefits(98). For example, a patient may arrive at this conclusion if they recognise that the symptoms for which a medicine was initially prescribed have now resolved, and the medicine is therefore no longer necessary. Paradoxically, the presence of symptoms whilst taking a medicine may also lead patients to consider deprescribing, due to a perceived lack of efficacy.

Experiencing ADEs such as a side effect and fear of becoming dependent are widely reported triggers for patients to consider deprescribing(98). Patient have reported that a formal trial of deprescribing which maintains the option of represcribing provides an opportunity to review the appropriateness of deprescribing and is therefore an enabler. Interestingly, fear of dependence has been reported by patients prescribed medicines that are not routinely considered addictive, such as selective-serotonin reuptake inhibitor antidepressants(106). This may suggest that patients perceive medicines prescribed to treat certain conditions to be associated with addiction, and therefore is an unanticipated enabler for deprescribing which could be capitalised upon(98).

1.4.6.3 Patient willingness to consider deprescribing

A questionnaire designed to measure patients' attitudes towards deprescribing was informed by Reeve *et al.*'s systematic review of patient barriers and enablers to deprescribing(98). The Patients' Attitudes Towards Deprescribing (PATD) questionnaire was developed and validated in Australia(107) and first administered to a sample of 100 older patients (median age 72 years) attending an outpatient clinic. Ninety-two percent of respondents reported willingness to consider deprescribing, which was found to be significantly associated with age and the number of prescribed medicines. The PATD has been subsequently administered in studies in a care homes(108) and hospitals(109,110), with similar reports of high willingness to consider deprescribing.

Incongruously, over half of older people approached in deprescribing trials decline participation. Exploration of predictors for this lack of motivation to participate in a trial of deprescribing has focussed on external characteristics such as age, gender and number of medications. A retrospective analysis of medical records found that all variables analysed, including PIM prevalence, number of medicines at admission and comorbidities, had no effect on motivation to participate in a trial of deprescribing(111). This is unsurprising given that there is a substantial body of evidence in the field of behavioural science confirming that a key predictor of behaviour is attitude towards the behaviour, which is poorly predicted by external characteristics(112–114). Furthermore, external demographic characteristics cannot be changed and therefore provide limited benefit to practitioners when attempting to identify appropriate patients to approach.

1.4.7 Healthcare practitioner views on deprescribing

There is no research measuring existing deprescribing practice, however high prevalence of PIMs prescribed across healthcare settings suggests practice is not routine(36). Qualitative reports from primary care practitioners suggested current practice is likely to be limited and dominated by reactive deprescribing, in response to an existing harm(115). Accordingly, there remains a need to understand the challenges and potential solutions to deprescribing from the perspective of practitioners.

A 2014 systematic review by Anderson *et al*. synthesised healthcare practitioner views towards deprescribing and included 21 qualitative articles capturing the views medical practitioners exclusively, of which the majority were based in the primary care setting and all had prescribing privileges(116). A summary of the barriers and enablers from the perspective of healthcare practitioners is provided in table 4.

Table 4 Summary of healthcare practitioner barriers and enablers to deprescribing (adapted from Anderson *et al.*(98))

Barriers	Enablers
Inertia because of a fear of negative consequences, for example litigation	Patient receptivity to deprescribing
Fear of a negative effect on the professional relationship with the patient	Capacity to change prescribing
Fear of the unknown, for example potential consequences of withdrawal	Guidance on how to deprescribe
Perceived patient ambivalence or resistance to change	Quantification of the benefits and harms of medicines
Lack of time to discuss and implement deprescribing with patients	Confidence to deviate from prescribing guidelines
Concern about undermining inter-professional relationships	Greater dialogue with patients to increase understanding and shared decision-making
Lack of awareness of inappropriate prescribing	Previous experience of deprescribing

1.4.7.1 Healthcare practitioner barriers to deprescribing

Practitioners require appropriate knowledge and skills in order to identify deprescribing opportunities and plan withdrawal and monitoring strategies, in partnership with patients and carers. Moreover, practitioners then need to be confident in their ability to apply their knowledge and skills, and a lack of confidence has been identified as an important barrier to deprescribing(116).

Practitioners need to be cognisant of their prescribing practice in order to consider deprescribing. Barriers related to self-awareness have been reported in instances when the process of weighing up the risks and benefits, or the appropriateness of a medication, is considered difficult and/or not routine. The absence of immediate observable harms, uncertainty regarding whether a medication is still providing benefits and incomplete medication histories (e.g. indication, duration of prescribing) contribute to the ambiguity regarding confirming whether a PIM is an ‘actually inappropriate medicine’. Unsurprisingly, preventative medication such as statins to reduce the risk of cardiovascular events have been identified by practitioners as particularly challenging to deprescribe, because of the limited evidence of both

harms and benefits regarding their use in the older people population. The importance of this barrier is further supported by practitioner reports that deprescribing becomes easier when patients receive a poor prognosis, because there is no longer a need to consider long-term benefits. However, given that a substantial proportion of older people without a poor prognosis could benefit from deprescribing, there is a clear need to address this barrier(34).

Despite high incidence of ADEs in older people(117), prescribers in some studies expressed that medicines are generally free of side effects(118). Interestingly, this was reported with reference to psychotropic medicines(119), a therapeutic group carrying amongst the highest risk of ADEs(46). Underestimating medication risks may lead prescribers to fail to recognise opportunities to deprescribe. Interestingly, there is some evidence to suggest that clinicians prescribing higher volumes are more likely to underestimate the risks of medicines relative to lower volume prescribers(116).

Prescribers that identify inappropriate medicines may not necessarily proceed to deprescribe. This was emulated in a qualitative study of general practitioners' (GPs) benzodiazepine prescribing behaviours, which reported that whilst there was agreement that there was frequently an identified need to deprescribe this class of medication, however practitioners rarely actioned the deprescribing opportunity(120). A potential explanation for this is that prescribers assign greater uncertainty to deprescribing versus continuing to prescribe for fear of unknown adverse outcomes(104,116). For their patients, this may be anticipation of ADWEs and for the prescriber, this may be increased workload and for potential litigation. GPs have also reported fear of conflict with peers, particularly specialists such as those working in the hospital setting, being a barrier to deprescribing the relevant medication.

Anticipated resistance to deprescribing by key stakeholders, primarily the patient and carers is a consistently reported barrier to deprescribing. Practitioners report being fearful of harming the practitioner-patient relationship by deprescribing being incongruously perceived by patients as withdrawal of healthcare(116). This perception does not align with the aforementioned evidence-base which suggests that the majority of patients are willing to consider deprescribing propositions(108)(108–110). Some prescribers have suggested that patients actively expressing an interest in deprescribing and being involved in decision-making enables deprescribing. The extent to which patients are likely to

demonstrate these behaviours is unknown, however there is evidence to suggest that older people vary significantly in their desire to be involved in decision-making, with some favouring a paternalistic approach(121–125). Accordingly, practitioners should not rely on patients actively seeking deprescribing opportunities and the barrier of anticipated patient and carer resistance to deprescribing requires addressing.

Some practitioners may feel confident in their ability to deprescribe, however other factors related to the environment may prevent them from doing so. Limited resources to support planning, initiation and monitoring of deprescribing activities is frequently reported, with insufficient time being an important factor. For example, in the UK setting, standard GP consultations are 10 minutes, which practitioners report is insufficient time for decision-making with patients. This may be exacerbated by patients attending GP consultations with an agenda of their own, and may not wish to spend time within the short consultation on deprescribing(98).

1.4.7.2 Healthcare practitioner enablers to deprescribing

The enablers to deprescribing from the perspective of healthcare practitioners identified by Anderson *et al.*(98) are largely antonyms of the barriers. For example, practitioners who recognise that inappropriate prescribing for older people is an important issue are more likely to actively seek deprescribing opportunities. This is supported by studies testing interventions designed to raise prescriber awareness of PIMs using screening tools, which have demonstrated some increases in deprescribing activity in the hospital setting(126–128).

Practitioners report that a key enabler is having confidence in their ability to identify inappropriate medication and work with patients and carers to initiate and monitor deprescribing. This confidence is underpinned by provision of relevant training, with experience in geriatric medicine being a key enabler(116). GPs without this experience have reported that access to a geriatric specialist and a pharmacist for advice improves confidence in their ability to safely deprescribe(129,130).

Fear of the unknown and potentially adverse consequences of failing to deprescribe an inappropriate medication for older people are reported motivators to practitioners deprescribing. In turn, deprescribing is a perceived opportunity to improve patient outcomes and efficient health resource utilisation.

1.4.8 Comparison of practitioner and patient views towards deprescribing

The views of practitioners (table 4) and patients (table 3) share commonality in terms of the barriers to deprescribing, which are largely a fear of the potential consequence of ADWEs. However, practitioners additionally fear the potential consequence of harming the practitioner-patient relationship, which has not been expressed by patients.

The practitioner enabler of patient receptivity to deprescribing is complemented by the patient enabler of a desire for practitioners to initiate the deprescribing discussion. ADEs are a reported patient enabler to deprescribing which aligns with practitioners recognising that greater dialogue with patients enables shared-decision making to enable deprescribing.

1.4.9 A gap in the literature regarding the barriers and enablers from the hospital practitioner perspective

The Anderson *et al*. systematic review of practitioner barriers and enablers to deprescribing provides an insight into the challenges and potential solutions from the primary care perspective(98). However, the hospital perspective is underrepresented in the existing literature(98). Anderson *et al*. identified a single qualitative hospital setting study, however noted that it focused on doctors' perceptions of the factors that lead to inappropriate prescribing, and not the barriers and enablers to deprescribing in hospital(131). Additionally, despite over half of existing deprescribing intervention studies undertaken in the hospital setting either involving or being led by pharmacists(84), no literature capturing the views of this professional group have been reported(116). In the UK, a core role of the hospital pharmacist is to generate an accurate medication history on admission, reconcile discrepancies and seek opportunities to optimise pharmaceutical therapy to avoid medication-related harms(132). The existing remit of hospital pharmacist therefore aligns with steps 1 (comprehensive medication history), 2 (identify potentially inappropriate medicines) and 3 (determine if medicines can be ceased and prioritised) of Reeve *et al*.'s deprescribing model(60). Accordingly, this professional group is already undertaking activities which could support deprescribing is therefore likely to be a key stakeholder for a hospital deprescribing intervention.

Given that the hospital setting has been identified as a strong candidate for developing a deprescribing intervention, there remains a need to explore the

challenges to deprescribing and potential solutions that are specific to this context and it's key stakeholders. Anecdotal recognition by consultant geriatricians and the chief pharmacist at the Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) that deprescribing by hospital practitioners was insufficient, combined with the poverty of medical ageing research, led to the NNUH and the University of East Anglia jointly funding this PhD.

1.5 Summary

Population ageing and people living with multi-morbidity has led to an increase in prescribing polypharmacy. As people continue to age, physiological changes result in altered medication processing, leading to increased susceptibility to ADEs such a side effects and diminished benefits. Medications, which on the balance of probabilities offer more risks than benefits, are termed PIMs and, older people are at highest risk of being exposed to them. Whilst PIMs are not necessarily 'actually inappropriate' when prescribed for all patients, studies quantifying PIM prescribing provide an indication of the scale of inappropriate prescribing.

Approximately half of older people admitted to hospital are prescribed at least one PIM and thus are potentially exposed to unnecessary risk of iatrogenic harm(34), leading to calls for these to be addressed through reviewing medicines to determine suitability for discontinuation and actually discontinuing them, a process termed 'deprescribing'(25,38,133). The hospital setting is a potentially conducive environment for deprescribing because some of the activities in Reeve *et al.*'s model (figure 1) are routine practice in hospital(60). In the UK, pharmacist-led medicines reconciliations (activity 1) should be completed within 24 hours of hospital admission(134). Physiological and biochemical monitoring (activity 5), which may include observing patient response to medication withdrawal, is also characteristic of hospital practice(132). Activities 2 to 4 require practitioners to collaboratively identify inappropriate medication with patients and carers and determine whether deprescribing is appropriate.

The barriers and enablers to deprescribing in the hospital setting have not been comprehensively explored and characterised(116). Whilst some of the barriers and enablers reported by GPs may overlap with those of practitioners in the hospital setting, others may be unique to the hospital setting. GPs have stated that training in geriatric medicine and access to a pharmacist are both enablers. Accordingly,

geriatricians and pharmacists in hospital may be the appropriate practitioners to lead deprescribing in hospital and thus the targets of a novel intervention.

Deprescribing has been proposed to lead to benefits including a reduction in ADEs and improvement in medication adherence and quality of life(25). The potential risks associated with deprescribing are precipitation of ADWEs such as symptom or condition relapse. While high quality studies investigating clinically significant outcomes are limited, deprescribing in hospital appears feasible, safe and has been associated with positive clinical outcomes in certain circumstances including a reduction in ADRs, improvements health-related quality of life and decreased incidents of falls(84).

Patients responding to surveys have indicated that they are amenable to deprescribing proposed by a doctor, however qualitative data also suggests there are significant barriers from the patient and carer perspective; this is supported by reports of high numbers of patients declining participation in deprescribing trials. Practitioners' views towards deprescribing have been characterised, however the existing literature focusses on the primary care perspective and, the challenges and potential solutions to deprescribing in the hospital setting are poorly understood. This is an important consideration given that the hospital setting is a strong candidate for developing a novel deprescribing intervention for older people.

Several tools and guidelines have been developed to support practitioners to identify opportunities to deprescribe. The main barrier addressed by these resources is practitioners' lack of confidence to deprescribe due to knowledge deficits. However, their implementation in isolation is likely to have limited or no impact unless Whilst knowledge has been reported as a barrier by primary care practitioners, others that are not addressed by these resources are also reported and likely require consideration when developing a novel intervention. Accordingly, implementation of the existing resources to support deprescribing in isolation is likely to have limited or no impact unless other barriers are overcome and enablers utilised effectively.

The development of a novel hospital deprescribing intervention for older people targeting the behaviours of geriatricians and pharmacists will require empirical research to address identified gaps in the existing evidence base. There is conclusive evidence that PIM prescribing is prevalent in hospital. Existing interventions have yielded little success, and this may be attributed to little or no consideration of the barriers and enablers to deprescribing from the perspective of

healthcare practitioners. There remains a need to understand existing deprescribing practice in hospital in order to establish whether there is sufficient scope to justify developing a novel intervention. Patient and carer motivation to participate in deprescribing in hospital also needs to be quantified, and any predictors that may inform intervention development explored. The barriers and enablers of geriatricians and pharmacists to deprescribing in hospital require exploration to identify the challenges and potential solutions which an intervention to change behaviour should aim to address.

Chapter 2 Development of theory based behaviour change interventions

2.1 Introduction

Chapter 1 characterised the nature, magnitude and implications of inappropriate medication use in the older people population and introduced the concept of deprescribing. An admission to hospital may provide an opportunity to identify and safely deprescribe inappropriate medication for older people. This could be achieved through the development of a novel intervention that targets the behaviour of healthcare practitioners and patients.

Emphasis is placed on underpinning the early intervention development phases with health psychology and behaviour change theory. This methodological approach is adopted in order to understand what needs to change to facilitate a change in the desired behaviour, and to guide selection of components to include in an intervention that may bring about this change. Evidence syntheses have demonstrated that existing hospital based interventions have led to limited or no clinically significant and sustained implementation of deprescribing. The majority of these studies do not provide details of the intervention development process and, for those which do, it is not apparent that these have been underpinned by theory and/or an evidence base. The absence of robust theory informed development processes within the current literature may provide some explanation for the limited effects observed from trials of existing deprescribing interventions.

This chapter provides an overview of historic approaches to intervention development and considers this in light of current guidance. Furthermore, theoretical approaches are considered within the context of developing a novel deprescribing intervention for the hospital setting. Finally, a theoretical approach to underpin the development of a novel hospital deprescribing intervention is selected.

2.2 Behaviour change is complex

Developing new models of care which are both effective and cost-effective are the intended outcomes of health services research. Translation of these new models of care into routine healthcare practice requires practitioners, patients and carers to change established patterns of behaviour(135). Problems can arise if adoption of a new practice is counter to established patterns of behavioural and/or professional/personal norms, which can lead to disparity between recognised best practice and the care received by patients. Failure to implement new models of care is a long standing and well established problem, which has led to a ‘translational

gap' between the evidence base and realities of healthcare practice(136). Results from studies conducted in the United States of America (USA) and the Netherlands suggest that between 30% to 40% of patients do not receive evidence-based healthcare and 20% to 25% receive unnecessary or harmful care(137). Interventions to promote adoption of new models of care frequently only focus on either the healthcare practitioner or the patient, and do not consider all elements which may affect the behaviours of those involved. Why and how humans behave is a result of several influencing and interacting factors, all of which require consideration when developing an intervention to change behaviour(138).

To date there is limited evidence for the effectiveness of interventions targeting deprescribing of inappropriate medication for older people in the hospital setting(84). The focus is frequently on pharmacists performing the initial medication review to identify inappropriate medication, there are often implicit assumptions that they have the required knowledge and skills to perform this and, that they are adequately incentivised to spend sufficient time undertaking the review and implementing their recommendations. The behaviour of the doctor in response to the pharmacist's recommendation to deprescribe is often not considered, similarly neither is that of the patient or carer. The reviews are frequently performed assuming that the patient is adherent to their medicines and that requisite monitoring will be undertaken after discharge.

A 2018 systematic review sought to deconstruct existing deprescribing interventions and identify the individual components that were included to bring about the desired behaviour change(139). In accordance with previous evidence syntheses(84), effectiveness of hospital based deprescribing interventions was negligible. The authors reported poor descriptions of intervention content across all included studies, which presented significant challenges to understanding intervention content. For the five hospital based interventions which were deconstructed, nine components were identified. Providing practitioners with feedback on their behaviour, social support, providing instructions on how to deprescribe and communication from a credible source were the components most frequently included. The majority of interventions contained only two components and focussed on a single practitioner group such as the doctor. Given the complexity of deprescribing and the plethora of barriers and facilitators from the practitioner, patient and carer perspectives(98,116), it is unsurprising that these interventions are not effective. This reflects limited consideration of the factors necessary to bring about change in the development of existing hospital deprescribing interventions.

Unfortunately, due to the small sample sizes and heterogeneity between studies, definitive associations between the nine components with either intervention success or failure could not be explored(139,140). This limits the utility of the existing deprescribing literature in informing the development of novel hospital interventions because it is not possible to learn from the successes and failures of the past.

There is a need for the development of a novel hospital deprescribing intervention which seeks to change behaviour through overcoming the barriers and enablers from the perspectives of practitioner, patients and carers. Prior to embarking on this task, an understanding of how interventions to change behaviour are developed and operationalised and, identification of a suitable methodological approach for application to the present context, is necessary.

2.2.1 Behaviour change interventions

Behaviour change interventions (BCIs) are widely used to promote adoption of desired behaviours by individuals and organisations, including changing practice in the healthcare context(141). The National Institute for Health and Care Excellence (NICE) describe BCIs as having "*enormous potential to alter current patterns of disease*"(141), because they target the key barriers and facilitators, or determinants, of behaviour(142). BCIs were described by Collins *et al.*(143) as an "*aggregation of a set of components, which may include behaviours, behaviour parameters ('dose' and 'frequency') and the specified mode of delivery*"(144). The granular components of BCIs are the 'active ingredients' and whilst these are key to intervention success, they can be challenging to define and are traditionally poorly reported in BCI evaluations(144). Akin to the behaviours which BCIs aim to change, they are themselves regarded as 'complex interventions' owing to multiple interacting components, number and difficulty of behaviours involved, number of target groups or organisation levels, number and variability of outcomes and the degree of flexibility or tailoring permitted in practice(96).

2.2.2 Historic approaches to behaviour change

Historic approaches to implementing new practices have followed a 'trial and error' approach which was empirically driven and researcher-led(141,145). There was also the absence of clear rationale for the methodological approaches used during

the design process, including selection of intervention components(145). This has led to limited understanding of the anticipated mechanisms of behaviour change and, is a proposed source of intervention failure(146). Moreover, ambiguity surrounding how interventions are theorised to bring about behaviour change renders negative results unhelpful, as there is limited scope to explore, learn and progress from an ineffective intervention. This restricts opportunities to identify factors predictive of successful implementation of a new practice and improve strategies to change behaviour(146)

A 2004 Health Technology Assessment systematic review assessed the effectiveness and efficiency of approaches to changing healthcare practitioners' behaviour(147). The majority of included studies involved the provision of education only and yielded modest to moderate changes in practice. Responses to an associated survey administered to policy makers revealed that respondents felt interventions comprising of the provision of education only to address knowledge gaps were feasible(147). Accordingly, the limited reported effectiveness of early BCIs is unsurprising given that in the majority of cases, only one of the likely several determinants of behaviour, such as knowledge, were being targeted(147). Similarly, a more recent overview of systematic reviews by O'Brien *et al.* identified and appraised BCIs targeting healthcare practitioners(138). A plethora of interventions and behaviours were identified alongside varying degrees of effectiveness. In accordance with previous reports, evidence was weak for behaviour change resulting from passive dissemination of education and recommendations(147), while educational outreach and reminders demonstrated greater success(138). BCIs targeting multiple determinants of behaviour were more effective than single-determinant interventions(138). O'Brien *et al.* also stressed the importance of considering the influence of environments in which interventions are implemented, because interventions appear to work in some settings and not in others(138). Accordingly, the context to which the planned implementation of an intervention relates, requires careful consideration when developing BCIs.

The aforementioned Health Technology Assessment called for the development of a "*…coherent theoretical framework of health professional and organisational behaviour and behaviour change to inform better choice of interventions…*"(147). Notwithstanding, the challenges associated with changing behaviour are not to be underestimated and as aptly put by Haynes *et al.*, there are "*no magic bullets*" to developing interventions to improve healthcare practitioners' practice(148).

2.3 Using theory to underpin Behaviour Change Interventions

The Medical Research Council (MRC) published guidance on the development and evaluation of complex interventions to improve health in 2000(144), later updated in 2008(96) to reflect accumulation of knowledge and experience. The 2008 update sought to address limitations identified in its predecessor, including divergence from a linear model of intervention development mirroring the phases of drug development and evaluation. The updated guidance places increased emphasis on early phase development, particularly the application of theory and recognition that complex interventions require tailoring to individual contexts. The resultant framework provides guidance for the development and evaluation of healthcare interventions for use by researchers and policymakers, surmised in figure 3.

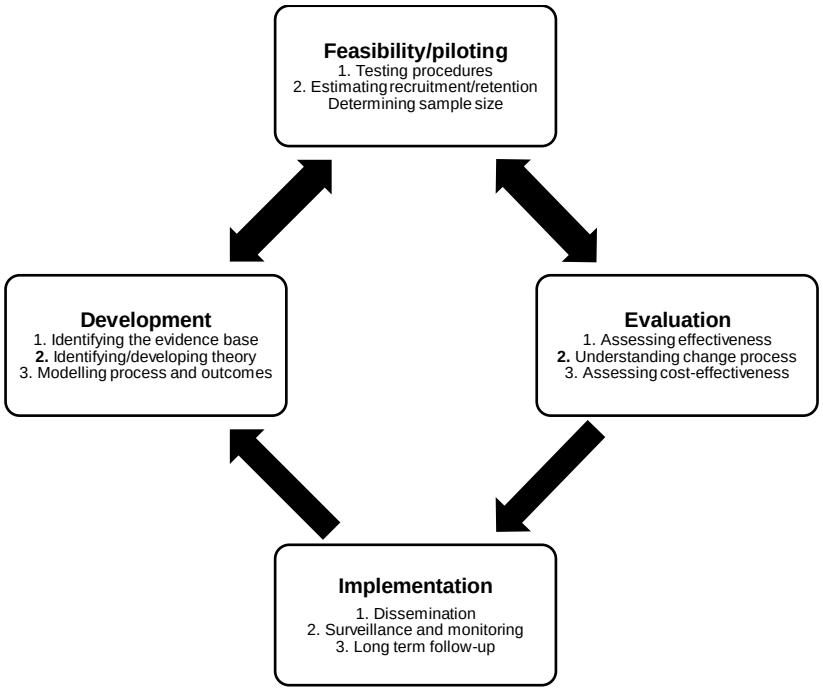

Figure 3 Key steps of the Medical Research Council guidance on developing and evaluating complex interventions (adapted from (96))

The rationale for identifying and developing theory is to understand the change process by drawing on the existing evidence, and health psychology and behaviour change theory. This approach seeks to identify the variables underpinning decisions to perform or not to perform a behaviour(149), providing a schematic of the mechanisms that may propel the behaviour into routine practice. This emphasis on theory contrasts the methodological approach to early BCI development discussed

earlier in this chapter. There is some evidence to suggest BCIs underpinned by theory are more likely to be effective than those which are empirically driven(150). However, despite advocating for its use, the MRC guidance does not advise researchers on how to select and apply appropriate theory. Accordingly, there is a need to navigate the plethora of available health psychology and behaviour change theories in order to determine which are appropriate for the behaviour and context of interest.

2.3.1 Classic theories used to develop behaviour change interventions

Nilsen defines a theory as "*a set of analytical principles or statements designed to structure our observation, understanding and explanation of the word*"(146). Theories are made up of relationships between dependent and independent variables existing in a domain where the theory applies, which together can predict an outcome, such as a behaviour(146).

Initially, theories applied to the development of BCIs were 'borrowed' from the fields of psychology, sociology and organisational theory and, are often referred to as the 'classic theories'(146). These theories were developed to explain how behaviour change occurs through describing the underlying mechanisms. Determinants of practitioners' behaviours are believed to be similar to those of people generally, therefore many classic theories have been applied to the study of practitioners' behaviour change(151). A systematic review of studies based on social cognitive theories identified 72 articles describing the application of theory to understand the determinants of practitioners' behaviour(152). The Theory of Planned Behaviour, which proposes that the constructs of attitude toward the behaviour, subjective norm and perceived behavioural control predict intention and behaviour, was the most frequently adopted theory. However, other, often overlapping theories, such as Triandis' Theory of Interpersonal Behaviour, whilst also considering attitudes and norms, consider other determinants such as emotions and habits(153).

Michie *et al.* suggest intervention developers are faced with three key challenges when attempting to select the most appropriate theory or theories to apply to their behaviour of interest(112). Firstly, no one theory comprehensively explains human behaviour and therefore with behavioural problems with multiple barriers and facilitators to address, several individual theories may be relevant. Incongruously, several of the classic theories overlap to some degree, incorporating redundancy when attempting to apply more than one potentially applicable theory to

comprehensively explore a behavioural problem. Secondly, there is no systematic basis on which to select the most relevant theories to apply to a given behavioural problem and, there is a risk of missing critical theories in doing this. Finally, theories in general only describe the underlying mechanisms of behaviour change and therefore they do not guide selection of intervention components which act on these mechanisms to bring about change(146). Accordingly, whilst expert health and behavioural psychologists developing interventions may be able to identify intervention components based on the mechanisms explained by classic theories, those without such knowledge and skills are unlikely to be successful(112). It is therefore unsurprising that researchers face significant challenges when attempting to underpin BCI development with theory(146,154).

Whilst the application of the classic theories represents a significant advancement towards developing theory-informed BCIs, they were not devised for this purpose and do not offer a systematic approach to comprehensively explaining behaviour and selecting appropriate intervention components. The field of implementation science has since emerged and is "*the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services*"(155). This is a broad field which considers the behaviour of patients, practitioners, organisations and policy makers and represents a paradigm shift from historic atheoretical and classic theory approaches to BCI development. Implementation science is rapidly developing, however in terms of facilitating theory-informed intervention development, a novel set of frameworks and theories have emerged from within the field which offer simplified and clarified access to psychology and behaviour change theory. These are considered herein for application to the development of a novel hospital deprescribing intervention.

2.3.2 Determinant frameworks

Rather than working with one theory, Michie *et al.* argue that researchers developing BCIs require access to a complete set of theoretical explanations for behaviour change in order to understand the underlying mechanisms. Determinant frameworks are a synthesis of several behaviour change theories and provide a structure of descriptive categories, and may describe the relationship between these categories, that are theorised to produce a phenomenon(146). Determinant frameworks describe the general categories of barriers and enablers that are

thought to influence an outcome such as practitioners' behaviour. These are particularly useful for designing interventions where a change in the determinants, such as overcoming barriers and/or utilisation of facilitators, is required to enact the desired change in behaviour(146).

2.3.2.1 The Fishbein *et al.* Theoretical Integration of Key Behavioural Determinants

The first attempt to combine several behaviour change theories into one determinant framework was led by Fishbein. Through a three day consensus conference, a group of theorists and health psychologists drew on theories to identify the key determinants of behaviour which could be applied universally to any behavioural analysis(149,156). This work was undertaken in the context of Human Immunodeficiency Virus prevention behaviours, with a focus on health promotion such as condom use during intercourse. Fishbein *et al.* concluded that there were eight key determinants of human behaviour (figure 4).

The determinants of behaviour were hypothesised to explain why some individuals or groups performed a behaviour whilst others do not. Three of the determinants, 'Intentions', 'Environmental constraints' and 'Skills' are regarded as essential to performing any behaviour. The remaining five determinants influence the strength and direction of 'Intentions' and, are not necessarily important determinants of all behaviours(149,156).

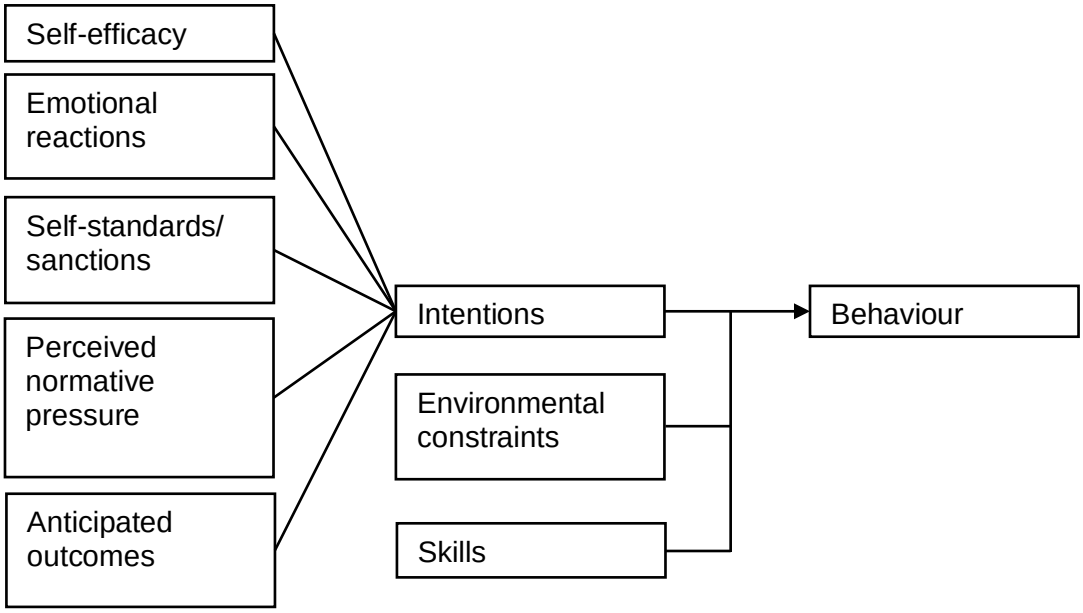

Figure 4 The Fishbein *et al*. Theoretical Integration of Key Behavioural Determinants (adapted from 19,34)

The Fishbein *et al.* conceptualisation of the determinant framework represented a significant advance in the field of behavioural science and has paved the way for further progress in applying theory to the development of BCIs. For the first time, developers of BCIs need not attempt to select from the plethora of potentially relevant theories. Instead, the Fishbein *et al.* work provided a vehicle for the application of several theoretical constructs simultaneously, with intervention developers able to identify the key determinants relevant to the behaviour, context and population of interest. However, as with all determinant frameworks, the causal model linking the eight determinants to behaviour have not been characterised.

Whilst this framework provides a useful foundation on which to establish determinant frameworks, there are several limitations. Firstly, the development work was undertaken in the context of patient's health behaviours and not that of people delivering health services, such as practitioners. Although overlapping behavioural determinants between these populations may exist, practitioners' behaviour may be determined by additional contributory factors not present in the Fishbein *et al.* framework, such as knowledge of a disease or medication. Subsequent frameworks have included several additional domains, suggesting the Fishbein *et al.* framework may not be comprehensive and therefore limits its utility to developing BCIs(157). Additionally, there exists no direct link between identifying the determinants of

behaviour using the framework and understanding how to bring about behaviour change.

2.3.2.2 Theoretical Domains Framework

The Theoretical Domains Framework (TDF) is an in an integrative framework of behaviour change theories developed through a collaboration between psychologists and health service researchers to allow non-behaviour scientists to select from a comprehensive theoretical framework(157). Developed by Michie *et al.* in 2005, the TDF is a synthesis of 33 behaviour change theories and 128 theoretical constructs judged to be most relevant to changing behaviour, which are organised into 14(157) (originally 12(158)) theoretical domains. Each theoretical domain represents a determinant of behaviour (table 5). It can be seen that eight of the domains overlap with the Fishbein *et al.* framework(156), indicated in parenthesis in table 5. However, Michie *et al.* identified an additional six determinants which are not included in the Fishbein *et al.* framework(156): 'Knowledge'; 'Memory, attention and decision processes'; 'Behavioural regulation'; 'Intentions'; 'Goals'; 'Optimism'.

The TDF does not explain relationships between determinants, however it is described as "*…theoretical lens through which to view the cognitive, affective, social and environmental influences on behaviour…*"(159). The TDF is therefore a framework for understanding a behaviour and provides a foundation for changing the behaviour through identifying areas to change in designing interventions.

The 14 domains are used to structure methods of gathering evidence to understand the behaviour within a context. This 'behavioural diagnosis' identifies what needs to change and within which theoretical domains. The TDF has been applied widely to the study of healthcare practitioners' behaviour and more recently to patients' and members of the public. A 2012 evidence synthesis of literature applying the TDF identified 133 articles spanning qualitative research, surveys, systematic reviews, randomised studies and a process evaluation(160). Uses of the TDF have included identifying influencers of behaviour, systematic intervention design, process evaluation of randomised trials and identification of intervention components(159).

Table 5 Domains of the Theoretical Domains Framework

Theoretical domain	Definition
1. Knowledge	An awareness of the existence of something
2. Skills *(Skills)*	An ability or proficiency acquired through practice
3. Social/ Professional Role and Identity *(Self-standards/sanctions)*	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting
4. Beliefs about Capabilities *(Self-efficacy)*	Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use
5. Optimism	The confidence that things will happen for the best or that desired goals will be attained
6. Beliefs about Consequences *(Anticipated outcomes)*	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
7. Reinforcement	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus
8. Intentions *(Intentions)*	A conscious decision to perform a behaviour or a resolve to act in a certain way
9. Goals	Mental representations of outcomes or end states that an individual wants to achieve
10. Memory, Attention and Decision Processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives
11. Environmental Context and Resources *(Environmental constraints)*	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour
12. Social Influence *(Perceived normative pressure)*	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours
13. Emotion *(Emotional sanctions)*	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event
14. Behavioural Regulation	Anything aimed at managing or changing objectively observed or measured actions

* Domains in parenthesis provide the corresponding domains of the Fishbein *et al.* Theoretical Integration of Key Behavioural Determinants (149,156)

The TDF's strengths are in its comprehensive set of underpinning theories and constructs that facilitate an accessible and systematic approach to understanding behaviour and developing BCIs. Whilst the TDF was developed independently to the Fishbein *et al.* framework, the significant overlap between eight of the TDF's domains and the eight behavioural determinants included in the Fishbein *et al.* framework affords some confidence in the importance of these domains in determining behaviour.

The array of methodological approaches, behaviours and contexts to which the TDF has been applied demonstrates that it is a broad and flexible tool. The wide coverage of potential behavioural determinants offered by the 14 theoretical domains facilitates isolation of important beliefs that may not be elicited through atheoretical or single theory approaches. Moreover, the TDF considers the influence of other groups of people on the individual whose behaviour is being targeted. However, critics of the TDF argue that empirical exploratory work confined to the rigid theoretical domains may restrict expression of views regarding a behaviour to align with the TDF domains only. For example, a qualitative topic guide informed by the TDF may produce results different to a traditionally inductive methodological approach. Accordingly, there is a potential risk of failing to identify barriers or facilitators that are instrumental to enacting behaviour change. This potential problem was explored in a mixed-methods study comparing application of the TDF with a parallel atheoretical approach to explore hand hygiene behaviour(161). There was considerable convergence in the barriers and facilitators identified by both approaches, however use of the TDF appeared to identify barriers which had an important influence on the behaviour which were not ordinarily reported, such as emotions. Accordingly, owing to a comprehensive coverage of behavioural determinants, application of the TDF appears to prompt identification of novel concepts not captured through purely inductive approaches(160).

2.3.3 Implementation theories

These theories focus on understanding and explaining the processes of implementing a new behaviour, often through a BCI, into a new context. Through the application of implementation theory, researchers prioritise critical aspects related to the ‘how’ and ‘why’ of implementation, which are often a derivation of the barriers and facilitators to the behaviour(146). Some implementation theories are completely novel whilst others, in addition to the determinant frameworks, were developed by adapting existing theories.

2.3.3.1 Normalization Process Theory

Normalization process theory (NPT) is a novel development from the field of implementation science that focuses on understanding and explaining what people do, rather than what they believe or intend, within a healthcare context. NPT was originally developed for use within the context of implementation of electronic health

applications, however more recently the theory has been applied widely, including for chronic disease management, maternity care and language interpretation services(162). A systematic review of studies employing NPT in BCIs identified 130 manuscripts spanning controlled and non-controlled trials, qualitative studies, survey studies and a prospective cohort study(163). Seven categories of studies were included: service organisation and delivery, implementation of diagnostic and therapeutic interventions, implementation of e-Health and telemedicine, implementation of screening and surveillance tools, decision support and shared decision making, implementing change in professional roles and guideline implementation.

NPT explains the conscious and deliberate processes by which complex interventions become routinely embedded into practice by focusing on the factors that promote or inhibit routine embedding of complex interventions(164,165). NPT proposes that "*material practices become routinely embedded in social contexts as the result of people working, individually and collectively, to implement them*"(165). The observable work required of people to implement practice is proposed to be operationalised through four 'generative mechanisms' or constructs: coherence, cognitive participation, collective action and reflexive monitoring, explained below:

- Coherence: the process and work of sense-making and understanding that individuals and organisations have to go through in order to promote or inhibit the routine embedding of a practice.
- Cognitive participation: the work that individuals and organisations have to do to enact the new practice.
- Collective action: is how people make the practice or behaviour work in reality, considering what they require to make it happen.
- Reflective monitoring: the work inherent in the informal and formal appraisal of a new practice once it is in use, in order to assess its advantages and disadvantages, and which develops users' comprehension of the effects of a practice.

The barriers and facilitators that promote or inhibit embedding of a practice or behaviour are theorised to act on one or more of these four generative mechanisms. Accordingly, people, both individuals and as a collective, need to exert work on these mechanisms to change their behaviour to embed a new practice. Figure 5 provides an overview of how the four generative mechanisms interact with each

other and with affective factors within NPT. The theory proposes that in order to achieve sustained embedding of practice or behaviour, people are required to continuously invest in actions that sustain change within the social context(165). NPT also considers that the environments in which healthcare practitioners' practice are dynamic, therefore people's investments in embedding a practice or behaviour are themselves affected by changes in the environment. For example, failure to refill alcohol gel dispensers in hospitals leading to a deterioration in practitioners' hand hygiene practice. Through an understanding of the generative mechanisms and affecters within a given social context, NPT was developed to involve stakeholders in the implementation process to understand the work required of them to embed a new practice or behaviour.

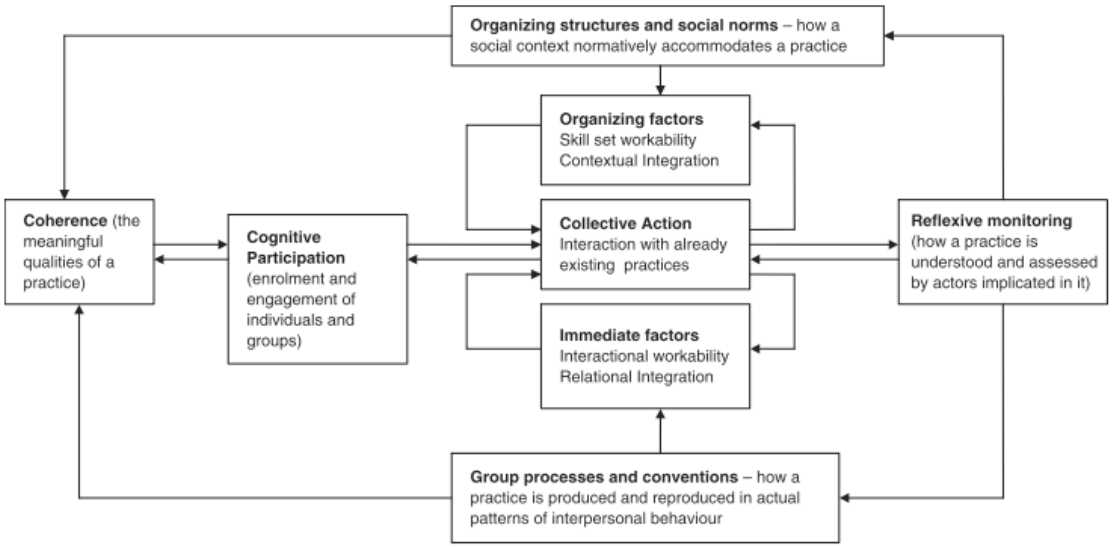

Figure 5 Model of the components of Normalization Process Theory (taken from May *et al.*(165))

NPT is an explanatory, theoretically-underpinned framework that informs identification of factors that promote or inhibit implementation of BCIs, such as those used to change healthcare practice. Underpinning implementation of BCIs with NPT facilitates formulation of clear implementation strategies and, informs analysis and large scale implementation and trial design(162). NPT is therefore particularly useful when an understanding of how a pre-developed intervention or a new technology can be implemented into the intended context.

Whilst NPT has been successfully applied to implement several BCIs, some criticisms of the theory have been reported, including an overemphasis on agents;

the people who are targeted by BCIs, at the expense of the social and environmental contexts in which a new practice or behaviour must embed. This is an important limitation given the wealth of literature suggesting contextual factors are important to changing behaviour and are themselves modifiable(138). This is of particular relevance to deprescribing in hospital, given that factors such as resource availability in healthcare environments have been identified as influencers on deprescribing behaviour in primary care(116). Whether this is also an important influencer on deprescribing behaviour in the hospital setting remains unknown, however given it is relevant in other healthcare settings, the theory selected for the present programme of work should consider this potentially important determinant.

NPT has also been criticised for a reported overemphasis on the target group's behaviour, such as healthcare practitioners, at the expense of groups who experience the effects of the change in behaviour, such as patients. This limitation may be of particular importance in cases where the consequences of behaviour change is perceived by practitioners to be negatively received by patients. This is also an important limitation in the context of deprescribing in hospital, given that primary care practitioners report the influence of other people, such as patients, carers and other practitioners as important influencers on deprescribing(116). It is conceivable that practitioners in the hospital setting's deprescribing behaviour may similarly be influenced by social factors and thus a theory selected for the present programme of should equally consider social influences.

2.3.3.2 Other implementation theories

Other theories developed within the field of implementation science that focus on embedding a new practice or behaviour include Organisational Readiness and Implementation Climate. Similar to NPT, Organisational Readiness and Implementation Climate focus on the individuals whose behaviour is being targeted. Organisational Readiness emphasises the importance of the psychological state in which organisational members feel committed to implementing a change and confidence in their abilities to do so(166). Implementation Climate on the other hand focuses on the strength of an organisation's climate for the implementation of an innovation and how well the innovation aligns with the user's values(158). For the purposes of this theory, an organisation's climate is defined as *"employees' shared summary perceptions of the extent to which their use of a specific innovation is rewarded, supported, and expected within their organization"*(158). Similar to NPT,

these theories allow researchers to prioritise mechanisms that are most critical to behaviour change, providing an understand the how and why of implementation(146).

As with all theories, implementation theories do not attempt to be all encompassing and thus the application of a single implementation theory risks omitting consideration of a mechanism which may be crucial to behaviour change when developing a BCI. Moreover, these theories are applied to the study of implementing an established BCI and do not facilitate initial development, including selection of intervention components. Accordingly, they are most useful after a BCI has been developed and researchers are looking to develop strategies for effective implementation.

2.3.4 From explaining behaviour to changing behaviour

A theoretical understanding of behaviour recognises the determinants that require change to be targeted in a BCI. However, there remains a need to identify how to change behaviour through acting on these determinants(167). Hardeman *et al.* noted in 2005 that there was a missing link between understanding behaviour with theory and choosing appropriate, corresponding intervention components(168).

A Behaviour Change Technique (BCT) is characterised in the Encyclopaedia of Behavioural Medicine as(169):

"*…a systematic procedure included as an active component of an intervention designed to change behaviour… A BCT is thus the smallest component compatible with retaining the postulated active ingredients, that is, the proposed mechanisms of change, and can be used alone or in combination with other BCTs*."

According to Michie *et al.*(170), the defining characteristics of a BCT are that they are:

- Observable
- Replicable
- Irreducible
- A component of an intervention designed to change behaviour
- A postulated active ingredient within the intervention

Clear and consistent reporting of BCTs is particularly important and should follow the standard scientific principles of transparency to allow others to learn, reproduce and build on the existing literature. BCT reporting in early interventions underpinned by health psychology theory was poor and inconsistent. Challenges arose with defining individual BCTs in a meaningful and replicable manner, complicated by language and formatting differences across research groups. Accordingly, several subjective author-defined labels for identical BCTs emerged alongside variation in practice in terms of label specificity(150,171).

In an attempt to establish a 'common language' of BCTs, in 2008 Abraham and Michie identified and assigned labels to 26 BCTs from published intervention descriptions and manuals using consistent terminology and standard definitions (172). For example, the BCT 'Provide information on consequences' was assigned the label 'Information about the benefits and costs of action or inaction, focusing on what will happen if the person does/ does not perform the behaviour'. The development of this early taxonomy of BCTs was described as a significant step forward in the field of implementation science and was poised to facilitate specificity in the reporting of BCI content. Moreover, common reporting of BCTs was proposed to enable meta-analytic review of BCI effectiveness, yielding a further advancement in the field.

Whilst consistent reporting of BCTs provided a basis for identifying those which are effective for certain behaviours and in certain contexts, the need remained to address the gap between explaining behaviour using theory and changing that behaviour. In 2008, group of expert health psychologists and health services researchers, led by Michie, sought to bridge this gap by linking standardised definitions for BCTs to the domains of the TDF that they were likely to effectively enact behaviour change(167). The original 26 BCTs defined in the taxonomy were added to through a brainstorming exercised and a total of 35 BCTs were linked to the TDF.

Further advancing the reporting of intervention contents, in 2013 Michie *et al.* developed the first extensive taxonomy of BCTs, expanding the original taxonomy of 26 BCTs(172) to 93 BCTs hierarchically clustered into 16 groups, yielding the 'Behaviour Change Technique Taxonomy version 1' (BCTTv1)(173). Building on this and the existing 2008 TDF work(167), Cane *et al.* subsequently mapped the BCTTv1 to the TDF(167). Fifty-nine BCTs were reliably mapped onto 12 of the 14 TDF domains. For the domains of 'Social/professional role and identity' and

‘Memory, attention and decision processes’, no BCTs have yet been linked. For the remaining 12 domains, there is variation in the number of BCTs linked, for example the domain of ‘Reinforcement’ is linked to 17 BCTs whilst only one BCT is linked to the ‘Optimism’ domain.

Mapping of the BCTTv1 onto the TDF provides a structured and systematic approach to applying health psychology theory and evidence-based intervention components to the understanding of behaviour and subsequent development of BCIs. This methodological approach has been widely adopted internationally to the development of healthcare BCIs, including encouraging timely cancer symptom presentation among people living in deprived communities(174), enhancing nurses’ use of electronic medication management and improving appropriate polypharmacy for older people in primary care(175).

2.3.5 Selecting a theoretical approach for developing a hospital deprescribing intervention for older people

The programme of worked described in this thesis involves the development of a hospital deprescribing intervention for older people targeting geriatricians’ and pharmacists’ behaviour, underpinned by health psychology theory. The impracticalities and drawbacks associated with applying classic theories, as described earlier in this chapter, to the development of BCIs renders this methodological approach unsuitable to the present programme of work(146). Accordingly, there is a need to select from underpinning the development of this intervention with either a determinant framework, such as the TDF, or an implementation theory, such as NPT.

Chapter 1 discussed the available literature concerning primary care practitioners’ views towards deprescribing and characterised the barriers and facilitators from the perspective of this group of practitioners(116). Whilst a number of the reported barriers and facilitators may also apply to the hospital, there are likely to be others such as those relating to the hospital environmental context, which remain unknown. Accordingly, there is a knowledge gap in terms of an understanding of the determinants of hospital practitioners’ deprescribing behaviour. In order to develop and implement a deprescribing intervention in hospital, there remains a need to understand the barriers to this behaviour in order to select appropriate intervention components in order for circumvention. Similarly, the factors that hospital

practitioners feel may facilitate deprescribing is also of interest in order to guide the selection of intervention components.

There is insufficient existing evidence on which to predicate and implement a deprescribing intervention in the hospital setting. Consequently, application of an implementation theory such as NPT, where the focus is on implementing a defined existing intervention or technology, is not an appropriate methodological approach to the development of a theory informed deprescribing intervention for the hospital setting.

There is therefore a need to conduct empirical research exploring hospital practitioners' barriers and enablers to deprescribing, and through underpinning this work with health psychology theory, identify and understand the behavioural determinants requiring targeting in a BCI. The use of a determinant framework to guide understanding of the behaviour therefore provides a vehicle for developing a deprescribing intervention for the hospital setting. The TDF's 14 domains provide comprehensive theoretical coverage of behavioural determinants, which is of particular relevance to the present research given the limited existing understanding of the behaviour. Moreover, there is precedent for applying the TDF to explore poorly understood behaviours, frequently through qualitative methodological approaches such as focus groups and interviews to inform both the discussions and analysis(159). Moreover, a unique advantage to the TDF over other determinant frameworks is the linking of theoretical domains to the BCTTv1, enabling intervention developers to progress from a theoretical understanding of the behaviour to developing an evidence-based intervention.

Once potential BCTs have been identified using the TDF and BCTTv1, there remains a need to select those which are most likely to facilitate adoption of a new behaviour. This is particularly relevant as many of the TDF's theoretical domains have each been linked to multiple BCTs thus there is likely to be a need to select from a list of potentially effective BCTs, those which are most likely to be implementable within the social and environmental context of interest. The APEASE criteria (table 6) for designing and evaluating interventions offers a systematic approach to selecting from the BCTs identified using the TDF. APEASE facilitates selection of BCTs which are most likely to be appropriate by considering six factors which are all equally relevant to intervention success(97). Application of APEASE facilitates selection from a list of potentially effective BCTs by considering factors related to implementation and feasibility. APEASE has been applied to the

development of numerous BCIs, and selection of BCTs using the criteria has been undertaken by both researchers(176) and the target audience such as healthcare professionals(177).

Table 6 The APEASE criteria for designing and evaluating interventions (reproduced from Michie, Atkins and West(97))

Criterion	Description
Affordability	Interventions often have an implicit or explicit budget. It does not matter how effective, or even cost effective it may be if it cannot be afforded. An intervention is affordable if within an acceptable budget it can be delivered to, or accessed by, all for whom it could be relevant or of benefit.
Practicability	An intervention is practicable to the extent that it can be delivered as designed through the means intended to the target population. For example, an intervention may be effective when delivered by highly trained staff with extensive resources but in routine practice this may not be achievable.
Effectiveness and cost-effectiveness	Effectiveness refers to the effect size of the intervention in relation to the desired objectives in a real world context. It is distinct from efficacy which refers to the effect size of the intervention when delivered under optimal conditions in comparative evaluations. Cost-effectiveness refers to the ratio of effect to cost. If two interventions are equally effective then clearly the most cost-effective should be chosen. If one is more effective but less cost-effective than another, other issues such as affordability come to the forefront of the decision-making process.
Acceptability	Acceptability refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders (public, professional, and political). Acceptability may be different for different stakeholders.
Side effects/safety	An intervention may be effective and practicable but have unwanted side-effects or unintended consequences. These need to be considered when deciding whether or not to proceed.
Equity	An important consideration is the extent to which an intervention may reduce or increase the disparities in standard of living, wellbeing, or health between different sectors of society.

Chapter 3 Deprescribing admission medication at a UK teaching hospital; a report on quantity and nature of activity

This chapter is derived from the publication:

Scott, S., Twigg, M. J., Farrow, C., May, H., Patel, M., Taylor, J., … Bhattacharya, D. (2019). Development of a hospital Deprescribing Implementation Framework: A focus group study with geriatricians and pharmacists. Age and Ageing, accepted in press.

3.1 Introduction

Chapter 1 discussed that the prescribing of a medication is informed by numerous factors including the diagnosis, general health and psycho-social circumstances of the patient(178). As these factors are not static; monitoring is required to ensure the prescribing does not result in a potentially inappropriate medicine (PIM), which are believed to afford more risks than benefits and are a pre-disposition to adverse drug events (ADEs)(85).

The term 'deprescribing' was introduced, which is "*the systematic process of identifying and discontinuing drugs in instances where existing or potential harms outweigh existing or potential benefits within the context of an individual patient's care goals, current level of functioning, life expectancy, values and preferences*"(58). The important element of this sentence is the differentiation of 'existing harms' from 'potential harms', suggesting deprescribing may be 'reactive' or 'proactive' respectively(115). Surmised in Chapter 1, evidence and opinion in the literature presents a strong case for the development and implementation of a novel hospital deprescribing intervention. A multi-centre prospective analysis of older people's admission medication reported PIM prevalence ranging from 34.7% to 77.3% across six European university teaching hospitals(34), suggesting there are opportunities to deprescribe during a hospital admission. However, deprescribing practice in hospital is poorly understood and it is unclear to what extent deprescribing is routine practice in hospital(116). There is a need to establish the scope to increase deprescribing practice in hospital prior to embarking on the development of a novel intervention. Older people are most likely to benefit from an intervention to deprescribe PIMs, given that this population is most at risk of being prescribed a PIM and sustaining resultant iatrogenic harm. However, extending an evaluation to all adults in hospital increases the probability of identifying and characterising any successful deprescribing activity which may be useful in informing the development of a novel intervention.

3.2 Aim

To describe admission medication deprescribing activity in adults in the hospital setting

3.3 Objectives

1. To identify the proportion of admission medications prescribed in the hospital setting that are deprescribed
2. To develop definitions for ‘reactive’ and ‘proactive’ deprescribing
3. Quantify the proportion of admission medication deprescribing activity that is ‘proactive’ and ‘reactive’ according to the definitions developed

3.4 Ethics approval

The study was confirmed as a service evaluation by the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (Reference: 2016/2017 - 52 SE) and the Audit and Improvement department at the Norfolk and Norwich University Hospitals NHS Foundation Trust (Reference: SW/ms). The study protocol and ethical and governance approval letters are provided in appendices 1 and 2 respectively.

3.5 Methods

A project management group was convened comprising academic supervisors representing the disciplines of behavioural science, trial design, statistics, qualitative research, geriatric medicine and hospital pharmacy practice. The patient and carer voice were represented by NN and JG respectively. NN was a National Institute for Health Research patient research ambassador and patient prescribed polypharmacy. JG was a research administrator and carer to a patient prescribed polypharmacy. The role of the project management group was to review all key methodologic and analytical decisions plus monitor project progress.

3.5.1 Methodological approach

The aim of this study requires a methodological approach that measures existing deprescribing practice and provides sufficient data to enable categorisation of any observed deprescribing activity into ‘reactive’ and ‘proactive’ deprescribing. A retrospective study design may be appropriate given that the required data are collected routinely using electronic prescribing (e-prescribing) systems and documented in patients’ medical records, and could therefore be retrospectively analysed. Whilst this approach can provide the required data quickly and efficiently,

some limitations have been reported. Notably, retrospective studies use existing data that have been recorded for reasons other than research, therefore the availability and accuracy of data, particularly when handwritten medical records are concerned, are uncertain(179).

An alternative approach may be a prospective design, such as asking practitioners to record their own deprescribing activity. This method permits researchers to specify the data to be collected, thus overcoming some of the challenges associated with a retrospective design. However, a prospective study could prompt a change in practitioners deprescribing practice and is an important consideration with reference to the aim of this study. This potential for subjects to alter their behaviour due to an awareness of being studied is a widely recognised phenomenon termed the 'Hawthorne effect'. First coined by French in 1953, the Hawthorne effect is described as "*…a marked increase in production related only to special social position and social treatment*"(180). Practitioners may therefore increase deprescribing activity for the study duration due to the Hawthorne effect and revert to usual practice upon completion. Additionally, given that addressing PIMs is a widely recognised priority, practitioners cognisant of a study measuring deprescribing activity may also exhibit social desirability bias, which is "*the pervasive tendency of individuals to present themselves in the most favourable manner relative to prevailing social norms…*"(181). Any study which prompted a change in deprescribing practice would constitute an intervention, which is a deviation from the aim of this study. The need to evaluate existing hospital deprescribing activity in the present study has led to adoption of a retrospective methodological approach. Limitations associated with accuracy or availability of data will be mitigated by extracting some data from a hospital's comprehensive e-prescribing database.

3.5.2 Data collection

A retrospective analysis of all admission medications prescribed and discontinued at a large United Kingdom (UK) teaching hospital was undertaken over four weeks in February 2017. Data were extracted from the hospital's electronic prescribing system for all wards and specialities except the Emergency Department and Intensive Care Unit as e-prescribing was not implemented in these areas. The hospital's policy was to complete medicines reconciliation for 90% of patients within 24 hours of admission, and data collection for all patients occurred at least 48 hours

after admission. Prescriptions newly initiated during the admission and medication recorded as temporarily suspended were excluded because the study was designed to capture the extent to which admission medicines are deprescribed. There were no patient exclusion criteria.

Patient sex and age, medication name and the e-prescribing reason for medication discontinuation (selected by the prescriber from a list of 20 pre-defined reasons on the e-prescribing system, provided in figure 6) were recorded and extracted for analyses.

Not all medications recorded as discontinued on the e-prescribing system are 'deprescribed', such as those assigned the e-prescribing reason 'Incorrect prescription' or 'Changed to when required'. Accordingly, a team of hospital pharmacists (n=3) and consultant geriatricians (n=2) classified the e-prescribing reasons into 'not considered deprescribing' (excluded from analysis) and 'potentially deprescribing' as described in figure 6.

A sample of 200 medication discontinuations assigned a 'potentially deprescribing' e-prescribing reason were further analysed by reviewing medical records to confirm or refute deprescribing activity and categorise the activity into proactive or reactive. This sample size was chosen because it was the maximum number of medication discontinuations for which the research team and hospital research site agreed was feasible to review, taking into consideration the need to recall archived medical records and the capacity for two members of the research team to independently review and categorise the discontinuation. As there are no estimates of deprescribing prevalence in usual hospital care, an estimate based on a UK deprescribing intervention trial reporting 8.5% of admission medicines deprescribed was used to inform the present study(182). Accepting this will be lower in the absence of an intervention, a maximum of 5.0% admission medicines likely to be deprescribed was estimated. This sample size (n=200) provides a 95% confidence interval of ±3.0% around the estimate of the quantity of admission medications that are confirmed deprescribing activities. Hence, the sample size is both practical and provides a precise estimate of the deprescribing rate.

The majority of e-prescribing reasons are unambiguous such as 'Acute kidney injury'. However, the reason 'No longer clinically necessary' was deemed ambiguous by the hospital site based research team of hospital pharmacists (n=3) and consultant geriatricians (n=2), as in their experience, this was often selected by prescribers when a suitable reason could not be identified. Medication

discontinuations not assigned an e-prescribing reason were also considered ambiguous. Accordingly, sampling of 200 medication discontinuations was stratified on e-prescribing reasons assigned to medication discontinuations, with a smaller number of discontinuations assigned unambiguous reasons (one-sixth of the total or 100% if three or less occurrences) sampled. Stratification was necessary as the hospital site based research team felt that the rates of reactive and proactive deprescribing varied between e-prescribing reason statements and, there was substantial uncertainty regarding the likely nature of deprescribing activity deemed ambiguous, hence stratification ensured that each reason was fairly represented in the overall sample.

Medication discontinuations assigned the ambiguous reason and where no reason was given were evenly sampled for the remaining reviews. Within each strata, medication discontinuations were randomly sampled using a random number generator. Figure 6 provides the numbers sampled across the e-prescribing reason strata.

Informed by the existing literature(115), academics pharmacists (n=4), senior hospital pharmacists (n=26), senior geriatricians (n=28), and a patient and carer representative, the definitions for reactive and proactive deprescribing were developed and used to categorise deprescribing behaviour. The process for definition development was initially to present the Scott *et al.*(58) definition for deprescribing introduced in Chapter 1 to the project management group at a meeting. Group brainstorming occurred and initial definitions were generated. The definitions were then refined through email communication between the project management group and presented to the wider audience of senior hospital pharmacists and senior geriatricians for comment and validation. The definitions were accepted without further refinement and are provided below:

- Reactive deprescribing: discontinuing a medicine in response to an adverse clinical trigger.
- Proactive deprescribing: discontinuing a medicine if future gains are unlikely to outweigh future harms.

One hospital pharmacist extracted the prescriber's rationale for medication discontinuation verbatim from medical records. Each discontinuation was independently categorised by a hospital pharmacist and consultant geriatrician into

proactive, reactive or not deprescribing. Inter-rater reliability was assessed using Cohen's Kappa, with κ=0.6-0.8 considered good and κ>0.8 excellent(183). Disagreements were resolved through reviewer discussion and referral to a third reviewer (hospital pharmacists or consultant geriatrician) if necessary.

Data from the stratified sample of 200 reviews were extrapolated to the total 'potentially deprescribing' discontinuations through multiplying sample deprescribing prevalence within each reason statement by the total number of discontinuations within each reason statement. These were summed to estimate the total proportion and 95% confidence interval (95% CI) of admission medicines deprescribed in hospital and the proportion (95% CI) which were reactive and proactive.

3.6 Results

From 24,552 admission medicines prescribed for 2,309 patients, 977 discontinuations were recorded across 415 patients, of which 682 (69.8%) were 'potentially deprescribing' according to the e-prescribing reason assigned by the prescriber discontinuing the medication. Of patients who had a medication discontinued, females constituted 228 (54.9%) patients and the median interquartile (IQ) age was 79.0 (66.0, 86.0) years. Figure 6 provides the e-prescribing reasons for discontinuation retained and excluded from the analysis according to whether they were potentially consistent with deprescribing as defined in the introduction.

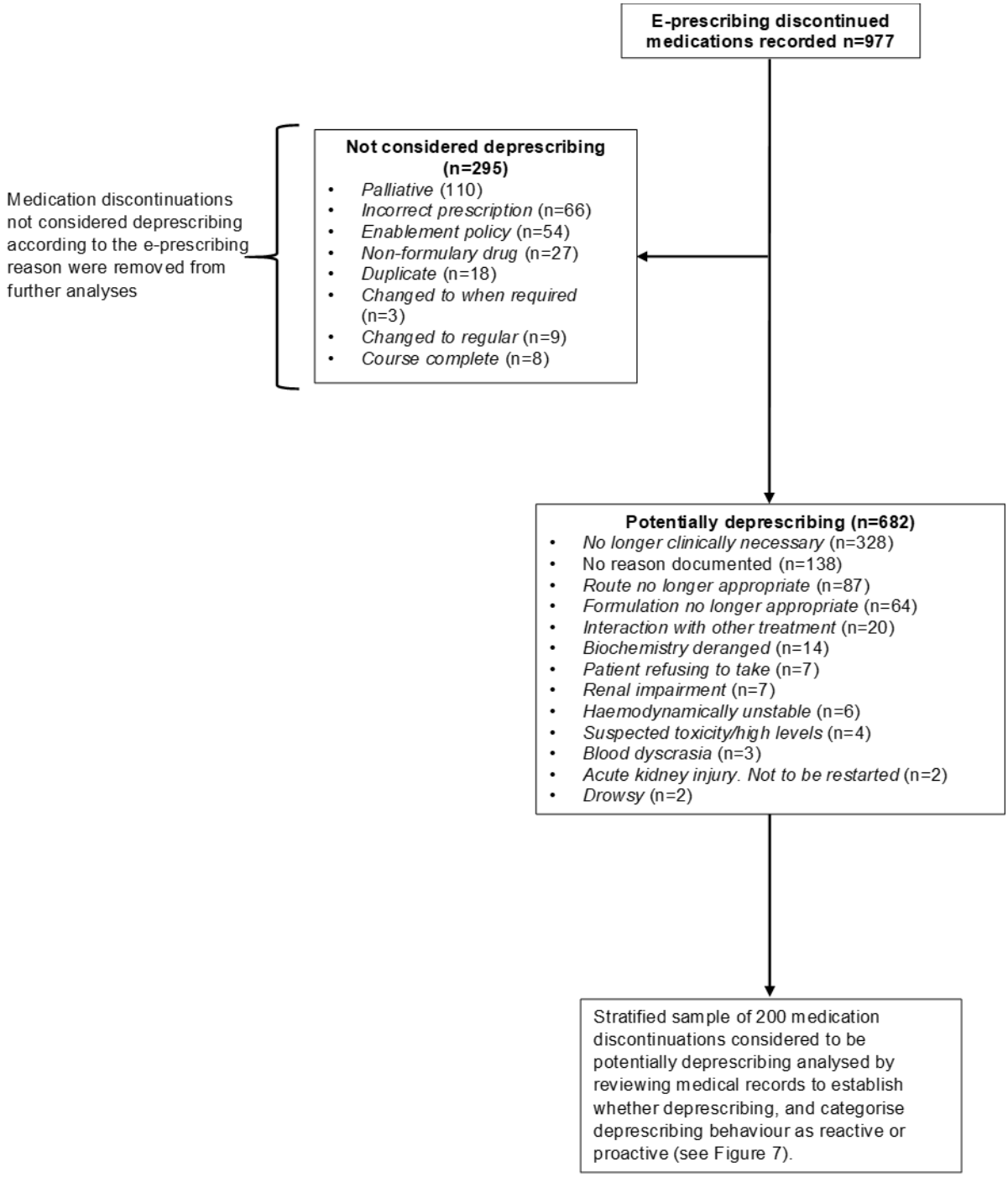

Figure 6 e-prescribing recorded medication discontinuations excluded and retained from analysis according to the e-prescribing reason selected by the prescriber

Stratified sampling and, proactive and reactive categorisation of the 200 medication discontinuations further analysed by reviewing the medical records are described in figure 7. Unambiguous e-prescribing reasons accounted for 21.0% of the sample. The remaining 158 (79.0%) records were evenly sampled from the ambiguous e-prescribing reason ‘No longer clinically necessary’ and from no e-prescribing reason recorded.

One-hundred and forty-three (71.5%) discontinuations reviewed were not consistent with the definitions for proactive or reactive deprescribing for the reasons; end of life care, treatment escalation or the medication being stopped in error. For a further 13 (6.5%), insufficient information was available for categorisation. The remaining 44 (22.0%) confirmed deprescribing activities were categorised into 7 (15.9%) proactive and 37 (84.1%) reactive. Agreement between reviewers categorising deprescribing activity was excellent ($\kappa=0.872$, $p<0.01$)(183).

Reasons provided in the medical records for medication deprescribed reactively were; side effect (21 (56.8%)), acute kidney injury (8 (21.6%)), treatment failure (5 (13.5%)), swallowing difficulty (1 (2.7%)), allergic reaction (1 (2.7%)) and interaction with other treatment (1 (2.7%)). All proactive deprescribing was in response to resolution of the indication for which the medication was first prescribed as reported by the patient or physiological parameters.

Data extrapolation calculations and formulae are provided in appendices 3 and 4 respectively. Extrapolation of the 200 stratified sample data to the 682 total discontinuations yielded 22.01% (95% CI 19.0%-25.2%) consistent with deprescribing, of which 19.3% (95% CI 13.0%-25.6%) are proactive and 80.7% (95% CI 74.4%-87.0%) are reactive. This corresponds to 0.6% (95% CI 0.5%-0.7%) of all admission medications prescribed being deprescribed

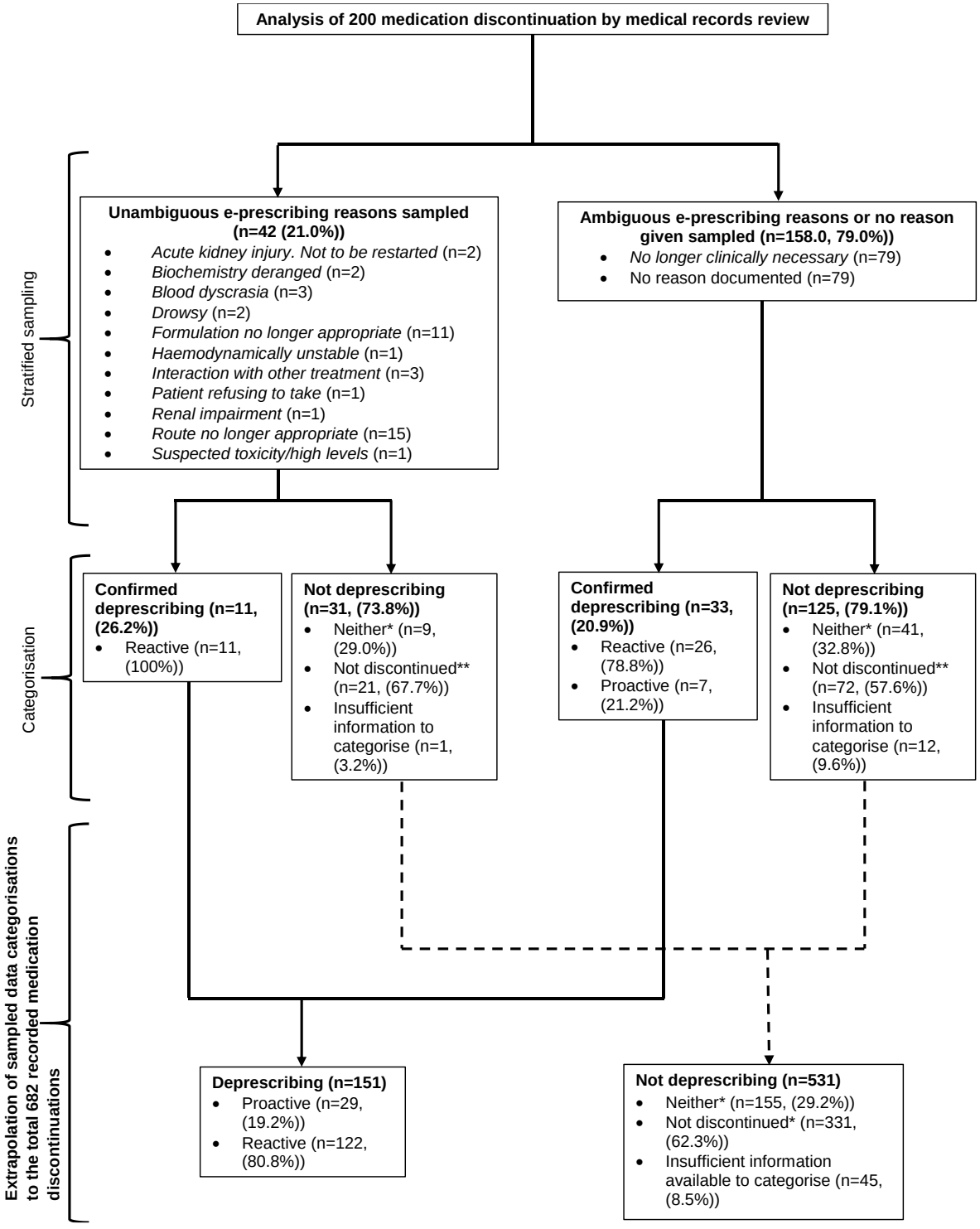

Figure 7 Categorisation of a stratified sample of 200 recorded medication discontinuations and extrapolation to the total 682 recorded medication discontinuations potentially considered deprescribing (according to the e-prescribing reason provided)

*Medication discontinued however rationale provided in the medical records was not consistent with proactive or reactive deprescribing e.g. medication discontinued due to end of life diagnosis. **Medication re-prescribed at the point of medical records review. Medication discontinuation recorded for an erroneous reason such as discontinued in error and immediately re-prescribed.

3.7 Discussion

This study addresses a key gap in the existing evidence base for deprescribing in hospital through quantifying the extent to which deprescribing occurs in the absence of an intervention. Moreover, the study is strengthened by its conceptualisation of reactive and proactive deprescribing and, subsequent multidisciplinary categorisation of identified activity according to these behaviours. Together with existing literature describing the extent of PIMs prescribed for hospitalised patients(34), an indication of the need for and scope of a novel hospital deprescribing intervention is provided.

Despite not excluding any deprescribing activity based on patients' age and with the exception of the emergency department and intensive care unit clinical specialities, the average age of patients who had an admission medication discontinued was almost 80 years. This is unsurprising given that older people are at highest of risk of being prescribed a PIM and experiencing resultant harms(34), and are therefore likely to require medication discontinuation. Very limited deprescribing activity was identified at the one UK teaching hospital under analysis in this study. Moreover, this activity was dominated by reactive deprescribing, suggesting that practitioners in hospital require the presence of a clinical trigger such as an adverse drug event to prompt deprescribing. The less than one fifth of deprescribing activity categorised as proactive accords with a qualitative primary care study, which reported that practitioners find it challenging to evaluate potential risks and harms associated with medication to inform deprescribing(115). It is conceivable that hospital practitioners may also find this challenging. Findings from the present study support this hypothesis, as the observed proactive deprescribing was only in cases with documented evidence of no clinical benefit thus only potential for harm. There was therefore no proactive deprescribing identified as a result from a complex evaluation of risks and benefits, underscoring the need for empirical research to explore practitioners' barrier and facilitators to proactive deprescribing in hospital.

Owing to the four week data collection window, a relatively large number of patients' admission medications were screened for subsequent discontinuation, affording some confidence in the trends reported. However, the restriction of data collection to a single UK hospital restricts generalisability of these findings and is an important limitation. Whilst there is no reason to suspect that practice between hospitals differs significantly, more widespread, international analysis of deprescribing in hospital is warranted. A further limitation is the large proportion of sampled medication discontinuations that were either categorised as not deprescribing or

where there was insufficient information to categorise, which incorporates a degree of ambiguity around the final proportions. Random, stratified sampling and extrapolation of almost a third of the total medication discontinuations was employed to mitigate this limitation. Moreover, the data accord with primary care reports of practitioners expressing difficulty with deprescribing, particularly activity which is characteristic of proactive deprescribing(115,116). Accordingly, whilst the aforementioned uncertainty may have resulted in deprescribing proportions deviating somewhat from the true values, the reported trends are in agreement with the existing literature. Given that the present study aimed to understand whether there was likely to be any scope to increase deprescribing in hospital, this limitation does not impact the recommendations derived from these data.

The sampling strategy for 'unambiguous' e-prescribing reasons (one-sixth of the total or 100% if three or less occurrences) resulted in five of the reasons being sampled for less than three occurrences. This limitation may have resulted in deprescribing proportions deviating somewhat from the true values within the affected reasons. This could have been mitigated by modifying the sampling strategy to be 'one-sixth of the total but a minimum of three' applied to the affected reasons.

This study could have been further strengthened by independently assessing the prevalence of PIMs within the prescribed admission medication using a validated tool such as the Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP)(31). Using these data to contextualise the observed deprescribing activity, rather than relying on a comparison with literature data, may have been preferable. The prevalence of PIMs in the study population could have been lower than that reported in the literature, which may have provided some explanation for the limited deprescribing activity observed. However, PIM prevalence in hospital has been extensively studied, and a significant deviation from the literature in the one hospital is unlikely(34,37,85,184–189).

The PIM prevalence within the confirmed deprescribing activity was also not assessed because the prescribers' medical records documented rationale was used to confirm whether medicines were 'actually' inappropriate, according to the definitions for reactive and proactive deprescribing. Accordingly, additional screening for medicines that were 'potentially' inappropriate was not relevant to the study aim.

Accepting the limitations of not assessing admission medication PIM prevalence in the present study, from the deprescribing prevalence of 0.6% reported in this study and the literature reported PIM prevalence of approximately 50%(34,37,85,184–189), it can be concluded that the vast majority of PIMs prescribed as part of patients' admission medication are unlikely being deprescribed in hospital. This finding contributes to the evidence base for deprescribing in hospital and indicates that there may be significant scope for increasing proactive deprescribing through the development and implementation of a novel intervention.

In Chapter 1, geriatricians' and pharmacists' deprescribing behaviours were identified as potential intervention targets. However, the extent to which an intervention to promote deprescribing is acceptable to these professional groups and feasible within existing resource constraints remains unknown(116). Moreover, given that addressing inappropriate prescribing is a widely recognised priority, the low activity reported in this study suggests there are significant barriers to effective deprescribing in hospital. Accordingly, there remains a need to explain the low proactive deprescribing activity in hospital and explore the support required for geriatricians and pharmacists to deprescribe.

It is unclear whether increasing deprescribing in the hospital setting is acceptable to both patients and their carers. For example, practitioners are reported to influence patients' willingness to deprescribe, and this influence may vary between a patients' regular general practitioner and hospital practitioners(98). Accordingly, establishing the extent to which deprescribing is acceptable to patients and their carers prior to the development of a novel intervention is necessary.

The low proactive deprescribing activity identified in this study suggests there is scope to develop a novel deprescribing intervention to identification and discontinuation of inappropriate medication in hospital. Identification of barriers and facilitators from both the practitioner, and patient and carer perspectives is necessary to understand the targets for such an intervention.

Chapter 4 Attitudinal predictors of older peoples' and carers' desire to deprescribe in hospital

This chapter is derived from the publication:

Scott S, Clark A, Farrow C, May H, Patel M, Twigg MJ, Wright DJ, Bhattacharya D. Attitudinal predictors of older peoples' and carers' desire to deprescribe in hospital. BMC geriatrics. 2019 Dec;19(1):108.

4.1 Introduction

The prevalence of potentially inappropriate medicines (PIMs) on hospital admission is estimated to be 51.3%(34), however the empirical work undertaken in Chapter 3 identified that deprescribing practice in hospitals is limited in number and largely reactive in response to iatrogenic harm rather than proactive to prevent future harm(190). Accordingly, there is likely to be scope to increase proactive deprescribing activity in hospital through the development of a novel intervention.

Prescribing should be based on a partnership as the prescriber is the disease expert and the patient is the expert on their illness(191). It is therefore unsurprising that patient engagement in decision-making is a proposed essential component of successful deprescribing(60). Consultations between practitioners and patients are an opportunity to determine whether deprescribing is appropriate, agree strategies for ongoing monitoring and establish the patient's desire to try deprescribing(60).

Trials across multiple settings report up to half of older patients decline deprescribing interventions(111,192–194). Exploration of predictors for this lack of desire to deprescribe has focussed on external characteristics such as age, gender and number of prescribed medications. A recent retrospective analysis of hospital electronic medical records reported that all external patient characteristics analysed, including PIM prevalence, number of medicines at admission and comorbidities had no effect on patients' willingness to accept deprescribing(111). It is unsurprising that these characteristics do not predict desire to deprescribe as there is a substantial body of evidence in the field of behavioural science confirming that a key predictor of behaviour is attitude towards the behaviour, which is poorly predicted by external characteristics(112–114). Furthermore, external demographic characteristics cannot be changed thus contribute little to guiding physicians or those developing deprescribing interventions. Identification of attitudinal predictors of desire to deprescribe may therefore provide modifiable targets for an intervention targeting patients' and carer' behaviour. Such attitudinal predictors are likely to be related to the patient reported barriers and enablers characterised in chapter 1 of this thesis(116), however the extent to which these may predict desire to deprescribe remains unknown.

Informal carers such as family members are increasingly involved in medication decision-making. For patients that are unable to participate in these decisions, such as those living with cognitive impairment, carers frequently assume sole responsibility(195,196). Furthermore, carers influence engagement with

deprescribing by physicians and patients who are able to participate in decision-making(98,116). Despite the wide ranging influence exerted by carers on the deprescribing processes, their level of engagement with and attitudinal factors influencing desire to deprescribe are unknown.

The Patients' Attitudes Towards Deprescribing (PATD) questionnaire was introduced in Chapter 1 of this thesis. Older people completing the PATD across the care homes, outpatient and acute hospital settings report being satisfied with existing medication whilst incongruously, over 90% also indicate willingness to accept deprescribing proposed by a doctor(107,109,110,197). This high level of willingness contrasts the significant proportion of participants in deprescribing trials declining deprescribing propositions(111,192–194). This gap between reported willingness and observed behaviour requires further exploration. Given that willingness to accept deprescribing proposed by a doctor has demonstrated limited variation in responses, this may not provide the best data for explaining this gap

The Australian-validated revised Patients' Attitudes Towards Deprescribing questionnaire (rPATD) explores factors that influence desire to deprescribe not captured by the PATD. The rPATD items are grouped into the four factors of *burden* of taking medication, *appropriateness* of medication (perceived harms and benefits), *concerns about stopping* the medication and level of *involvement* in making decisions about medicines. The *appropriateness* factor provides the new item "*I would like to try stopping one of my medicines to see how I feel without it*". This item provides an indication of the patient's attitude towards their prescribed medication by indicating their desire to try stopping a medicine. Furthermore, given that a significant proportion of previously reported deprescribing trials have been pharmacist-led(84), this item may provide better data for explaining the gap between reported willingness to accept deprescribing proposed by a doctor and observed declining of deprescribing propositions.

Given the similarities between the two English speaking nations, the Australian-validated rPATD is likely to be an appropriate survey to capture attitudes towards deprescribing in the United Kingdom (UK) hospital setting. However, contextual differences between the two nations such as prescription medicines being free of charge to all older people in the UK, may require minor adaptations to be made to the rPATD prior to use in the UK setting.

4.2 Aim

To describe the desire and attitudes of older people and carers in hospital to be involved in deprescribing

4.3 Objectives

1. Adapt the revised Patients' Attitudes Towards Deprescribing (rPATD) questionnaire for the UK older people and carer population.
2. Describe the attitudes of older people and carers in hospital towards deprescribing.
3. Estimate older people and carers in hospitals' desire to be involved in medicine decision-making.
4. Estimate older people and carers in hospital' desire to try deprescribing.
5. Identify any attitudinal predictors of older people and carers in hospitals' desire to try deprescribing.

4.4 Ethics approval

Ethical and governance approval were obtained from the Greater Manchester West Research Ethics Committee (REC reference: 17/NW/0582) and the UK Health Research Authority respectively. The study protocol and ethical and governance approval letters are provided in appendices 5 and 6 respectively.

4.5 Justification for and critique of the revised Patients' Attitudes Towards Deprescribing questionnaire (rPATD)

The rPATD was developed through retention of the original 10 items from the original validated PATD and additional items generated from a systematic review of patient barriers and enablers to deprescribing(198) a qualitative focus groups with older people and carers(199). The comprehensive review of the literature and additional exploratory work informing the rPATD items affords confidence that it is an appropriate tool to measure patients' and carers' desire to deprescribe and identify the attitudinal predictors of this desire. It is unsurprising that the rPATD explores additional potential barriers and enablers to deprescribing relative to the PATD given the methodological approach use to generate items, and some of these differences are described earlier in the chapter introduction.

The rPATD was initially piloted in the Australian setting with 12 older people (mean age 83.1 years) and 11 carers (mean age 70.3 years) of such people. Participants self-administered the questionnaire, which was iteratively refined to improve wording between participants. Concurrent cognitive interviews with a think-aloud (see section 1 below for more information on this methodological approach) was also employed with the first five participants from each group to facilitate rPATD refinement. Participants were also asked whether there were any additional barriers or enablers to deprescribing not capture by the rPATD which should be included. The piloting was concluded when no further refinements were deemed necessary, resulting in a 45-item and 40-item rPATD for patients and carers respectively, with face validity established.

Investigation of the rPATD's psychometric properties and validation followed the piloting and was undertaken through widespread dissemination of the questionnaire, with 583 valid responses (383 patients and 200 carers). Internal consistency, which is an assessment of how reliably items within a factor (e.g. *Burden* of taking medication) measure the same construct as intended, was evaluated using Cronbach's alpha(200). The Cronbach's alpha for both the patient and carer versions were 0.648 and 0.670 respectively, indicating moderate internal consistency(200).

Content validity, which is the degree to which an item is relevant to, and measures, the target construct barrier or enabler)(201), was evaluated by an expert panel of geriatricians, nurses, clinical pharmacologists, pharmacists and researchers. The panel scored each item according to whether or not it was an accurate measure of the construct. All items were deemed both relevant and to accurately measure the construct(201).

Construct validity is the extent to which items organise into a structure that is explanatory of the factors under investigation(202). Exploratory Factor Analysis was used to select the items that best represented each rPATD factor. The final four factors retained, explained 55.8% and 62% of the variance for the patient and carer rPATD versions respectively.

Finally, test-retest reliability was evaluated, which assesses the within-participant consistency of questionnaire items. This is undertaken through administration of the questionnaire to the same participants twice, and comparing the responses. The rPATD was administered to 22 and 19 patient and carer respondents respectively twice, three weeks apart. Test-retest reliability was evaluated using weighted

Cohen's Kappa; no rPATD items performed poorly, 11 items performed 'fair', 18 items performed 'moderately', 11 items performed 'good' and one item performed 'very good'(183).

The rPATD provides comprehensive coverage of potential barriers and enablers to deprescribing and has been validated in a context very similar to the UK setting. Whilst the rPATD performed less favourably in some psychometric tests, it was deemed an appropriate tool to address the aim of the study which was to capture likely desire of patients and carers to deprescribe in the hospital setting.

The remainder of this chapter is divided into two sections:

Section 1

Refinement and testing of the Australian-validated rPATD questionnaire for the UK setting

Section 2

Administration of the rPATD, adapted for the UK setting, to older people and carers in hospital

4.6 Section 1: Refinement and testing of the Australian-validated rPATD questionnaire for the UK setting

With the author's consent, minor adaptations were made to the rPATD(203) prior to UK use. People aged ≥65 years in the UK are exempt from prescription charges thus an item in the rPATD *burden* factor exploring views towards paying for medication was rephrased to explore perceptions of the National Health Service's (NHS) medication expenditure. The item was phrased "*I feel my medicines are value for money for the NHS*" and appropriate variation for carers. The *burden* factor captures the burden, such as financial, on the individual patient (or carer), whilst the re-rephrased item relating to burden on the NHS represents burden to the state. In recognition of this difference, for the purposes of data reporting, the re-phrased question was presented separately from the *burden* factor under the heading *burden to the National Health Service*.

For survey responses to be valid, respondents must interpret the questions as the researcher intended and the response choices must allow participants to answer in a way that best reflects their views(204). Failure of a survey item to satisfy these criteria may result in response error, which is a discrepancy between the theoretical truth and that which is reported by the respondent(205).

The Australian context in which the rPATD was developed and validated is very similar to the UK setting, for example in both countries, English is the predominant language and both adopt the principle of universal access to healthcare. It is therefore very unlikely that using the rPATD in the UK context will lead to a significant change in the questionnaire's psychometric properties. Accordingly, it was deemed unnecessary to re-evaluate all rPATD psychometric properties, such as internal consistency using Cronbach's alpha. This is supported by recent use of the rPATD in contexts which deviate greater from the Australian setting relative to the UK including Ethiopia(206), Malaysia(207), United States of America(208), without revalidation.

However, it was felt that the face and content validity of the re-phrased question relating to *burden to the National Health Service* required assessment by the target population prior to a definitive study. Additionally, whilst there are no reasons to anticipate that this rephrasing would lead to UK participants experiencing difficulties completing the remainder of the Australian-validated rPATD, it was felt that assessment of the entire questionnaire in the UK population was warranted to determine face and content validity. Minor re-phrasing of one question is very

unlikely to lead to a change in other psychometric properties therefore additional assessments of the refined rPATD's psychometric properties were not deemed necessary.

4.6.1 Methodological approach

The stages of information processing by questionnaire respondents required to select a response are provided in figure 8. A respondent must be able to undertake each of these stages in order to select a response that accurately reflects their opinion.

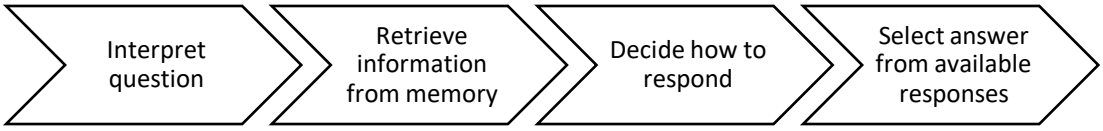

Figure 8 Stages of information processing undertake to answer questionnaire items(204,209)

Question interpretation requires respondents to understand the meaning of the words and phrases contained within a question. Including complex jargon resulting from an overestimation of the target population's ability is a common course of confusion. Retrieving information from memory involves participants recalling a familiar event or situation relevant to forming a response to the question. If the question topic is insignificant or unfamiliar, respondents may select an answering by 'guessing' at random or fail to provide an answer all together. When deciding how to respond, participants order their initial thoughts in order to form an internal answer, which a perceived socially desirable response. Self-censoring is more prominent when questions request information perceived as private or confidential such as those related to income or lifestyle behaviours(209). Finally, respondents select from the available options a response that is an adequately reflection of the internally formulated answer. If an option corresponding with the internal answer is not available, respondents may become confused or frustrated. Participants may select an option that is not representative of their answer to the question or fail to provide an answer(204).

Responses provided following a breakdown in one or more of the information processing stages cannot be reliably considered a participant's views. It is therefore

necessary to understand how the target population perceive a questionnaire and identify and correct flaws prior to dissemination in a future study.

4.6.1.1 Cognitive interviewing

Verbal reporting techniques are increasingly used in the testing of health services surveys(210). Cognitive interviewing is a form of verbal reporting that allows evaluation of how the target audience perceives survey instruments and their constructs. How a participant interprets a question, processes the information, applies information stored in memory and prepares a response are captured as verbal data during the cognitive interview process. Data gathered may be used to identify survey flaws and improve questions prior to administration in a study(205).

Guiding participants to 'think aloud' as a direct method of understanding cognitive processes was a technique largely developed by Ericsson and Simon in the 1980s(211). Participants are instructed to perform a task, such as completion of a survey, and concurrently verbalise their thought processes allowing the researcher to experience how a participant arrives at a given response(212,213). Verbal probing is a technique that can be used by researchers in cognitive interviews to gain a rich understanding of how a participant has interpreted a question and processed specific constructs of a task such as questions in a survey(205,211). Testing questionnaire through cognitive interviews has high face validity, as the data generated are respondent's thought processes verbalised as they complete the questionnaire, rather than a formed judgement(214).

A questionnaire designed to capture patients' experiences of living with end stage renal failure was developed and refined using the hybrid think-aloud-verbal probing approach(213). Post questionnaire development, participants representative of the population of interest underwent cognitive interviewing and were asked to complete the questionnaire while 'reading aloud' and 'thinking aloud' as they responded. The addition of verbal probing allowed the interviewer to explore unanticipated verbal/non-verbal behaviours such as hesitation. The authors delineated between cognitive interviewing and standard piloting, declaring the former allowed for refinement in the study population and "*clarifying the precise nature and cause of [these] issues*"(213).

There is no specific strategy to determine the number of cognitive interviews required to test and refine questionnaires. Researchers must therefore apply their own judgement. The number of participants required will depend on the how easily

interpretable and answerable the questions contained are. The questionnaire may proceed through a handful of cognitive interviews without encountering problems. On the other hand, new problems may arise with each successive interview and any adaptations by the researcher must be tested and may present new problems. Sufficient interviews have been conducted when participants express little or no difficulty in interpreting and responding to the questionnaire.

Modest samples sizes of between 5 and 15 individuals are generally used(205) based on the following three assumptions(215):

- Observing four or five participants will identify 80% of problems.
- Observing additional participants will reveal fewer and fewer new problems.
- Severe problems are easier to identify with the first few participants.

Assuring the validity of cognitive interviewing as a method of questionnaire testing and refinement is challenging and Willis proposes several limitations to this methodological approach(205). Participants are generally self-selecting and are unlikely to be fully representative of the target population. As such, recruitment gravitates towards participants of higher educational levels than average questionnaire respondents, unless the recruitment strategy is been developed to limit this occurrence.

The physical and social environments between a cognitive interview study and a definitive study will likely differ which may impact on the results. The extent to which this is of relevance depends on how likely these factors are to impact on the process of question interpretation and answer forming. Additionally, cognitive interviews are unlikely to explore motivational barriers as these participants are generally patient and forgiving. As a result, cognitive interviews may underestimate problems encountered in the field.

Cognitive interviews tend to focus exclusively on the respondent and do not consider problems arising from a researcher who is administering a questionnaire in the field. Accordingly, cognitive interviews are not appropriate tools for detecting measurement errors arising from the researcher. However, developers can be mindful of this and anticipate and address such problems if necessary.

The aim of cognitive interview data analysis is to review verbalisations on a question by question basis and identify and describe problems mapped to modifiable question features. There are a range of methods available and two overarching

analyses are described by Willis(205); informal analysis and formal coding. In its simplest form, informal analysis consists of the researcher hand documenting summaries of participants' verbalisations. This method requires the researcher to continuously listen, identify what is relevant and record. While this is the fastest method, the cognitive demands on the researcher are significant and non-detection of important problems is a risk. Audio recording the sessions is a significant improvement(205) and may lend to greater sensitivity as the data can be reviewed several times and by additional researchers if necessary.

Analysis by formal coding involves transcription of verbalisations and examining sections of text by assigning coding categories such as "*Respondent changes question to fit their knowledge*"(205). While formal coding may appear rigorous, Willis argues that codes do not necessarily reflect the problems. Instead, codes represent the behaviours and strategies enacted in response to a problem. Owing to this, formal coding may not be the most appropriate method of analysis for pretesting questionnaires.

Willis suggests it is unnecessary and in fact undesirable to pursue formal coding for cognitive interviews where the aim is diagnosing problems and making question modifications(210). Coding ultimately results in data reduction and removing the 'problem' from its context, the original comment, provides less information to facilitate adaptation. As a result, the researcher is required to return to the original text for context, rendering the code useless. Accordingly, Willis advocates qualitative written comments derived from informal analysis, which are "*wholly suitable-and even preferable-for this purpose*"(210).

4.6.2 Methods

This project was overseen by the project management group described in Chapter 3.

Face and content validity of the UK adapted rPATD were assessed using cognitive interviews with older people and carers.

4.6.2.1 Participant identification and recruitment

Members of the public with demographic characteristics similar to the older people and carers populations in which the UK adapted rPATD is intended to be used in a future hospital study were recruited.

4.6.2.1.1 Study sample

Older people aged ≥65 years prescribed ≥5 medicines (polypharmacy(216)) were eligible. Anyone self-reporting an unpaid role in managing the medication of somebody satisfying the inclusion criteria for the study's older people participant arm were eligible as carers. People unable to speak or read English and carers aged <18 years old were excluded.

4.6.2.1.2 Recruitment

Participants were recruited from the large pool of students and employees at the University of East Anglia (UEA).

Due to the rPATD having been validated in a context similar to the UK and only the one minor adaptation made, it was envisaged the number of interviews necessary would be on the lower end of the five to 15 guide cited in the literature(205). Given that the patient and carer rPATD versions are very similar except for the item perspectives, the combined number of patients and carers required to test the adapted rPATD versions required was estimated to be five.

Posters inviting eligible people to participate in the study were placed across the university campus in permitted locations such as coffee shops, advertising boards and social spaces. Additionally, an advertisement was placed in the university-wide weekly email bulletin

A summary of the participant recruitment process is provided in figure 9. People contacting the researcher expressing an interest in the study were offered a participant information leaflet (PIL) relevant to the participant group relevant to them (older person or carer) including details of the study and how to enrol sent via email, UEA internal mail (if UEA staff or student) or by post.

Eligible potential participants expressing a desire to participate were invited by a researcher to a mutually convenient 30-40 minute appointment at the UEA.

4.6.2.1.3 The cognitive interview appointment

Written, informed consent was obtained prior to any data collection. Participants were also asked to provide the following demographic information using a data collection form:

- Type of participant (older person or carer)
- Gender
- Age
- Number of prescribed medicines (taken by care recipient if carer)

During the cognitive interviews, the researcher directed the participants through the think-aloud procedure. The interviews were audio recorded and the researcher observed the participant completing the questionnaire and concomitant think-aloud process, taking notes where appropriate. The researcher used verbal probing where necessary during the think-aloud process and/or at the end of the interview.

The procedure was as follows:

1. The think-aloud procedure requires the participant to be taught how to undertake the task. This involves a brief practice exercise at the beginning of the interview to prepare the participant for the process. The training task employed is provided below:
2. "*Try to visualize the place where you live, and think about how many windows there are in that place. As you count up the windows, tell me what you are seeing and thinking about it*"(205).
3. After the practice exercise, the researcher invited questions and provided clarification where necessary.
4. Once satisfied the participants is familiar with the think-aloud process, the researcher read out the following instructions verbatim:
5. "*Think-aloud as you complete the questionnaire. Please pretend as if I am not here and do not ask for my assistance during the task. If you fall silent for a while, I will remind you to continue to think aloud and I may ask some questions during the process. If you feel uncomfortable at any stage, please let me know that you'd like to stop. Finally, please remember I am testing the questionnaire and not you during this process. Do you have any questions before we start?*"

6. The researcher minimised their influence on the participants think-aloud process by sitting out of line of sight. Participants were not interrupted during the think-aloud, however prompt to continue thinking-aloud during period of silence and asked probing questions where appropriate.
7. Upon completion of the questionnaire, the researcher undertook verbal probing to further explore participant interpretation and processing of questionnaire construct where necessary.
8. Once the interview is complete, participants were thanked for their participation and provided an opportunity to submit additional feedback on any part of the research process.

Figure 9 characterises how the questionnaire adaptation and cognitive interviewing process continued until no further refinements were necessary.

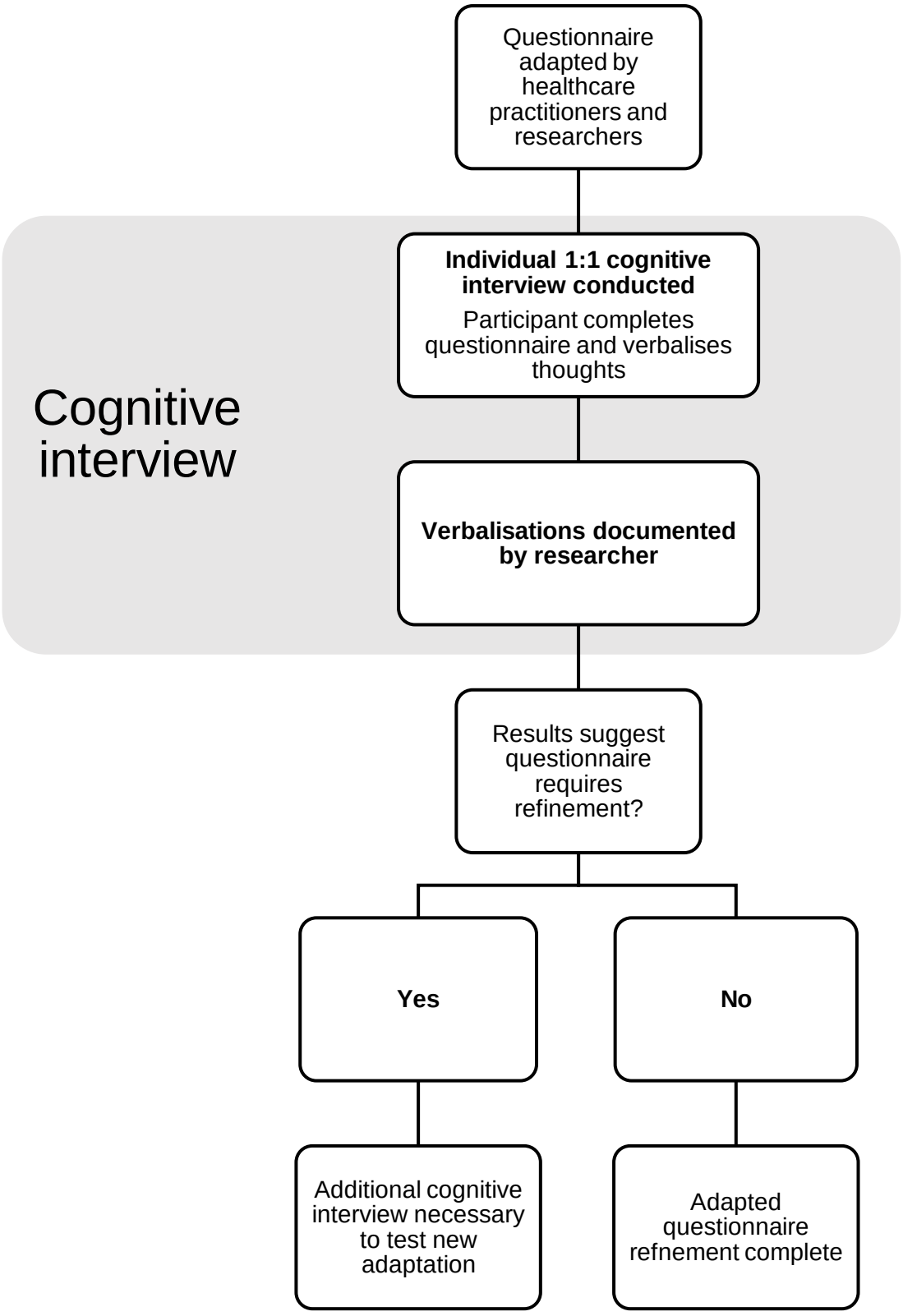

Figure 9 Process of questionnaire adaptation and refinement using the cognitive interview method

4.6.2.1.4 Data analysis

No analysis of participant questionnaire responses was undertaken as the aim was to determine face and content validity of the rPATD adapted for the UK context.

The research team applied judgement in determining the implications of cognitive interview findings. The required number of interviews was determined by the research team was dictated by the number of interviews required for questionnaire refinement.

Informal analysis of cognitive interviews as described earlier in this chapter was undertaken. Handwritten notes made by the researcher during the cognitive interviews and subsequent review of audio recordings with the wider research team were analysed to inform problem identification and questionnaire refinement.

After completing each cognitive interview, a report was prepared comprising:

1. A summary of any problems identified for each question.
2. An overall summary including general observations of how participants described their experience of completing the questionnaire.

The report was presented to the wider research team for comment and a decision made to either make adaptations and re-enter cognitive interviewing for further testing or terminate the adaptation process as detailed in figure 9.

4.6.3 Results

After three cognitive interviews with older people and carers (six in total), no further recommendations for improving the rPATD items were suggested. Patient participant's ages ranged between 69 and 73 years and two were male. Patients were taking between five and 15 medicines. All three carer participants were female aged between 28 and 54 years and, two of their care recipients were female. Carers' care recipients were taking between five and 11 medicines.

A summary of the problems identified and changes made to patient and carer questionnaire versions are provided in tables 7 and 8 respectively. No recommendations for improving the original rPATD items were identified. However, the first participant, a carer, expressed difficulty with responding to the adapted item regarding NHS spending on medication, citing insufficient knowledge of the cost-effectiveness of medicines. This in turn led to difficulties with expressing a view on

whether they felt medicines were providing value for money to the NHS. The participant acknowledged the relevance of exploring views towards medication expenditure and suggested rephrasing the item as follows: "*I feel the NHS spends a lot of money on my care recipient's medicines*". The proposed revision was accepted by the research team and presented to subsequent participants, with appropriate adaptation for the patient rPATD version. The adapted item was acceptable to the remaining two carers and three patients, thus no further refinements were necessary. No additional factors potentially influencing attitudes towards deprescribing not already present in the rPATD were proposed. As face and content validity were demonstrated, no further adaptations to the rPATD were necessary.

Table 7 Report for patient questionnaire cognitive interviews

1. Participant and cognitive interview characteristics			
	Patient 1 (participant 2)	**Patient 2** (participant 4)	**Patient 3** (participant 6)
Age	69	87	73
Gender	Male	Male	Female
Number of medicines	6	5	15
Time taken to complete questionnaire (mm:ss)	12:52	14:49	06:57
2. Questionnaire review			
Burden to the National Health Service			
I feel my medicines are value for money for the NHS*	Question not present in the questionnaire version completed by this participant	Question not present in the questionnaire version completed by this participant	Question not present in the questionnaire version completed by this participant
I feel the National Health Service (NHS) spends a lot of money on my medicines**	No issues	No issues	No issues
Burden			
Taking my medicines every day is very inconvenient	No issues	No issues	No issues
I feel that I am taking a large number of medicines	No issues	No issues	No issues
I feel that my medicines are a burden to me	No issues	No issues	No issues
Sometimes I think I take too many medicines	No issues	No issues	No issues
Appropriateness			
I feel that I may be taking one or more medicines that I no longer need	No issues	No issues	No issues

Table 7 (continued)

I would like to try stopping one of my medicines to see how I feel without it	No issues	No issues	No issues
I would like my doctor to reduce the dose of one or more of my medicines	No issues	No issues	No issues
I think one or more of my medicines may not be working	No issues	No issues	No issues
I believe one or more of my medicines may be currently giving me side effects	No issues	No issues	No issues
Concerns about stopping			
I would be reluctant to stop a medicine that I had been taking for a long time	No issues	No issues	No issues
If one of my medicines was stopped, I would be worried about missing out on future benefits	No issues	No issues	No issues
I get stressed whenever changes are made to my medicines	No issues	No issues	No issues
If my doctor recommended stopping a medicine, I would feel that he/she was giving up on me	No issues	No issues	No issues

Table 7 (continued)

I have had a bad experience when stopping a medicine before	No issues	No issues	No issues
Involvement			
I have a good understanding of the reasons I was prescribed each of my medicines	No issues	No issues	No issues
I know exactly what medicines I am currently taking, and/or I keep an up-to-date list of my medicines	No issues	No issues	No issues
I like to know as much as possible about my medicines	No issues	No issues	No issues
I like to be involved in making decisions about my medicines with my doctors	No issues	No issues	No issues
I always ask my doctor, pharmacist or other healthcare professional if there is something I don't understand about my medicines	No issues	No issues	No issues
Global			
If my doctor said it was possible I would be willing to stop one or more of my regular medicines	No issues	No issues	No issues
Overall, I am satisfied with my current medicines	No issues	No issues	No issues

Table 7 (continued)

Additional comments	Questionnaire was aesthetically appropriate and easy to complete in an acceptable amount of time.	Questionnaire was aesthetically appropriate and easy to complete in an acceptable amount of time.	Questionnaire was aesthetically appropriate and easy to complete in an acceptable amount of time.
3. Conclusion			
Additional researcher comments	Nil	Nil	Participant wanted the researcher to be aware that they had dyslexia and were able to complete the questionnaire with no problems.
4. Research team refinement decisions			
	No refinements necessary	No refinements necessary	No refinements necessary

*Question removed and replaced by a re-phrased version (see below) based on feedback from carer 1 (table 8)

**Question re-phrased from "*I feel my medicines are value for money for the NHS*" as originally proposed by the research team based on feedback from carer 1 (table 8)

Table 8 Report for carer questionnaire cognitive interviews

1. Participant and cognitive interview characteristics			
	Carer 1 (participant 1)	**Carer 2** (participant 3)	**Carer 3** (participant 5)
Age	54	28	49
Gender	Female	Female	Female
Number of medicines taken by care recipient	11	8	5
Time taken to complete questionnaire (mm:ss)	16:30	23:16	14:00
2. Questionnaire review			
Burden to the National Health Service			
I feel my care recipients' medicines are value for money for the NHS	Issue: The participant felt this question was difficult to answer as their care recipient was exempt from paying for medicines and thus it was difficult to determine whether the medicines were value for money. The participant conveyed an appreciation for the rationale behind the question however felt it requested them to 'calculate' the value of medicines. The participant suggested the revised question following probing.	Question not present in the questionnaire version completed by this participant	Question not present in the questionnaire version completed by this participant
I feel the National Health Service (NHS) spends a lot of money on my care recipient's medicines	Question added after this participant completed the questionnaire	No issues	No issues

Table 8 (continued)

Burden			
I feel that the person I care for is taking a large number of medicines	No issues	No issues	No issues
I feel that my care recipient's medicines are a burden to them	No issues	No issues	No issues
Sometimes I think the person I care for takes too many medicines	No issues	No issues	No issues
Appropriateness			
I feel that the person that I care for may be taking one or more medicines that they no longer need	No issues	No issues	No issues
I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it	No issues	No issues	No issues
I would like the doctor to reduce the dose of one or more of my care recipient's medicines	No issues	No issues	No issues
I think one or more of my care recipient's medicines may not be working	No issues	No issues	No issues
I believe one or more of my care recipient's medicines may be currently giving them side effects	No issues	No issues	No issues

Table 8 (continued)

Concerns about stopping			
I would be reluctant to stop one of my care recipient's medicines that they had been taking for a long time	No issues	No issues	No issues
I get stressed whenever changes are made to my care recipient's medicines	No issues	No issues	No issues
I feel that if I agreed to stopping one of my care recipient's medicines then this is giving up on them	No issues	No issues	No issues
The person that I care for has had a bad experience when stopping a medicine before	No issues	No issues	No issues
Involvement			
I know exactly what medicines the person that I care for is currently taking and/or I have an up-to-date list of their medicines	No issues	No issues	No issues
I like to know as much as possible about my care recipient's medicines	No issues	No issues	No issues
I like to be involved in making decisions about my care recipients medicines with their doctors	No issues	No issues	No issues
I always ask the doctor, pharmacist or other healthcare professional if there is something I don't understand about my care recipient's medicines	No issues	No issues	No issues

Table 8 (continued)

Global			
If their doctor said it was possible I would be willing to stop one or more of my care recipient's medicines	No issues	No issues	No issues
Overall, I am satisfied with my care recipient's current medicines	No issues	No issues	No issues
Additional comments	Question: "*I feel my care recipients' medicines are value for money for the NHS*" suggested to be re-phrased to capture whether participants felt a lot of money was spent on medicines. Questionnaire was aesthetically appropriate and easy to complete in an acceptable amount of time.	Questionnaire was aesthetically appropriate and easy to complete in an acceptable amount of time.	Questionnaire was aesthetically appropriate and easy to complete in an acceptable amount of time.
3. Conclusion			
Additional researcher comments	Nil	Nil	Nil

Table 8 (continued)

4. Research team refinement decisions			
	Question: "*I feel my care recipients' medicines are value for money for the NHS*" revised based on participants' feedback and the carer research team representative to "*I feel the National Health Service (NHS) spends a lot of money on my care recipient's medicines*". The patient version of the question was also rephrased to "*I feel the National Health Service (NHS) spends a lot of money on my medicines*" on the advice of the patient research team representative.	No refinements necessary	No refinements necessary

4.7 Section 2: Administration of the rPATD, adapted for the UK setting, to older people and carers in hospital

4.7.1 Methods

This project was overseen by the project management group described in Chapter 3.

4.7.1.1 Study sample and setting

Patients and visiting carers were independently recruited (i.e. they were not paired) from seven Older People's Medicine (OPM) wards at one and two UK hospitals respectively. Criteria for patients triaged to an OPM ward were minimum age (ranging between 70 to 80 years across sites) and either multiple co-morbidities or physical frailty.

All inpatients from OPM wards prescribed at least five pre-admission medicines (polypharmacy(216)) were eligible. The number of pre-admission medicines was determined from the hospitals' pharmacy medicines reconciliation records, which use at least two sources of information, such as a community pharmacy record and a patient's own report, to establish an accurate medication history. Patients unable to speak or read English, deemed by the healthcare team as unable to provide informed consent, inappropriate to approach for recruitment for reasons such as being seriously unwell or unable to make informed decisions about medicines were excluded. For patients who were unable to provide informed consent or make informed decisions about medicines, any of their visitors during the study period were screened as carer participants. Accordingly, patients and carers were not paired.

All visitors self-reporting an unpaid role in managing the medication of an inpatient satisfying the inclusion criteria for the study's patient participant arm were eligible as carers. Carers unable to speak or read English and aged <18 years old were excluded.

4.7.1.2 Recruitment and survey administration

Patients were screened for eligibility and approached for inclusion by an OPM doctor, nurse or pharmacist. Patients expressing an interest were approached by a

researcher who provided an information leaflet and answered questions. Written, informed consent was obtained for rPATD administration and collection of demographic information. The rPATD was self-completed on an electronic tablet by patients at the bedside with a researcher present to assist if necessary. Patient demographics and the number of pre-admission medicines were recorded.

Visitors of OPM wards were screened by a research nurse for eligibility to determine whether they were carers self-reporting an unpaid role in managing the medication of an OPM patient. Only one carer per OPM patient was approached for recruitment as it was deemed unethical by the study team's patient and carer members to approach several carers for one patient. As no identifiable personal information was collected from carers, consent was implied through self-completion of the questionnaire. Carers who agreed to participante were provided with a questionnaire pack including an anonymous demographic information collection form and the rPATD. Carers were invited to self-complete the questionnaire and provide demographic information for themselves and their care recipient in addition to indicating their relationship with the care recipient and the number of pre-admission medications. Carers were instructed to return the pack to a member of ward staff.

Participants were asked to respond to the rPATD reflecting on medication as prescribed prior to admission (pre-admission medicines) but in the context of deprescribing in the hospital setting.

4.7.1.3 Sample size justification

No participant data are reported for the rPATD to inform sample size estimation. Participant data from the original PATD indicate the largest difference in the proportion of respondents agreeing with a dichotomised outcome was 65% to 35%, representing the 'worst case scenario' in terms of precision(109). This was reported for the item "*I feel that I am taking a large number of medications*". Accordingly, responses for all items are estimated to a reasonable degree of precision.

Based on the 65% to 35% PATD response distribution, assuming a similar distribution for the rPATD and anticipated minimal adaptations required for UK use, a sample of 75 participants per population provides a 95% confidence interval (CI) of ±11.0% or smaller around the estimates of agreement with each rPATD item. This sample size is therefore appropriate for estimating the percentage 'agreement' with dichotomised rPATD items.

4.7.1.4 Statistical analysis

Analyses were performed using IBM SPSS Statistics version 23.0 for Windows. Descriptive statistics were used to characterise the participants and rPATD responses. Items are reported grouped under the four rPATD factors; *burden*, *appropriateness*, *concerns about stopping* and *involvement* and new heading *burden to the National Health Service*. Global item 1 captures willingness to accept deprescribing proposed by a doctor and global item 2 captures satisfaction with current medications.

The primary outcome of desire to try stopping a medicine was the *appropriateness* question "*I would like to try stopping one of my medicines to see how I feel without it*" (patients) and "*I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it*" (carers).

In order to identify respondents with a desire to try stopping a medicine, responses to the primary outcome, *involvement* item relating to likely desire to be involved in medicine decision-making and the and two global rPATD questions were dichotomised into those in agreement (agree and strongly agree) and those ambivalent or in disagreement (strongly disagree, disagree and neither agree nor disagree).

4.7.1.4.1 Logistic regression

Logistic regression analysis is a statistical modelling approach used to describe the relationship between several predictor variables to a dichotomous dependent variable, where the latter is typically coded as 1 or 0 for its possible two categories(217). The logistic model is defined as a probability of the occurrence of one of two possible outcomes. The resultant logistic model is useful in situations where the response variable takes only one of two possible values. The first step of a logistic regression analysis is to postulate a statistical model describing the relationship between the dependent and independent variables. The model is then fitted to the data and the adequacy of fit is verified. Appropriate statistical inferences are then made and the relationship between predictors and the dependent variable is quantified by a parameter termed the odds ratio.

Backward binary logistic regression was performed between statements in the four factors and the primary outcome. To identify perceived barriers predicting desire to

try stopping a medicine, responses to each statement were dichotomised into those who disagreed that it was a barrier (strongly disagree and disagree) and those who were ambivalent or in agreement (neither agree nor disagree, agree and strongly agree) that it was a barrier. Variables with less than 5.0% distribution in responses cross-tabulated with the primary outcome were excluded as it was felt that these had insufficient variability to be reliably modelled.

4.7.2 Results

Figure 10 summarises recruitment of patients and carers; the primary reason for patient ineligibility was being unable to provide informed consent. For carers, non-involvement with medicines was the primary reason for exclusion.

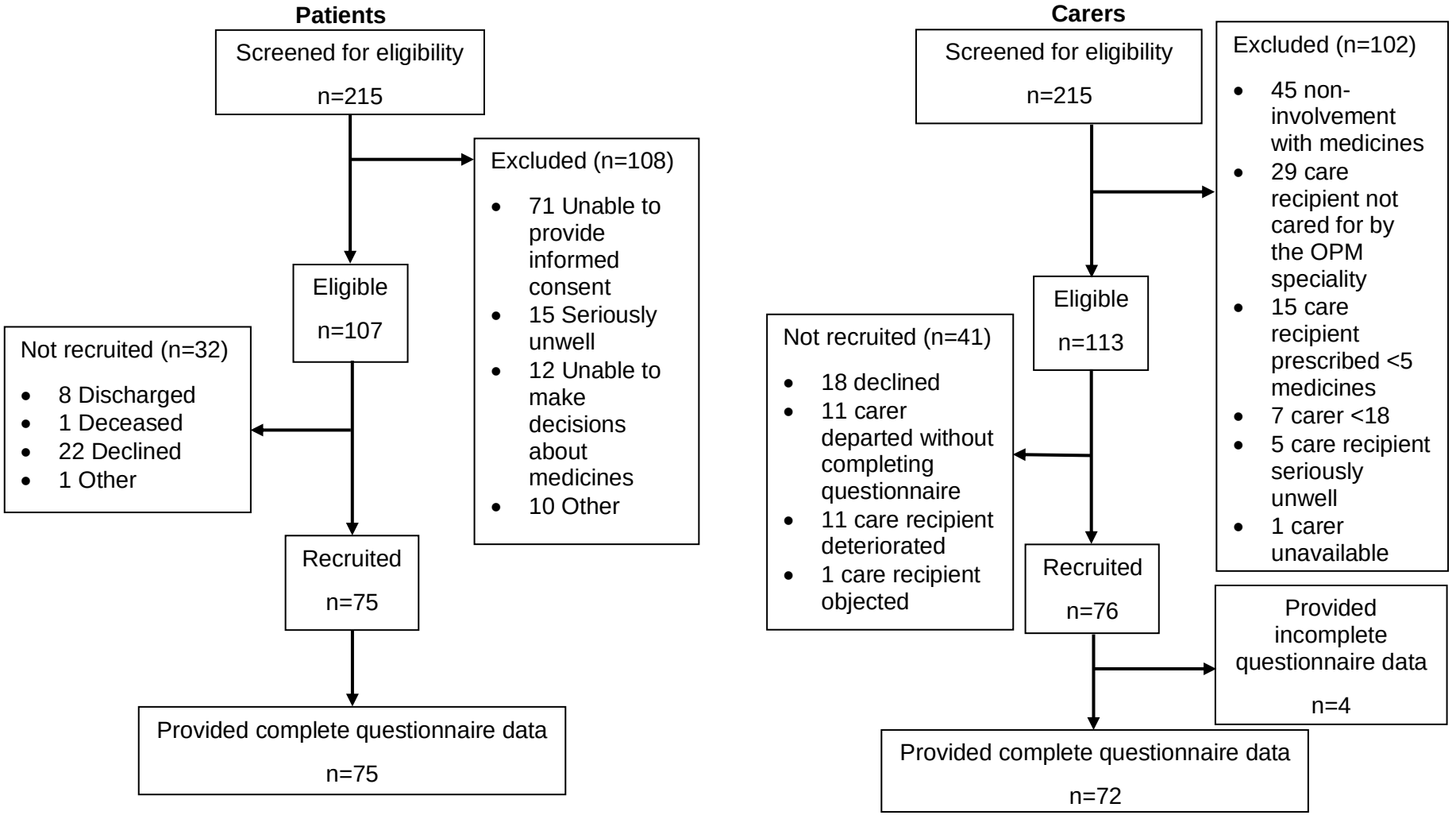

Figure 10 Participant recruitment flow

4.7.2.1 Patients

Recruitment of the target 75 patients from those eligible produced a recruitment rate of 70.1% (95% CI: 52.7, 87.5). The median (IQ) age was 87.0 (83.0, 90.0) years and 34 (45.3%) were female. The median (IQ) number of medications prescribed prior to admission was 8.0 (6.0, 10.0).

4.7.2.1.1 Responses to the rPATD questionnaire

Table 9 illustrates patients' rPATD responses. Agreement with deprescribing proposed by a doctor was high, with 97.4% (95% confidence interval (CI) (93.8-100.0)) agreeing with global item 1 (If my doctor said it was possible I would be willing to stop one or more of my regular medicines). Conversely, only 29.3% (95% CI 19.0-39.6) agreed with the primary outcome item (I would like to try stopping one of my medicines to see how I feel without it). A further 92.0% (95% CI 85.9-98.1) agreed with global item 2 (Overall, I am satisfied with my current medicines), indicating high satisfaction with current medications. Just over half (58.7% (95% CI 47.6-69.8)) of patients expressed a desire to be involved in medication-decision making in response to the relevant involvement item (I like to be involved in making decisions about my medicines with my doctors).

Table 9 Patients' responses to the rPATD

Item	Strongly disagree Number (%)	Disagree Number (%)	Neither agree nor disagree Number (%)	Agree Number (%)	Strongly agree Number (%)	% (95% CI) agree*
Burden to the National Health Service						
I feel the National Health Service (NHS) spends a lot of money on my medicines	1 (1.3)	4 (5.3)	7 (9.3)	44 (58.7)	19 (25.3)	84.0 (75.7-92.2
Burden						
Taking my medicines every day is very inconvenient	22 (29.3)	37 (49.3)	4 (5.3)	11 (14.7)	1 (1.3)	16.0 (7.7-24.3)
I feel that I am taking a large number of medicines	6 (8.0)	26 (34.7)	7 (9.3)	27 (36.0)	9 (12.0)	48.0 (37.0-59.3)
I feel that my medicines are a burden to me	21 (28.0)	38 (50.7)	5 (6.7)	7 (9.3)	4 (5.3)	14.6 (6.6-22.6)
Sometimes I think I take too many medicines	11 (14.7)	26 (34.7)	7 (9.3)	23 (30.7)	8 (10.7)	41.4 (30.3-52.5)
Appropriateness						
I feel that I may be taking one or more medicines that I no longer need	13 (17.3)	29 (38.7)	8 (10.7)	17 (22.7)	8 (10.7)	33.4 (22.7-44.1)
I would like to try stopping one of my medicines to see how I feel without it*	14 (18.7)	30 (40.0)	9 (12.0)	16 (21.3)	6 (8.0)	29.3 (19.0-39.6)
I would like my doctor to reduce the dose of one or more of my medicines	13 (17.3)	32 (42.7)	15 (20.0)	11 (14.7)	4 (5.3)	20.0 (10.9-29.1)

Table 9 (continued)

Item	Strongly disagree Number (%)	Disagree Number (%)	Neither agree nor disagree Number (%)	Agree Number (%)	Strongly agree Number (%)	% (95% CI) agree*
I think one or more of my medicines may not be working	12 (16.0)	26 (34.7)	22 (29.3)	13 (17.3)	2 (2.7)	20.0 (10.9-29.1)
I believe one or more of my medicines may be currently giving me side effects	21 (28.0)	29 (38.7)	4 (5.3)	15 (20.0)	6 (8.0)	28.0 (17.8-38.1)
Concerns about stopping						
I would be reluctant to stop a medicine that I had been taking for a long time	7 (9.3)	35 (46.7)	5 (6.7)	21 (28.0)	7 (9.3)	37.3 (26.4-48.4)
If one of my medicines was stopped, I would be worried about missing out on future benefits	14 (18.7)	28 (37.3)	5 (6.7)	25 (33.3)	3 (4.0)	37.3 (26.4-48.4)
I get stressed whenever changes are made to my medicines	17 (22.7)	39 (52.0)	7 (9.3)	10 (13.3)	2 (2.7)	16.0 (7.7-24.3)
If my doctor recommended stopping a medicine, I would feel that he/she was giving up on me	30 (40.0)	31 (41.3)	2 (2.7)	8 (10.7)	4 (5.3)	16.0 (7.7-24.3)
I have had a bad experience when stopping a medicine before	53 (70.7)	11 (14.6)	5 (6.7)	4 (5.3)	2 (2.7)	20.7 (11.5-29.9)

Table 9 (continued)

Item	Strongly disagree Number (%)	Disagree Number (%)	Neither agree nor disagree Number (%)	Agree Number (%)	Strongly agree Number (%)	% (95% CI) agree*
Involvement						
I have a good understanding of the reasons I was prescribed each of my medicines	6 (8.0)	3 (4.0)	6 (8.0)	38 (50.7)	22 (29.3)	80.0 (70.9-89.1)
I know exactly what medicines I am currently taking, and/or I keep an up-to-date list of my medicines	5 (6.7)	10 (13.3)	3 (4.0)	28 (37.3)	29 (38.7)	76.0 (66.3-85.7)
I like to know as much as possible about my medicines	3 (4.0)	10 (13.3)	5 (6.7)	35 (46.7)	22 (29.3)	76.0 (66.3-85.7)
I like to be involved in making decisions about my medicines with my doctors	6 (8.0)	19 (25.3)	6 (8.0)	23 (30.7)	21 (28.0)	58.7 (47.6-69.8
I always ask my doctor, pharmacist or other healthcare professional if there is something I don't understand about my medicines	1 (1.3)	13 (17.3)	2 (2.7)	33 (44.0)	26 (34.7)	78.7 (69.4-88.0

Table 9 (continued)

Item	Strongly disagree Number (%)	Disagree Number (%)	Neither agree nor disagree Number (%)	Agree Number (%)	Strongly agree Number (%)	% (95% CI) agree*
Global						
If my doctor said it was possible I would be willing to stop one or more of my regular medicines	1 (1.3)	1 (1.3)	0	50 (66.7)	23 (30.7)	97.4 (93.8-100)
Overall, I am satisfied with my current medicines	0	1 (1.3)	5 (6.7)	49 (65.3)	20 (26.7)	92.0 (85.9-98.1)

*Sum of agree and strongly agree

4.7.2.1.2 Regression analysis

All items had at least 5% distribution in responses when cross-tabulated with the primary outcome (appendix 8) and were therefore all entered into the regression analysis. The resulting model predicted 62.9% (Negelkerke R2) of the variance and the Hosmer and Lemeshow goodness-of-fit test implied the model's estimates fit the data to an acceptable level (p=0.238). The full regression analysis is provided in table 10. The predictors of a patients' lack of desire to try stopping a medicine were the burden item "*Sometimes I think I take too many medicines*" and the appropriateness items "*I feel that I may be taking one or more medicines that I no longer need*" and "*I would like my doctor to reduce the dose of one or more of my medicines*".

Table 10 Regression analysis of rPATD items predicting lack of patients' desire to try stopping a medicine

rPATD item	Number agree with item* (% not willing to deprescribe**)	Unadjusted OR	p-value	Adjusted OR	p-value
Burden to the National Health Service					
I feel the National Health Service (NHS) spends a lot of money on my medicines	70 (58.6)	0.943	0.950		
Burden					
Taking my medicines every day is very inconvenient	16 (43.8)	0.462	0.177		
I feel that I am taking a large number of medicines	43 (46.5)	0.290	0.015*		
I feel that my medicines are a burden to me	16 (31.3)	0.233	0.016*		
Sometimes I think I take too many medicines	38 (31.6)	0.072	<0.001**	0.195	0.045*
Appropriateness					
I feel that I may be taking one or more medicines that I no longer need	33 (27.3)	0.075	<0.001**	0.179	0.016*
I would like to try stopping one of my medicines to see how I feel without it (entered as the dependent variable/primary outcome)					
I would like my doctor to reduce the dose of one or more of my medicines	30 (23.3)	0.066	<0.001**	0.199	0.021*
I think one or more of my medicines may not be working	37 (37.8)	0.162	0.001*		
I believe one or more of my medicines may be currently giving me side effects	25 (44.0)	0.405	0.071		
Concerns about stopping					
I would be reluctant to stop a medicine that I had been taking for a long time	33 (57.6)	1.084	0.865		
If one of my medicines was stopped, I would be worried about missing out on future benefits	33 (60.6)	0.867	0.762		

Table 10 (continued)

rPATD item	Number agree with item* (% not willing to deprescribe**)	Unadjusted OR	p-value	Adjusted OR	p-value
I get stressed whenever changes are made to my medicines	19 (47.4)	1.852	0.250		
If my doctor recommended stopping a medicine, I would feel that he/she was giving up on me	14 (57.1)	1.080	0.898		
I have had a bad experience when stopping a medicine before	11 (63.6)	0.783	0.718		
Involvement					
I have a good understanding of the reasons I was prescribed each of my medicines	66 (65.2)	14.957	0.013*		
I know exactly what medicines I am currently taking, and/or I keep an up-to-date list of my medicines	60 (63.3)	2.591	0.107		
I like to know as much as possible about my medicines	62 (58.1)	0.865	0.817		
I like to be involved in making decisions about my medicines with my doctors	50 (58.0)	0.921	0.868		
I always ask my doctor, pharmacist or other healthcare professional if there is something I don't understand about my medicines	61 (57.4)	0.748	0.637		

*Number of participants out of total of n=75 who agree (agreed or strongly agree) that the rPATD item was a barrier or enabler

**Proportion of participants who disagree (disagree or strongly disagree) with the primary outcome question of expressing a desire to try stopping a medicine ("*I would like to try stopping one of my medicines to see how I feel without it*")

4.7.2.2 Carers

The carer arm over recruited by one participant producing a recruitment rate of 67.2% (95% CI: 49.9, 84.5) for the 76 carers who completed the questionnaire. Thirty-five (46.1%) carers were a spouse or partner and the remaining 41 (53.9%) were another relative. The median (IQ) age of carers and care recipients were 70.0 (57.0, 83.0) and 86 (83.0, 89.0) respectively. Females constituted 47 (61.8%) and 48 (63.2%) of carers and care recipients respectively. The median (IQ) number of medicines prescribed for care recipients prior to admission was 8.0 (6.0, 10.3).

4.7.2.2.1 Responses to the rPATD questionnaire

Table 11 illustrates carers' rPATD responses. Agreement with deprescribing proposed by a doctor was high, with 76.3% (95% CI 66.7-85.9) of carers agreeing with global item 1 (If their doctor said it was possible I would be willing to stop one or more of my care recipient's medicines). Conversely, only 43.5% (95% CI 32.4-54.6) agreed with the primary outcome (I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it). A further 80.3% (95% CI 71.3-89.3) agreed with global item 2 (Overall, I am satisfied with my care recipient's current medicines), indicating high satisfaction with current medications. Approximately two thirds of carers (65.8% (95% CI 55.1-76.5)) expressed a desire to be involved in medication-decision making in response to the relevant *involvement* item (I like to be involved in making decisions about my care recipients medicines with their doctors).

Table 11 Carers' responses to the rPATD

Item	Strongly disagree Number %	Disagree Number %	Neither agree nor disagree Number %	Agree Number %	Strongly agree Number %	% (95% CI) agree*
Burden to the National Health Service						
I feel the National Health Service (NHS) spends a lot of money on my care recipient's medicines	0	5 (6.6)	28 (36.8)	26 (34.2)	17 (22.4)	56.6 (45.5-67.7)
Burden						
I feel that the person I care for is taking a large number of medicines	4 (5.3)	14 (18.4)	18 (23.7)	31 (40.8)	9 (11.8)	52.6 (41.4-63.8)
I feel that my care recipient's medicines are a burden to them	8 (10.5)	37 (48.7)	14 (18.4)	16 (21.1)	1 (1.3)	22.4 (13.0-31.8)
Sometimes I think the person I care for takes too many medicines	8 (10.5)	21 (27.6)	23 (30.3)	21 (27.6)	3 (3.9)	31.5 (21.1-41.9)
Appropriateness						
I feel that the person that I care for may be taking one or more medicines that they no longer need	4 (5.3)	22 (28.9)	22 (28.9)	25 (32.9)	3 (3.9)	36.8 (26.0-47.6)

Table 11 (continued)

Item	Strongly disagree Number %	Disagree Number %	Neither agree nor disagree Number %	Agree Number %	Strongly agree Number %	% (95% CI) agree*
I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it*	7 (9.2)	22 (28.9)	14 (18.4)	29 (38.2)	4 (5.3)	43.5 (32.4-54.6)
I would like the doctor to reduce the dose of one or more of my care recipient's medicines	7 (9.2)	22 (28.9)	29 (38.2)	16 (21.1)	2 (2.6)	23.7 (14.1-33.3)
I think one or more of my care recipient's medicines may not be working	5 (6.6)	22 (28.9)	32 (42.1)	17 (22.4)	0	22.4 (13.0-31.8)
I believe one or more of my care recipient's medicines may be currently giving them side effects	6 (7.9)	25 (32.9)	18 (23.7)	23 (30.3)	4 (5.3)	35.6 (24.8-46.4)
Concerns about stopping						
I would be reluctant to stop one of my care recipient's medicines that they had been taking for a long time	2 (2.6)	20 (26.3)	13 (17.1)	35 (46.1)	6 (7.9)	54.0 (42.8-65.2)

Table 11 (continued)

Item	Strongly disagree Number %	Disagree Number %	Neither agree nor disagree Number %	Agree Number %	Strongly agree Number %	% (95% CI) agree*
I get stressed whenever changes are made to my care recipient's medicines	16 (21.1)	28 (36.8)	19 (25.0)	13 (17.1)	0	17.1 (8.6-25.6)
I feel that if I agreed to stopping one of my care recipient's medicines then this is giving up on them	15 (19.7)	29 (38.2)	16 (21.1)	13 (17.1)	3 (3.9)	21.0 (11.8-30.2)
The person that I care for has had a bad experience when stopping a medicine before	43 (56.6)	22 (28.9)	6 (7.9)	5 (6.6)	0	6.6 (1.0-12.2)
Involvement						
I know exactly what medicines the person that I care for is currently taking and/or I have an up-to-date list of their medicines	0	12 (15.8)	3 (3.9)	41 (53.9)	16 (21.1)	75.0 (65.0-85.0)
I like to know as much as possible about my care recipient's medicines	0	3 (3.9)	8 (10.5)	39 (51.3)	22 (28.9)	80.2 (71.0-89.4)

Table 11 (continued)

Item	Strongly disagree Number %	Disagree Number %	Neither agree nor disagree Number %	Agree Number %	Strongly agree Number %	% (95% CI) agree*
I like to be involved in making decisions about my care recipients medicines with their doctors	2 (2.6)	10 (13.2)	10 (13.2)	33 (43.4)	17 (22.4)	65.8 (54.8-76.8)
I always ask the doctor, pharmacist or other healthcare professional if there is something I don't understand about my care recipient's medicines	1 (1.3)	10 (13.2)	7 (9.2)	39 (51.3)	15 (19.7)	41.0 (29.6-52.4)
Global						
If their doctor said it was possible I would be willing to stop one or more of my care recipient's medicines	2 (2.6)	1 (1.3)	14 (18.4)	50 (65.8)	8 (10.5)	76.3 (66.7-85.9)
Overall, I am satisfied with my care recipient's current medicines	2 (2.6)	2 (2.6)	10 (13.2)	51 (67.1)	10 (13.2)	80.3 (71.3-89.3)

*Sum of agree and strongly agree

4.7.2.2.2 Regression analysis

Item 1 from *burden* and 2 from *involvement* were not entered into the regression due to them having <5% distribution in responses when cross-tabulated with the outcome. All other items had at least 5% distribution in responses when cross-tabulated with the primary outcome (appendix 9). The resulting model predicted 70.1% of the variance (Negelkerke R^2) and the Hosmer and Lemeshow goodness-of-fit test implied the model's estimates fit the data to an acceptable level (p=0.852). The full regression analysis is provided in table 12. The predictors of a carers' lack of desire to try stopping a medicine were the *appropriateness* items "*I feel that the person that I care for may be taking one or more medicines that they no longer need*" and "*I would like the doctor to reduce the dose of one or more of my care recipient's medicines*".

Table 12 Regression analysis of rPATD items predicting lack of carers' desire to try stopping a medicine

Question	Number agree with item* (% not willing to deprescribe**)	Unadjusted OR	p-value	Adjusted OR	p-value
Burden to the National Health Service					
I feel the National Health Service (NHS) spends a lot of money on my care recipient's medicines	71 (35.2)	0.136	0.081		
Burden					
I feel that the person I care for is taking a large number of medicines	58 (34.5)	0.526	0.240		
I feel that my care recipient's medicines are a burden to them	31 (22.6)	0.305	0.023*		
Sometimes I think the person I care for takes too many medicines	47 (21.3)	0.142	<0.001***		
Appropriateness					
I feel that the person that I care for may be taking one or more medicines that they no longer need	50 (20.0)	0.092	<0.001***	0.056	0.005
I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it (entered as the dependent variable/primary outcome)					
I would like the doctor to reduce the dose of one or more of my care recipient's medicines	47 (10.6)	0.025	<0.001***	0.022	<0.001***
I think one or more of my care recipient's medicines may not be working	49 (22.4)	0.145	<0.001***		
I believe one or more of my care recipient's medicines may be currently giving them side effects	45 (24.4)	0.234	0.004**		

Table 12 (continued)

Question	Number agree with item* (% not willing to deprescribe**)	Unadjusted OR	p-value	Adjusted OR	p-value
Concerns about stopping					
I would be reluctant to stop one of my care recipient's medicines that they had been taking for a long time	54 (44.4)	2.720	0.083		
I get stressed whenever changes are made to my care recipient's medicines	32 (40.6)	1.197	0.706		
I feel that if I agreed to stopping one of my care recipient's medicines then this is giving up on them	32 (43.8)	1.504	0.393		
The person that I care for has had a bad experience when stopping a medicine before	11 (18.2)	0.313	0.157		
Involvement					
I know exactly what medicines the person that I care for is currently taking and/or I have an up-to-date list of their medicines	60 (41.7)	2.143	0.287		
I like to know as much as possible about my care recipient's medicines	69 (39.1)	1.286	0.841		
I like to be involved in making decisions about my care recipients medicines with their doctors	60 (40.0)	1.333	0.666	9.799	0.089
I always ask the doctor, pharmacist or other healthcare professional if there is something I don't understand about my care recipient's medicines	61 (42.6)	3.343	0.143		

*Number of participants out of total of n=76 who agree (agreed or strongly agree) that the rPATD item was a barrier or enabler

**Proportion of participants who disagree (disagree or strongly disagree) with the primary outcome question of expressing a desire to try stopping a medicine ("*I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it*")

4.8 Discussion

Engagement of patients and carers is a core component of deprescribing, yet a substantial proportion indicated limited desire to be involved in medication decision-making. Furthermore, the low desire to try stopping a medicine is in agreement with the substantial proportions of participants declining deprescribing in the trial environment(111,192–194). However, patients and carers overwhelmingly report agreement with deprescribing proposed by a doctor. Practitioners should not therefore dismiss deprescribing opportunities due to patients and carers choosing to be less involved in decision-making. The three diagnostic indicators for establishing desire to try stopping a medicine are perceptions of the number and necessity of medicines and, a desire for dose reduction. These may also assist physicians with targeting relevant attitudinal predictors during deprescribing discussions.

Given similarities between the two English-speaking nations, it is unsurprising that minimal adaptations to the Australian rPATD were required before UK use as a result of the cognitive interviews. The item exploring burden of paying for medication was adapted to reflect the UK context. Recruiting the cognitive interview participants from the pool of university staff and students may have resulted in a highly self-selecting audience, which may not necessarily be representative of the main study participants. Efforts were made to mitigate this, for example the participant eligibility criteria for both the cognitive interviews and main study being identical except for the settings (university versus hospital wards). As discussed in in section 4.6, self-selecting audiences tend to be from higher educational backgrounds than the average questionnaire respondent(205). This could have led to results which suggested that the rPATD had face and content validity in a highly educated population which may not be generalisable to the main study population. It was not practical to conduct the cognitive interviews in the hospital ward environment owing to a number of restrictions including prohibition of audio recording in shared ward bed bays. However, a potential strategy to mitigate this limitation could have been to recruit participants from other sources such as the charity Age UK, who may have been able to facilitate recruitment of participants more representative of the main study population.

Whilst the sample size estimation was based on PATD data, the distribution of patients' agreement responses to the rPATD yielded confidence intervals equal to or narrower than predicted. For carers however, the distributions of agreement to five rPATD items yielded confidence intervals of up to 0.5% wider than predicted. This may be a limitation of the carer sample size justification being based on

patients' responses to the original PATD. Based on the present study, whilst trends in patient and carer attitudes towards deprescribing appear to accord, there appears to be a larger distribution across responses for carers, thus requiring a larger sample size. Nonetheless, the deviation in predicted confidence intervals for the five aforementioned carer rPATD items is very small, affording some confidence in these findings.

The high consent rates provides some confidence in the generalisability of the findings to the populations of the hospitals at which the research was conducted. The presence of a researcher to support patients self-completing the rPATD may have biased responses. However, similarities with the carer rPATD responses indicate that researcher presence is unlikely to have unduly influenced the findings.

Half of potentially eligible patients were excluded due to inability to participate in medication decision-making. Inclusion of carers therefore provides representation of this previously under-researched population(108–110,197). The patient participant population is comparable to previous PATD studies(108–110,197) and to a pan European study evaluating older people's hospital admissions(34). The carer population was comparable with a US study exploring treatment preferences of carers involved in medication decision-making(195). These similarities indicate that the study findings may be generalisable beyond the two hospital study sites.

Similar to previous patient PATD responses in the outpatient clinic, acute hospital and care home settings, the global rPATD items in the present study demonstrated little variation, with the majority of respondents agreeing with deprescribing proposed by a doctor whilst also being satisfied with current medicines(108–110,197). There was, however, greater variation in responses to the items relating to patients' and carers' desire to be involved in medicine decision-making. This agrees with the existing literature in relation to some older people expressing preference for a passive role in decision-making(121–125) and may also be true of carers, who were similarly older in age(218).

Medication expenditure was acknowledged as a burden to the NHS by the majority of respondents, however this did not predict desire to try stopping a medicine. Patients did not consider their medications a burden as evidenced by no items in the *burden* factor attracting general agreement. Carer responses were similar, however the majority felt care recipients were taking a large number of medicines.

The *appropriateness* factor demonstrated greatest divergence between patients and carers. The majority of patients perceived their medicines were appropriate,

whereas carers were ambivalent. This may be due to carers feeling that they lack understanding of their care recipient's treatments(121).

Whilst there is qualitative literature indicating that deprescribing generates concerns for patients(98), the majority of patient respondents indicated that they did not hold concerns about stopping medication. This may be due to differences between actively inviting people to generate potential concerns versus inviting an opinion on specific concerns as in the present study(219). Carer responses were similar to patients', however resistance to deprescribing long-standing medication was conveyed but did not predict lack desire to try stopping a medicine. Physicians report reluctance to propose deprescribing for fear of patients perceiving this as withdrawal of care(116); the present study suggests neither patients nor carers hold this view.

Some caution should be applied to this message, as whilst the majority of respondents agreed with deprescribing proposed by a doctor, they also reported content with existing medication. This potentially reflects a desire to conform, which may lead to agreement with a doctor's recommendation to deprescribe despite concerns(125) and reluctance to report adverse outcomes such as return of symptoms(124).

The reported preference for a passive role in medication decision-making by older people in the literature(121) was expressed by some patients and carers in their responses to items in the *involvement* factor. Whilst items relating to the passive behaviour of knowledge acquisition regarding prescribed medicines attracted high agreement, the item relating to liking to be involved in decisions about medicines was lower.

The attitudinal predictors of desire to try stopping a medicine for both patients and carers are perceived necessity and a desire for dose reduction. As both items are from the *appropriateness* factor, this may represent a limitation of using an *appropriateness* item as the primary outcome. However, this could also suggest that attitude towards the *appropriateness* of medication is the most suitable target for a behaviour change intervention. Additionally, the predictive ability of the *burden* item regarding taking too many medicines for patients and not for carers suggests that a patients' perceived burden of medicine taking is an important indicator of their desire to try stopping a medicine.

The high agreement with deprescribing proposed by a doctor reported in this study endorses the development of a hospital deprescribing intervention for older people

which focusses on targeting practitioners' behaviours to ensure they are routinely proposing appropriate deprescribing. However, deprescribing should be a patient centred process(60), therefore the views of patients and carers should be considered when developing such an intervention. As the target behaviour for both patients and carer is wanting to try deprescribing and a key predictor of this behaviour is attitude towards deprescribing(112–114), the three attitudinal predictors are potential intervention targets. The finding that perceived medication necessity and a desire for dose reduction are predictors of both patients' and carers' desire to try stopping a medicine may offer efficiencies for intervention design. Behaviour change techniques offer an evidence-based approach to modifying attitudes towards a behaviour. For example, a practitioner may identify that a patient is prescribed an inappropriate medicine who is ambivalent to deprescribing. The present study indicates that one or more of three attitudinal predictors of desire to try stopping a medicine may alter this ambivalence. For example, the patient's perception that they are not taking too many medicines can be targeted with the evidence-based behaviour change technique 'information about emotional consequences'(172,220). This theory-based approach to changing patients' attitude towards deprescribing has been reported in the EMPOWER trial, which includes the behaviour change technique 'information about health consequences'(221).

Patients and carers overwhelmingly report agreement with deprescribing proposed by a doctor yet vary in the extent to which they want to be involved in medicine decision-making. Practitioners should not therefore dismiss deprescribing opportunities due to patients and carers choosing to be less involved in decision-making. Three attitudinal predictors of reported desire to try stopping a medicine provide potentially modifiable targets for developing a hospital deprescribing intervention which considers patients' and carers' behaviour in addition to that of the healthcare practitioner.

Chapter 5 Geriatricians' and pharmacists' barriers and enablers to deprescribing for older people in hospital: A focus group study using the Theoretical Domains Framework

This chapter is derived from the publication:

Scott, S., Twigg, M. J., Clark, A., Farrow, C., May, H., Patel, M., … Bhattacharya, D. Development of a deprescribing implementation framework for the hospital setting: A focus group study with geriatricians and pharmacists. Age and Ageing. 2019. Accepted in press.

5.1 Introduction

Chapter 3 identified that deprescribing practice in hospital is limited and dominated by reactive deprescribing in response to existing harms. Accordingly, there is likely to be significant scope to increase the proactive deprescribing practice in hospital, where a medication is discontinued if future gains are unlikely to outweigh future harms. Chapter 4 explored older patients' and carers' views towards deprescribing in hospital and concluded that the vast majority were willing to have one of their medicines deprescribed if this is proposed by a doctor. Accordingly, a hospital deprescribing intervention should focus on supporting practitioners in hospital to work with patients and carers to deprescribe inappropriate medication.

An overview of the current literature presented in Chapter 1 proposed that geriatrician-led deprescribing in hospital may overcome some of the barriers to deprescribing from the primary care setting perspective. Pharmacists in National Health Service (NHS) hospitals play an important role in medicines management and optimisation of pharmacological treatments(132), thus they are also likely to play a key role in hospital deprescribing. The barriers and enablers to deprescribing from the perspective of geriatricians and pharmacists in hospital remain unknown, therefore empirical research is indicated to inform the development of a novel deprescribing intervention. The extent to which these might also vary between hospital organisations is also unclear. Large teaching hospitals may benefit from greater resources relative to smaller district general hospitals; however, the former may treat patients with more severe illness, potentially limiting capacity to adopt new models of care(222–224). The nature and relative importance of barriers and enablers to deprescribing may differ across hospital contexts. There is therefore a need to understand the implementation problems and potential solutions to guide the development of a scalable deprescribing intervention for the hospital setting.

Chapter 2 emphasised the importance of applying theory when developing complex interventions to understand the processes of change required to adopt a new behaviour such as deprescribing(142). The Theoretical Domains Framework (TDF), which is an integrative framework of behaviour change theories organised into 14 theoretical domains(157), was selected as the theoretical approach underpinning the development of a hospital deprescribing intervention. Identification of domains that are important to the target behaviour provides the theoretical understanding required to develop an intervention.

5.2 Aim

To understand geriatricians' and pharmacists' perceived barriers and enablers to deprescribing in hospital.

5.3 Objectives

1. Describe the barriers and enablers of geriatricians and pharmacists to deprescribing in hospital.
2. Identify the TDF domains that are relevant to geriatricians and pharmacists deprescribing behaviour in hospital.
3. Prioritise TDF domains within which geriatricians' and pharmacists' behaviour are required to change to facilitate them to deprescribe in hospital.

5.4 Ethics approval

Ethical and governance approval were obtained from the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (Reference 2017/2018 – 59) and UK Health Research Authority respectively. The study protocol and ethical and governance approval letters are provided in appendices 10 and 11 respectively.

5.5 Methods

This project was overseen by the project management group described in Chapter 3.

5.5.1 Study design

Given the need to explore in-depth the thoughts and ideas of geriatricians and pharmacists regarding deprescribing and the absence of published literature from which to derive a survey(116), an exploratory qualitative approach was selected. Qualitative research is described as a "*naturalistic, interpretative approach, concerned with exploring phenomena 'from the interior' and taking the perspectives and accounts of research participants as a starting point*"(219). The key features of qualitative research are a focus on process, flexibility and a concern with 'what', 'why' and 'how', rather than 'how many'. Focus groups were chosen to address the

study aim as they generate data through interactions between participants thus yielding additional material not otherwise captured through other qualitative methods such as in-depth interviews(219). This group 'brainstorming' and 'problem solving' mirrors team-based clinical decision-making in hospital(225). Participants assume some responsibility for directing the discussion and the researcher's role is less pronounced and thus less influential than in individual interviews. The consolidated criteria for reporting qualitative research (COREQ) checklist guided reporting (appendix 12).

5.5.1.1 Reflexivity

The lead researcher (SS) was a practicing hospital pharmacist when the research activities described in this chapter were undertaken. Moreover, members of SS's supervisory team and the wider project management group comprised academic pharmacists, senior hospital pharmacists, consultant geriatricians, a patient and carer. It is therefore inevitable that the research team will have had preconceptions around the barriers and enablers to deprescribing in. Moreover, all members of the research team had actively sought involvement with the project, therefore they were likely to bring a vested interest in the research's success, which may also have led to the introduction of biases.

There is potential for researchers' preconceptions to influence and contaminate study processes such as data collection and interpretation in all methodological approaches, which may lead to findings which are biassed and not an accurate reflection of the truth. Qualitative enquiry however is particularly vulnerable to this effect owing to researchers' intimate involvement in both the research process and product. This introduces challenges to objectively conducting the research and analysing data(226). Accordingly, there is a need for continuous self-critique and self-appraisal in order to explain how preconceptions and experiences more broadly may or may not influence the research. This attribute is termed 'reflexivity', which has been defined as "*the analytic attention to the researcher's role in qualitative research*"(227).

Reflexive researchers must be aware of and acknowledge the factors which may influence their behaviour throughout the research process. This involves exploration of the researcher(s) relationship with the subject matter. Whilst the aim of reflexivity is to promote and sustain objectivity in qualitative research, it is inevitable that a researcher will influence the product. Reflexivity therefore also acknowledges this,

and researchers are encouraged to be transparent thorough the research process. This is achieved in part by completing agreed quality checklists such as COREQ (appendix 12).

The strategy adopted to promote objectivity in the study described in this chapter is termed 'bracketing'(228), which is defined as "*the suspension of all biases and beliefs regarding the phenomenon being researched prior to collecting data about it*"(226). The process described by Wall *et al.*(229) was adopted for the study in this chapter, which encompassed SS keeping a reflexive diary. Initially (before any data collection), SS documented his specific beliefs and issues regarding the subject matter that he felt required bracketing (pre action bracketing). For example, SS felt that a barrier to deprescribing in hospital was likely to be that practitioners lack the required knowledge and skills, which was documented in the reflexive diary and bracketed. Being actively aware of these preconceptions facilitated SS in suspending them during the data collection and analysis process. Subsequently, after each focus group SS reflected on and documented learning from the discussions and research process (in action bracketing). In accordance with the pre action bracketing process, this new knowledge was suspended to ensure continued objectivity in subsequent focus groups.

The reflexive process was shared with the wider research team in order to facilitate objectivity at the research team level.

5.5.2 Setting

Four hospitals across three English counties, two of which were 1000 and 1200 inpatient bed teaching hospitals with four and six geriatric wards respectively, and two were 450 and 550 inpatient bed district general hospitals with 3 geriatric wards each.

The proportion of prescribing pharmacists across the four hospital sites varied from approximately one fifth to one quarter of all pharmacists. Whilst the proportions of prescribing pharmacists were typical of hospitals across the region (East of England), they were lower than other regions. The proportion of prescribing pharmacists in hospitals nationally varies significantly, from 2.5% to 71% of pharmacists(230). Accordingly, the four hospitals included in this study were in the lower 50% of hospitals nationally for the proportion of pharmacist prescribers.

Standard care across the four hospitals was for patients to receive a pharmacy-led medicines reconciliation within 24 hours of admission. None of the four hospitals adopted full clinical pharmacy service seven days a week, however all operated a dispensary service on weekends and an emergency on-call service out of hours.

This sample setting was used to explore influencers of deprescribing for older people during a hospital admission and capture any variation arising from differing resources and patient populations.

5.5.3 Sample

Greater specificity in defining whose behaviour needs changing leads to greater specificity of the enablers and barriers identified(159). This study therefore focussed on geriatricians and pharmacists who were the target professional groups for behaviour change. We included senior geriatricians and pharmacists who worked in the four hospitals based on practice experience (minimum six and four years respectively). Senior geriatricians were defined as those with at least six years of practice experience whilst senior pharmacists were defined as those with at least four years of practice experience and a post-graduate qualification in clinical pharmacy. Senior pharmacists from all clinical specialities were invited in recognition of the range of responsibilities often adopted despite speciality.

Eight focus groups were planned to explore similarities and differences in attitudes between geriatricians and pharmacists, and identify hospital characteristics that might influence deprescribing. Each hospital site hosted two focus groups: one with geriatricians and one with pharmacists, with five to eight participants each (n=40 to 64 in total).

The principles for deciding saturation in theory-based qualitative studies outlined by Francis *et al.* were followed to determine whether data saturation had been achieved(231). However, as a study objective was to explore any differences in views between district general and teaching hospital contexts, an *a priori* decision was made to convene all eight planned focus groups irrespective of whether data saturation was achieved prior to conducting all focus groups.

5.5.4 Recruitment

All potentially eligible participants at the hospital sites were invited by email from a nominated gatekeeper of their respective specialities. The email comprised a participant information leaflet (including details of the study aims) and focus group scheduling arrangements. Potential participants were directed to complete an online expression of interest survey requesting the following information: professional group, gender, hospital seniority grade and prescribing authority status (pharmacists only). Potential participants were purposively sampled to maximise variation in demographic and seniority grade. A mixture of prescribing and non-prescribing pharmacists were sought to explore any differences in attitudes arising from the acquisition of additional prescribing competencies. Employing hospitals were remunerated for participants' time commitment to the research.

All potential participants sampled for recruitment participated in the study. Three pharmacists who were not purposively sampled and did not complete the online expression of interest survey attempted to attend the focus group at hospital 1 (table 9). In line with the study protocol and conditions of ethical and governance approval (maximum eight participants), the three aforementioned pharmacists were declined participation.

5.5.5 Data collection

Researchers, geriatricians, clinical pharmacists, and patient and carer representatives developed a semi-structured topic guide informed by the deprescribing literature. Guiding questions were designed to elicit participants' views regarding the following:

1. Perception of existing deprescribing practice.
2. Barriers to increasing deprescribing practice.
3. Enablers for increasing deprescribing practice.

Standard questions were adapted to elicit the barriers and enablers to deprescribing within all 14 TDF domains and served as probes where necessary to ensure full coverage of the TDF in discussions(97). The topic guide was piloted with clinical pharmacists and geriatricians yielding minor rephrasing and ordering of guiding questions (available in appendix 10). Piloting of the topic guide and discussions with

gatekeepers indicated that a one-hour focus group was feasible for in depth discussions.

Standard questions were adapted to elicit barriers and enablers to deprescribing within all 14 TDF domains and used them as probes to ensure full coverage of the TDF in discussions. The topic guide was piloted with geriatrician and pharmacist collaborators (n=3) who were representative of the target focus group population; they did not participate in the study. The purpose of the piloting was to check understanding of questions, ascertain the depth of data generated from the guide, and assess the feasibility of covering all TDF domains in the allotted time.

Focus group data were collected between February and May 2018. Written, informed consent was obtained from participants at the beginning of each focus group, which were convened in meeting rooms at the hospital sites. Two academic pharmacist researchers (SS and DB) facilitated the focus groups, made field notes during the discussions and audio recorded the events. SS completed training in qualitative research methodology and the principles and practice of behaviour change research prior to the study. DB has extensive experience of conducting qualitative research underpinned by behaviour change theory.

5.5.6 Analysis

A research administrator transcribed verbatim focus group recordings which were then anonymised and checked for accuracy by a researcher (SS). Data were imported into NVivo 11 (QSR International, Melbourne, Australia) to facilitate the following three phases of analysis:

1. Thematic analysis to identify determinants of deprescribing for older people in hospital.
2. Mapping of all identified determinants of deprescribing to the TDF.
3. Prioritising TDF domains for targeting in a deprescribing intervention.

This methodological approach draws on recent theory-based intervention development research(161,232,233). All processes of the analysis were shared with the study management group which included geriatricians, pharmacists and, patient and carer representatives, to enhance transparency and validity of interpretation.

5.5.6.1 Phase 1: Thematic analysis

Data were initially analysed through the five customary steps of thematic analysis as described by Braun and Clarke(234) to ensure resultant themes were not restricted to the pre-defined TDF domains.

Step 1: Data familiarisation

SS and DB facilitated all focus groups and therefore had some prior knowledge of the data. SS re-read the transcripts several times to facilitate familiarity the breadth and depth of content. During this process, SS made informal notes regarding initial ideas for coding, which were to be referred to during later phases of the analysis.

Step 2: Generating initial codes

SS coded inductively by organising the data into the barriers and enablers to deprescribing. Data extracts were coded inclusively, i.e. relevant text surrounding the phenomena of interest was retained, to ensure no loss of context. Two researchers experienced in qualitative (MJT) and behaviour change (DB) research then reviewed the codes and associated data extracts, and codes were refined through discussions.

Steps 3, 4 and 5: Searching for themes, reviewing themes and defining themes

Three researchers (SS, MJT and DB) sorted the codes by considering how different codes could be combined to form an overarching theme and sub-themes. All relevant data extracts were collated within the identified themes. Themes were then refined to ensure that the data within each theme cohered together meaningfully, and there were clear and distinct differences between themes. Finally, themes were defined in order to capture the essence of what the themes were about in order to present for analysis.

Inductive coding and thematic analysis were undertaken concurrently after each focus group. Geriatrician and pharmacist transcripts were initially coded separately and grouped into categories as appropriate. Categories for both professional groups were then combined to form overarching themes. At all times of data abstraction,

constant referral back to transcripts, demographics and inductive codes was undertaken to ensure that the analysis remained true to, and reflected appropriately, the developing themes.

5.5.6.2 Phase 2: Mapping of all determinants of deprescribing to the TDF

SS and DB re-read the transcripts and mapped all inductive codes from the phase 1 thematic analysis to the relevant TDF domain(s). The TDF domain definitions (table 5, chapter 2) were used to guide this mapping and organised the coded data within each domain into barriers and enablers to deprescribing(157). Mapping was compared and any disagreements resolved through discussion and referral to a third researcher experienced in health psychology and qualitative research (JT).

5.5.6.3 Phase 3: Prioritising TDF domains for targeting in a deprescribing intervention

The phase 1 thematic analysis provided a contextualised understanding of the barriers and enablers most important to participants for effecting deprescribing behaviour change. This information was used to prioritise the TDF domains most relevant for a deprescribing intervention. Relevant TDF domains were identified through consensus discussion between the three researchers (SS, MJT, DB) and confirmed by a health psychologist (JT).

For each theme, all barriers and enablers expressed by the collective as exerting a strong impact on deprescribing behaviour and no significant conflicting views were collated(233). The mapped domain for each of these barriers was prioritised. For the enablers, if participants expressed that a change in the status quo was required, then the associated domain was prioritised, whilst those enablers already present by virtue of implementing the intervention in the hospital setting did not lead to domain prioritisation.

5.6 Results

5.6.1 Sample

All geriatricians and pharmacists who were purposively sampled participated in the focus groups. Fifty-four participants; 28 geriatricians and 26 pharmacists,

participated across the eight focus groups. Table 13 provides participant characteristics. The mean (SD) focus group duration was 55 (5) minutes.

Table 13 Focus group characteristics

Hospital	Professional group	Number of participants	Number with prescribing authority
Hospital 1[a]	Pharmacists	8 (4 female 4 male)	3
Hospital 1[a]	Geriatricians	7 (5 female 2 male)	7
Hospital 2[a]	Pharmacists	7 (7 female)	1
Hospital 2[a]	Geriatricians	8 (3 female 5 male)	8
Hospital 3[b]	Pharmacists	6 (3 female 3 male)	1
Hospital 3[b]	Geriatricians	7 (4 female 3 male)	7
Hospital 4[b]	Pharmacists	5 (2 female 3 male)	1
Hospital 4[b]	Geriatricians	6 (1 female 5 male)	6

[a]Teaching hospital [b]District general hospital

5.6.2 Phase 1: Thematic analysis

Four themes were identified:

1. Role of different professionals
2. The inpatient environment
3. Consideration of outcomes
4. Attitudes towards medicines

Themes were recurring after the third focus group and no new themes emerged after the sixth focus group. There were no discernible differences between participants from teaching and district general hospitals or prescribing and non-prescribing pharmacists.

Role of different professionals

There was high motivation to increase deprescribing in hospital, with both geriatrician and pharmacist participants recognising that existing deprescribing practice in hospital was limited and dominated by reactive behaviour.

"I think we do a lot more reactive deprescribing probably and a lot less proactive deprescribing than we should." (Pharmacist 2, Hospital 2)

Geriatricians and pharmacists acknowledged that increasing deprescribing practice aligned with the generalist nature of their professions' roles and responsibilities. They indicated that this generalist nature meant that they could assume key roles in the deprescribing process. There was also agreed scope for other healthcare practitioners such as nurses and physiotherapists to support deprescribing in hospital. However, the role of practitioners with a restricted focus, such as therapeutic area specialists (for example cardiology, infectious diseases and surgery), was described as potentially incompatible with deprescribing for older people.

Participants indicated that junior healthcare practitioners, including junior geriatricians and pharmacists, lacked the required competencies to lead deprescribing. This was a recognised consequence of insufficient trainee healthcare practitioner experience and limited education regarding deprescribing within training programmes.

Whilst the scope for several professional groups working in hospital to contribute to deprescribing was recognised, there was consensus that overall responsibility for deprescribing in hospital rested with one nominated professional group. Participants from both professional groups agreed that geriatricians should be the professional group nominated to assume overall responsibility for deprescribing decision-making in hospital. Furthermore, in the geriatrician focus groups, many participants expressed confidence in their ability to weigh up the risks and benefits of deprescribing to inform decision-making. For geriatricians therefore, the principal barriers to deprescribing were the environmental and resource factors in the hospital setting.

"It's interesting how all of the barriers to deprescribing are practical rather than I just don't know whether I should stop it. So we're extremely competent in our ability to decide this is why this is what we should do." (Geriatrician 5, Hospital 2)

Pharmacist participants suggested their skill set better aligns with identifying potentially inappropriate medication and advising on deprescribing, which was endorsed by geriatrician participants. Pharmacist participants were reluctant to assume overall responsibility for deprescribing because of an expressed lack of confidence in decision-making.

"And then it's just the difficulty of clinical relevance of these medications and the context of the patient that maybe pharmacists wouldn't be happy with. It would have to be somebody who's feeling happy enough to do it" (Pharmacist 2, Hospital 3)

However, existing working patterns and priorities in hospital was reported to limit pharmacists' capacity to assume any role in deprescribing and was a significant barrier to them supporting deprescribing in hospital.

"The time that we have on the ward as pharmacists is well so it's basically discharges, missed doses if you can do a medication reconciliation great and that's about it. The actual clinical review of charts is so squeezed … before you know it you've been on the ward four hours and you've not really clinically reviewed anything you've just been a [discharge prescription] machine, ordered the missed doses and that's it so it's it can be difficult to clinically review stuff" (Pharmacist 5, Hospital 4)

The inpatient environment

The influence of the inpatient environment on deprescribing was discussed in relation to the interacting dynamics of the clinical picture, communication and access to resources. Both geriatrician and pharmacist participants acknowledged that there was significant scope to increase deprescribing in hospital, however at present these opportunities were not being seized. The scope to increase deprescribing was complemented by the necessary resources and capacity available in the hospital environment to safely trial deprescribing and monitor patients' responses to medication withdrawal.

"… if they're in hospital they can be monitored more closely when you do stop the more riskier medication and if they're in for a length of time like you say then there's the time to stop medication if they can be and you can essentially ensure the patients concordance if you have to titrate it down." (Pharmacist 5, Hospital 3)

Furthermore, participants were reassured by the network of other specialist healthcare practitioners working in the hospital setting available to support the deprescribing process.

Conversely, significant challenges to deprescribing in the hospital setting were acknowledged. Limited information available to hospital practitioners regarding patients' medications was raised as a barrier. Strength, dose and formulation of patients' usual medications were routinely ascertained by pharmacists on admission using various sources such as discussion with patients/family or accessing electronic medication records. However, hospital practitioners reported that key information required to determine whether deprescribing was appropriate, such as the reason why the medication was prescribed and for how long were rarely known.

"You don't always have all the information in hospital. So it's very difficult to as we said make that decision… there's always the risk you might end up stopping something they really do need. And it might not be obvious that they really do need it from the information you've got in front of you." (Pharmacist 7, Hospital 1)

Some participants thought that a potential solution to this problem is recent advances in communication with some hospitals gaining access to primary care-held comprehensive medication records. However, both professional groups were sceptical about navigating records to find the required information. This was described as a time consuming, impractical and often unsuccessful exercise.

A barrier to deprescribing was the acute nature of a hospital admission requiring prioritisation of the patients' problems requiring immediate action.

I think we're also under huge pressures to just get people out of hospital so sometimes the for ourselves and for other specialities actually let's just deal with the infection and lets concentrate on getting them out of hospital back home to a care home to rehab and certainly during the winter I think there was huge pressure there that we didn't have that opportunity so much to take a step back and think what else can we do to think about making the holistic care of the patient better… (Geriatricians 3, Hospital 2)

This was confounded by patients' artificial lifestyle whilst in hospital, including acute immobility, scheduled meals and medications being managed by healthcare practitioners. These factors were perceived to potentially distort the assessments undertaken in hospital to inform long-term deprescribing decisions.

"…things might change so dramatically when they leave hospital, either they've recovered from their sepsis and they need their antihypertensives or they've started eating again and they need more of their gliclazide..." (Geriatrician 5, Hospital 2)

Participants asserted a clear need to establish a safety net through sharing information with primary care providers responsible for ongoing care after patients are discharged from hospital. It was suggested that such correspondence could include directions for monitoring for changes that may indicate re-prescribing was necessary. However, participants agreed that the existing transfer of information between care settings is poor and may undermine deprescribing efforts.

"I think we're very bad at relaying changes to the [primary care practitioners]. I don't know about you but I get a lot of letters from [primary care practitioners] saying this person was discharged and you stopped this list of medications and then you look at the discharge letter and there's no reason why, or sometimes it doesn't mention it was stopped at all. So I think I can see how it's frustrating for [primary care practitioners] that long term medications are stopped without a rationale." (Geriatrician 5, Hospital 4)

Similarly, pharmacist participants voiced concerns regarding communicating medication changes with patients in hospital. Barriers identified included patients being unable to participate in decision-making because of ill health and deprescribing being regarded by patients as a low priority relative to the acute condition responsible for the admission. However, the availability of family members as both sources of medication information and participants in decision-making were facilitators identified by pharmacists and geriatricians.

"I think often as well patients, some patients don't take information on board quite as well because they're worried about the surgery they've got to have or you know they're kept awake all night by what's it over the ward. You know and then so actually they're just kind of nodding and but when you've got someone in their home environment they feel much more empowered perhaps and you know." (Pharmacist 2, Hospital 2)

Participants expressed disappointment about not receiving feedback on positive outcomes resulting from hospital-initiated deprescribing once patients were discharged. Both professional groups recognised the successes of schemes to incentivise changes in antimicrobial prescribing practice in the UK hospital setting. This led to suggestions that similar approaches may also be enablers of deprescribing.

"…incentives C. Diff years and years no one cared financial incentive it was sorted... Somehow that seems to be what works in community with treating and monitoring with blood pressures that seems to be working with our infection control that seems to be working with our antimicrobial deprescribing so if there is a way to measurably make this work then maybe financial incentives" (Pharmacist 7, Hospital 2)

Consideration of outcomes

The perceived risks and potential benefits of deprescribing versus continuing to prescribe were identified by participants as key factors influencing deprescribing behaviours, with decisions predicated on finely balancing the medication, the patient's clinical condition and their preferences. Potential patient orientated positive outcomes arising from deprescribing were reduced medication burden and incidence of adverse drug events leading to improved quality of life.

"They have got to try and swallow each one and they've got to read what one to take and then they've got to take them a different times and it just takes a lot out of their day. So actually if you're deprescribing and that frees up and improves their quality of life then that's our main goal." (Pharmacist 5, Hospital 2)

A reduction in unnecessary medication expenditure, reduced treatment costs associated with adverse drug events and rationalising use of health resources were suggested as potential benefits to healthcare systems. In turn, patient and health system benefits were proposed to lead to individual practitioner benefits, with geriatrician and pharmacist participants suggesting deprescribing may lead to reduced workload.

"Exactly, I mean to be honest that work life balance which we are all craving for might come back if we have prescribed just four medications rather than you know 20 that would be an advantage." (Geriatrician 2, Hospital 1)

The perceived risks of deprescribing were associated with the consequences of discontinuing a medication rather than the process itself. Potential adverse clinical outcomes were predominantly discussed, such as adverse drug withdrawal events leading to hospital readmissions and increased workload. The potential for adverse deprescribing outcomes to lead to a negative response from patients and family was recognised as comparable to any healthcare intervention. However, concerns were expressed that unrelated adverse events may be incorrectly attributed to deprescribing by patients and family.

"And all the patients I've stopped statins and then they've had heart attacks and been acute you know." (Geriatrician 1, Hospital 1)

"Even though you've stopped their statin you're like the statin is not why they've had a heart attack." (Geriatrician 6, Hospital 1)

"Exactly but there is a sort of perception." (Geriatrician 1, Hospital 1)

"That perception that can be quite a negative impact that if something then does happen to that patient that they feel it was the medication alone that was the reason not the fact that they're extremely elderly." (Geriatrician 6, Hospital 1)

"Yes." (Geriatrician 1, Hospital 1)

The potential adverse outcomes of deprescribing were balanced with those associated with medication use in older people. Deprescribing was perceived as a necessary intervention to prevent the harms associated with inappropriate medication.

"It is pretty short sighted when it comes to medication we just reap the whirlwind later on if you don't think about it [deprescribing] now." (Geriatrician 5, Hospital 2)

The absence of evidence supporting both deprescribing and prescribing of many medicines for older people contributed to the challenge of balancing the risks and potential benefits of deprescribing:

"… I mean our patients if they're on so many drugs we have really no research background to suggest what's actually happening within their body. Most of the trials are mono therapy single disease based so a lot of the evidence for

antihypertensives, statins and all of this are in not in our patient groups so the evidence base is lacking…" (Geriatrician 4, Hospital 2)

There was divergence in views between geriatrician and pharmacist participants regarding whether deprescribing was perceived to carry greater risk than continuing potentially inappropriate medicines. Pharmacist participants felt that on balance, passively continuing to prescribe a medication in the absence of an immediate need to deprescribe was safer than proactively deprescribing.

"… but we all sort of feel more comfortable because we didn't do anything [deprescribing] as opposed to I did do something [deprescribing]." (Pharmacist 2, Hospital 2)

Conversely, geriatricians felt that both deprescribing and continuing to prescribe were active decisions, with no inherent differences in the risks between the two decisions.

"I would feel better if thought has gone into either the prescribing or the deprescribing episode. Because that's on your mind when you're making those decisions you are thinking of both scenarios." (Geriatrician 4, Hospital 2)

Attitudes towards medicines

Geriatrician and pharmacist participants' deprescribing behaviour were influenced by patient, family, healthcare provider, and wider societal attitudes towards medicines. Participants felt that patients and carers were resistant to deprescribing because of their attachment to their long-term medication, which was a significant barrier to deprescribing.

"Yes sometimes patients who have been on a medication for a long long time they don't want to stop it because if we stop that one it might affect them adversely or something like that they just totally don't want to stop it." (Geriatrician 7, Hospital 1)

Conversely, participants also characterised a significant proportion of older people who disliked taking medication and are amenable to deprescribing.

Healthcare culture's attitudes towards medication use was acknowledged as changing in favour of deprescribing efforts, with the burden of inappropriate medication use increasingly recognised in calls for medicines optimisation initiatives.

"… generally medical expertise with deprescribing has improved. I think that all the sort of national drives around polypharmacy have really helped support them…" (Pharmacist 6, Hospital 2)

Nevertheless, healthcare culture's positive attitudes towards deprescribing were not perceived by participants to be reflected in treatment guidelines, which were described as overemphasising commencing pharmacological treatment in the absence of considering opportunities for deprescribing. However, geriatricians noted that deviation from treatment guidelines was a characteristic of their generalist speciality.

"Do you not think that a lot of other specialities are guideline driven the fact that they don't feel as empowered to stop it … if the patient has got something, diabetes and, they're not on those drugs and they're at risk of heart failure and it has to be quite a sort of a brave and empowered doctor to go against that. Of course we [geriatricians] don't work in a guideline driven speciality but if you are a cardiologist and somebody comes in with a myocardial infarction, they have to go home on those medications" (Geriatrician 6, Hospital 1)

5.6.3 Phase 2: Mapping to the TDF

All of the inductive codes within the four themes were mapped to nine TDF domains. These codes are presented within their respective domains, according to whether they were barriers or enablers to deprescribing (i.e. influencers of deprescribing behaviours), in table 14. Codes in the theme 'Attitudes towards medicines' were only mapped to one TDF domain, whilst the remaining three themes incorporated multiple domains

Table 14 Thematic analysis barrier and enabler inductive codes mapped to nine TDF domains

Barrier inductive code	Enabler inductive code	Theoretical domain
Theme: Attitudes towards medicines		
Patient resistance to deprescribing [G, P] Carer resistance to deprescribing [G, P] Patients perceive medications are primary care's remit [G] Societal perception that medications are always good [G] Prescribing guidelines hinder deprescribing [G] Patients are passive to medication decision-making [G] Primary care attachment to medication [G] Reactive health system culture [G] Deprescribing is not part of the culture outside geriatrics [G] Medical team unwillingness to engage with pharmacists' deprescribing recommendations [P] Patients perceive deprescribing is a cost-cutting measure [P] Historic labelling of medication as 'long term' [P] Carer may perceive deprescribing as palliation [P] Lack of confidence to approach others about deprescribing [P] Prescribing by therapeutic area specialists hinders deprescribing [P]	Patients dislike medication [G, P] Patient informed deprescribing decision-making [G, P] Patient and carer deprescribing endorsement [G, P] Patient trust in deprescribing practitioner [G] Medical team appreciation of pharmacists [P] Hospital support network [P] Primary care respect of hospital decision-making [P] National campaigns [P]	Social influence

Table 14 (continued)

Barrier inductive code	Enabler inductive code	Theoretical domain
Theme: Consideration of outcomes		
Deprescribing not followed-up in primary care [G, P]	No perceived difference in risk between deprescribing and continuing a medication [G]	Beliefs about consequences
Deprescribing may lead to patient or carer complaints [G]	Deprescribing leads to reduced medication expenditure [G, P]	
Adverse drug withdrawal events [G, P]	Failing to deprescribe may lead to adverse drug events [G, P]	
Perceived continuing medication presents less risk than deprescribing [P]	Deprescribing may improve patients' quality of life [G, P]	
Patients may incorrectly attribute future adverse events to deprescribing [G, P]	Deprescribing may lead to reduced workload [G, P]	
Deprescribing may cause readmissions [G, P]	Deprescribing may prevent readmissions [G, P]	
Primary care may not adhere to hospital deprescribing [P]	Deprescribing may reduce the need for acute interventions [G, P]	
Patients may not adhere to deprescribing [P]	Patient involvement in deprescribing decision-making absolves prescriber [G]	
Deprescribing is risky [P]	Deprescribing may lead to improved medication adherence [G, P]	
Poor deprescribing outcomes negatively impact on relationships with patients [P]	Deprescribing reduces medication burden [G]	
Deprescribing may lead to increased workload [P]	Deprescribing is a vehicle for setting realistic patient expectations [G]	
	Deprescribing leads to benefits (general) [P]	

Table 14 (continued)

Barrier inductive code	Enabler inductive code	Theoretical domain
	Deprescribing means patients are prescribed only necessary medication [P]	
Fear of deprescribing consequences [P] Fear of assuming responsibility for deprescribing [P]	Deprescribing is rewarding emotionally [G]	Emotion
Theme: Role of different healthcare professionals		
Pharmacists lack confidence in ability to make deprescribing decisions [G, P]	Confidence in ability to deprescribe [G] Pharmacists can make deprescribing recommendations [G, P]	Beliefs about capabilities
Other's awareness of deprescribing [G] Lack of guidance to support deprescribing [G, P] Lack of evidence to support deprescribing [G, P] Deprescribing education is poor [G, P] Junior practitioners lack the required knowledge to deprescribe [P]	Educational sessions [G, P] Adverse outcomes of drugs in older people [G] Lack of evidence to support use of medication in older people [G, P] Provision of evidence to support deprescribing [G] Generalists' knowledge [G, P] Deprescribing practice in Geriatrics is greater compared to other specialities [P] Awareness that deprescribing practice is limited [P] Knowledge and awareness of medicines requiring deprescribing [P] Senior and specialist pharmacists have the required knowledge to recommend deprescribing [P] Broad experience has fostered the required knowledge to deprescribe [G]	Knowledge

Table 14 (continued)

Barrier inductive code	Enabler inductive code	Theoretical domain
Deprescribing perceived to be primary care's remit [G, P] Hospital's remit is currently to address acute problems [P] Pharmacist role is currently to advise and check other's work [P] Therapeutic area specialisation hinders deprescribing [P]	Seniors to lead deprescribing [G, P] Pharmacists have a potential role in deprescribing [G, P] Geriatrician's role is to deprescribe [G] Geriatricians to oversee deprescribing [G, P]	Social/professional Role and Identity
Junior practitioners not to deprescribe [P] Deprescribing is not part of current practice [P] Deprescribing is a doctor's responsibility [G, P]	Deprescribing is not primary care's role [G] Someone needs to take ownership of deprescribing [G] Primary care responsible for ongoing monitoring [G] Empowering pharmacists to assume deprescribing roles [P] Generalist care facilitates deprescribing [P] Deprescribing is perceived to be the hospital's role [P] Pharmacists to advise on deprescribing [P] Pharmacists' role currently includes deprescribing [P] Therapeutic area specialists can advise on deprescribing [P]	
Pharmacists working patterns limits capacity to support deprescribing [G, P]	Changing pharmacists working patterns to support deprescribing [P]	Environmental context and resources
Theme: The inpatient environment		
Deprescribing is lower priority than treating acute patient problems [G, P]	Setting deprescribing goals [G, P]	Goals

Table 14 (continued)

Barrier inductive code	Enabler inductive code	Theoretical domain
Lack of feedback on positive outcomes of deprescribing [P]	'Checkbox' for deprescribing review [G] Geriatric prescribing not guided by national payment structures [G] Incentives to deprescribe [G, P] Feedback on outcomes of deprescribing [P]	Reinforcement
Poor communication both within the hospital and between the hospital and primary care [G, P] Patients are not their usual selves in hospital [G, P] Hospital is an artificial clinical environment [G] Multiple specialities managing patients hinders deprescribing [G] Insufficient time [G, P] Incomplete medication history [G, P] Unable to monitor medium-term effects [P] Lack of relationship with patients [P]	Primary care is not well resources to deprescribe [G, P] Patients present to hospital with medications requiring deprescribing [G] Opportunity to trial deprescribing [G, P] Hospital is well resourced to deprescribe [G, P] Deprescribing clinic [G, P] Community of healthcare professionals to support deprescribing [G, P] Carers accessible in hospital [G, P] Opportunity to discuss deprescribing with patients [P] Improved communication with primary care [P]	Environmental context and resources

[G] Geriatrician expressed barrier or enabler [P] Pharmacist expressed barrier or enabler

5.6.4 Phase 3: Prioritising TDF domains for targeting in a deprescribing behaviour change intervention

Figure 11 provides the five TDF domains prioritised for behaviour change targeting in a practitioner deprescribing intervention.

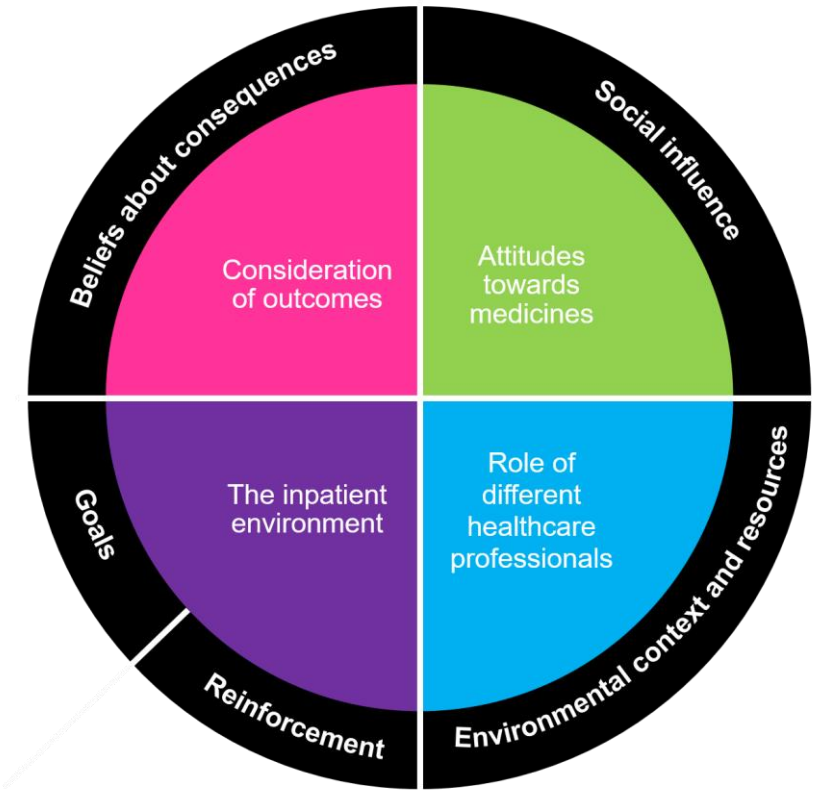

Figure 11 Themes (inner four quadrants) linked to five prioritised TDF domains (outer ring)

'Social professional role and identity' and 'Knowledge' are not prioritised domains because whilst these represented strong enablers, both geriatricians and pharmacists asserted that deprescribing aligns with existing perceptions of their complementary roles and knowledge. Similarly, 'Beliefs about capabilities' is not represented because both professions had confidence in their ability to undertake the roles that they had defined for themselves. It can be seen that the 'Emotion' domain, which was exclusively expressed with barriers by pharmacists being fearful of assuming responsibility for any negative consequences of deprescribing, is not represented. This is in recognition of participants across both professional groups agreeing that the geriatrician should be the professional assuming overall responsibility for deprescribing in hospital.

The three TDF domains of ‘Social influence’, ‘Environmental Context and Resources’ and ‘Goals’ represented strong barriers to both geriatricians and pharmacists deprescribing behaviour and therefore are prioritised for targeting. Additionally, for pharmacists the ‘Beliefs about consequences’ domain is prioritised in recognition of their perception that continuing to prescribe a medication presents less risk than deprescribing.

The ‘Reinforcement’ domain is prioritised because participants expressed a strong desire for feedback on their behaviour and patient outcomes in order to facilitate deprescribing.

5.7 Discussion

Geriatricians and pharmacists perceive that deprescribing in hospital is a part of their generalist role. The hospital setting therefore potentially offers a significant advantage over primary care for implementing deprescribing, as primary care physicians are ambivalent to undertaking this role(116). A hospital deprescribing intervention for older people led by geriatricians and supported by pharmacists was the preferred configuration with incentivisation as an enabler. The four strong barriers to address are the misconception that patients and carers are resistant to deprescribing, pharmacists’ negative beliefs about deprescribing consequences, pharmacists’ working patterns limiting their capacity to support deprescribing and deprescribing not being a hospital priority.

Key drivers emerging for implementing a hospital deprescribing intervention for older people are that both geriatricians and pharmacists perceive it to align with their ‘Social/professional role and identity’(25). They are also confident in their existing ‘Knowledge’ and ‘Beliefs about capabilities’ to undertake their identified roles. For geriatricians, this was leading deprescribing, and for pharmacists it was supporting through opportunities to deprescribe. For pharmacists to adopt this supportive role, the ‘Environmental Context and Resources’ domain needs targeting to facilitate pharmacists’ working patterns aligning with active participation in core clinical team activity(235,236).

In accordance with the primary care literature(116), pharmacists’ discussions in the consideration of outcomes theme reported numerous risks which they perceived outweigh the potential benefits of deprescribing. This may provide some explanation for the limited deprescribing activity observed in pharmacist-led hospital

deprescribing interventions(84), and indicates the importance of the 'Beliefs about consequences' domain to pharmacists' deprescribing activity. Unlike geriatricians, pharmacists reported numerous risks that they perceived outweigh the potential benefits of deprescribing. An intervention enlisting the support of pharmacists should therefore include components to recalibrate their perceptions of the relative risks and benefits of deprescribing. A notable distinction between geriatricians and, pharmacists and primary care physicians is that geriatricians expressed less concern about the risks and described numerous potential benefits. 'Beliefs about consequences' for geriatricians therefore favoured deprescribing. A further contrast between the primary care and hospital settings is that primary care practitioners perceive medicines as rarely causing adverse events(116). Geriatricians and pharmacists in this study however consistently questioned the appropriateness of medicines commonly prescribed for older people due to their potential for causing adverse drug events and limited evidence for use in this population.

The evidence presented in Chapter 4 and the wider literature suggests that deprescribing is widely acceptable to patients and carers(52,237,238), yet geriatricians and pharmacists believe there to be resistance. An intervention should therefore target pharmacists' 'Beliefs about consequences' to recalibrate their perceptions of the relative risks and benefits of deprescribing.

Encouragingly, participants felt that deprescribing is not only acceptable but desirable within the wider healthcare community(239). A restriction for primary care and therapeutic area specialist practitioners in realising this aspiration is that the national UK guidelines driving practice recommend initiation of several medications for a single health condition(116), whilst none discuss when and how to stop medication(52). Contrary to prescribing guidelines being a recognised barrier to deprescribing(52,116), geriatricians perceived deviation from guidelines as a characteristic of their speciality. However, for practitioners reticent to deviate from guidelines, emerging deprescribing guidelines are potentially relevant intervention components(65,66,71,72,240).

The inpatient environment offered enablers to deprescribing such as routine monitoring and access to multi-disciplinary teams. It also presented the barrier of prioritising acute patient problems over deprescribing. Targeting the 'Goals' domain to raise the priority of deprescribing in hospital may therefore be an appropriate solution. Encouragingly, participants acknowledged that there is significant scope to increase deprescribing in hospital(190). The proposed enabler of incentivisation

mapped to the ‘Reinforcement’ domain may be an appropriate intervention component given that it has demonstrated efficacy in influencing hospital prescribing behaviours(241).

The influencers of whether geriatricians and pharmacists deprescribe in the hospital setting have been identified and may now be mapped to the Behaviour Change Technique Taxonomy version 1 (BCTTv1)(172,220) to enable identification of evidence-based Behaviour Change Techniques (BCTs). This will provide a theory informed framework for developing and implementing a hospital deprescribing intervention targeting practitioner behaviour. Emerging patient focussed interventions such as the Eliminating Medications through Patient OWnership of End Results (EMPOWER) brochure, which is an interactive knowledge transfer tool that provides the risks associated with benzodiazepines, safer alternatives and steps for tapering(242). The theory underpinning EMPOWER is that providing the aforementioned knowledge is hypothesised to trigger patients’ motivation, capacity and opportunity to initiate deprescribing discussion with practitioners(243). Results from a cluster-RCT demonstrated a 22% increase in the rate of benzodiazepine deprescribing with EMPOWER compared to usual care in the community pharmacy setting(244). Ongoing research to evaluate the feasibility and acceptability of patient focussed interventions in the hospital setting(245) may therefore complement the programme of work in this thesis through encouraging patient engagement in practitioner-led deprescribing(221).

Data triangulation arising from intra and inter-professional convergence around the key issues was frequently observed, affording confidence in the reliability of these findings(246,247). Furthermore, the transferability of barriers and enablers between district general and teaching hospitals indicates that an intervention based on the results from this study may be applicable to multiple hospital contexts(248). Capturing the perspectives of the two professions primarily responsible for prescribing decisions for older people in the UK hospital context has allowed exploration of a wide range of barriers and enablers.

Confining the study to the UK hospital population may limit the international transferability of these findings, particularly where roles and resource factors differ from this sample. For example, in some contexts geriatricians and pharmacists may not be available to lead deprescribing, and other practitioners such as nurses may undertake the deprescribing activities of geriatricians and pharmacists described in this study. Additionally, given that even geriatricians and pharmacists in the UK

context work within a multidisciplinary team, a potential limitation of this study may be that the views of the wider team have not been fully considered. The required specificity when developing behaviour change interventions focussed this study on geriatricians and pharmacists, therefore the views of other potentially relevant professionals have intentionally not been captured. Accordingly, the adopted methodological approach could be duplicated in other countries and other professional groups, particularly where the deprescribing role is less likely to be assumed by geriatricians and pharmacists.

The results from this chapter suggest that the deprescribing research agenda to change hospital practitioner behaviour should recognise the five TDF domains of 'Social influence', 'Beliefs about consequences', 'Environmental context and resources', 'Goals' and 'Reinforcement'. A hospital deprescribing intervention for older people should focus on geriatricians' and pharmacists' behaviour within the prioritised TDF domains. Future work should identify intervention components with evidence for changing behaviour within the prioritised TDF domains, and seek to select those components that are most likely to be appropriate for operationalising in the hospital setting.

In Chapter 6, the evidence-based BCTs that are mapped to the five prioritised TDF domains will be identified and presented. Tailored selection of these BCTs according to the UK hospital context will be undertaken by geriatricians and pharmacists representative of this study sample according to whether they are likely to be affordable, practical, effective and cost-effective, acceptable, safe and equitable(249).

Chapter 6 Selecting Behaviour Change Techniques for a hospital deprescribing intervention: An expert consensus study with geriatricians and pharmacists

This chapter is in part derived from the publication:

Scott, S., Twigg, M. J., Clark, A., Farrow, C., May, H., Patel, M., … Bhattacharya, D. Development of a deprescribing implementation framework for the hospital setting: A focus group study with geriatricians and pharmacists. Age and Ageing. 2019. Accepted in press.

6.1 Introduction

Chapter 5 presented empirical research addressing a gap in the existing literature regarding the views of geriatricians and pharmacists towards deprescribing in hospital. Both professional groups expressed a strong desire to increase deprescribing activity in hospital, and that this aligned with their roles and responsibilities. A hospital deprescribing intervention for older people led by geriatricians and supported by pharmacists was the preferred configuration with incentivisation as an enabler. The four strong barriers to address are the misconception that patients and carers are resistant to deprescribing, pharmacists' perceptions that deprescribing is riskier than continuing to prescribe, pharmacists' working patterns limiting capacity to support deprescribing and deprescribing not a being a hospital priority

Chapter 2 provided the rationale for underpinning the development of interventions with theory. The Theoretical Domains Framework (TDF), was introduced and is an integrative framework of behaviour change theories for developing and implementing interventions(157). It comprises 14 domains representing determinants of behaviour. Collectively, the 14 TDF domains are linked to a taxonomy of Behaviour Change Techniques (BCTs)(220), which are the 'building blocks' of interventions that lead to behaviour change. The TDF has been applied extensively to develop interventions targeting practitioners' behaviours including promoting uptake of a screening tool in geriatric oncology(250).

The one enabler and four barriers to deprescribing identified in Chapter 5 were mapped to the TDF, and five domains were prioritised for behaviour change: Social influence; Beliefs about consequences; Environmental context and resources; Goals; Reinforcement. For these five domains, the mapping table developed by Cane *et al.*(220) provides a total of 44 linked evidence-based BCTs. Figure 12 provides the barriers and enabler to deprescribing, five prioritised TDF domains and the 44-linked BCTs as a 'hospital Deprescribing Implementation Framework (hDIF)(251).

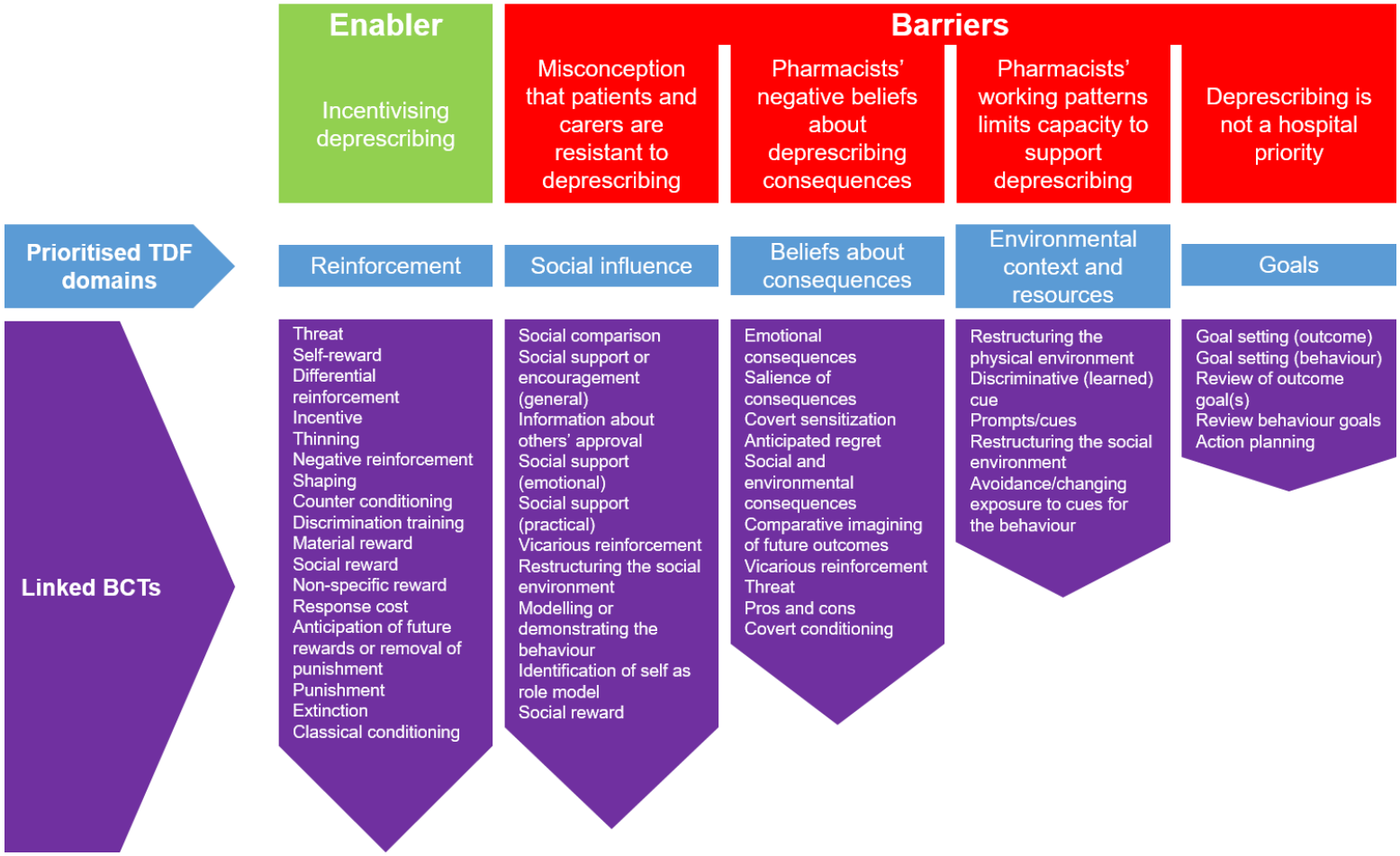

Figure 12 hospital Deprescribing Implementation Framework (hDIF)

TDF: Theoretical Domains Framework, BCTs: Behaviour Change Techniques

Selection of BCTs from the hDIF should be according to health system contexts using criteria such as APEASE (affordability, practicability, effectiveness, acceptability, safety and equity) (97), which was introduced in Chapter 2. This should be achieved through engagement with the practitioners whose behaviour requires changing using consensus methods.

6.2 Aim

To develop a theory and evidence-based intervention for geriatricians and pharmacists to implement deprescribing in the UK hospital context.

6.3 Objectives

1. To select geriatricians' and pharmacists' preferred BCTs from the hDIF (figure 12) for inclusion in a hospital deprescribing intervention
2. To characterise how selected BCTs may be operationalised in the hospital setting

6.4 Ethics approval

Ethical approval was obtained from the University of East Anglia Faculty of Medicine and Health Sciences Research Ethics Committee (Reference 2018/19 - 009). The study protocol and ethical approval letter are provided in appendices 13 and 14 respectively.

6.5 Methods

This project was overseen by the project management group described in Chapter 3.

6.5.1 Study design

Consensus methods are used in research to problem solve, generate ideas or determine priorities, and ultimately achieve agreement or convergence of opinion amongst a group or groups of stakeholders(252). These stakeholder groups are usually an expert panel, defined in this context as 'a panel of informed individuals'(253). How consensus is defined and operationalised varies

significantly(254), and is guided by the research question and methodological approach applied to achieve consensus. The two consensus methods most frequently applied in health services research are the Delphi technique and the Nominal Group Technique (NGT). These methods share characteristics with focus groups, such as generation of ideas through group interaction. However, a key difference is that whilst focus groups explore in-depth the thoughts and ideas of participants towards the subject matter, consensus methods aim to generate solutions or answers to a question.

The Delphi technique is a highly structured process involving participants responding to several iterations of a survey in 'rounds' to achieve consensus(253,255). The first round survey invites responses to statements, such as on a Likert scale with supporting extended responses. These responses are then analysed and collated, and inform the second round survey. Here, participants are provided with the first round statements, their original response and the median group response along with any extended responses. Participants are then asked to re-respond to the statements after considering the group responses; they may or may not provide a different response to round one. The number of rounds is usually determined *a priori*, with two rounds being most frequently selected. There are no rules regarding how many participants are required for a Delphi technique, and samples vary from 15 to over 60(253).

The Delphi technique it useful when working with a geographically diverse group of respondents and surveys are usually administered online for added convenience. Participants are also afforded the flexibility of asynchronous responding, however this can prolong a Delphi technique if multiple reminders are required to facilitate engagement. There is minimal interaction between respondents to Delphi surveys, which may present a disadvantage of this methodological approach depending on the study aims. Whilst respondents will be exposed to the group's responses in subsequent rounds, there is no generation of novel concepts or iteration of the presented concepts. This is likely to be a disadvantage for studies whose aim extends further than merely achieving consensus regarding concepts prescribed by those who are facilitating the Delphi technique.

NGT is another consensus method used to generate potential solutions to research questions through idea generation, problem solving, prioritisation and agreement. NGT is a highly structured and facilitated face-to-face group interaction of between two and 14 participants designed to enable presentation, listening and discussion of

thoughts and ideas through a five step cycle (figure 13)(252). Participants are usually provided with questions to consider in advance of the session.

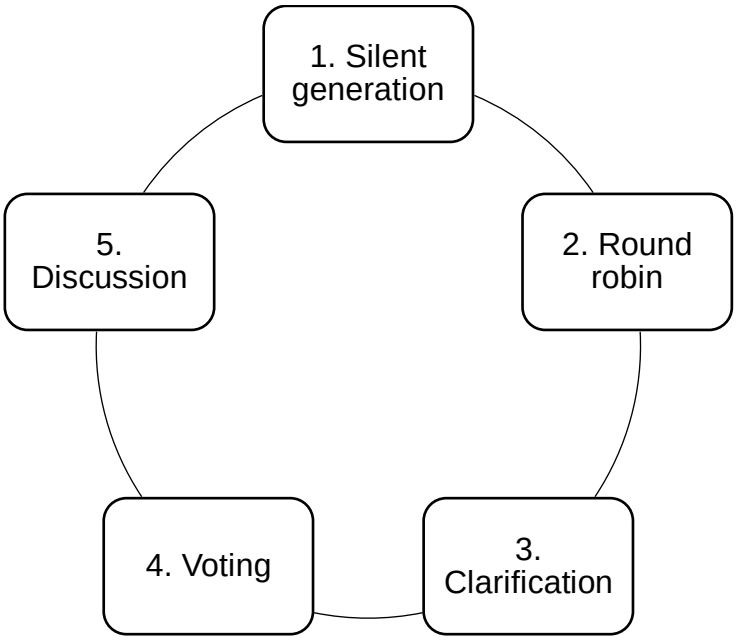

Figure 13 The five steps of Nominal Group Technique (adapted from Tully *et al.*(252))

Each round is allocated approximately 30 minutes. For silent generation, participants are allowed approximately 30 minutes to silently reflect and record their individual thoughts and ideas about the questions provided beforehand. One participant at a time is then asked to propose a single idea to the group during the 'round robin' step this is recorded verbatim. Participants are encouraged to think of new ideas during this process, however they must wait their turn before sharing with the group and no discussion of ideas occurs. The round robin stage continues until no new ideas are generated. Clarification follows, where participants are encouraged to discuss ideas and ensure understanding to enable informed decision-making. Participants are encouraged to group similar ideas together and modify or exclude ideas as necessary. Participants are then asked to select their top ideas from the previous stages and rank these in order of preference by assigning a number to each item, with a larger number indicating greater importance. The facilitator asserts the number of ideas to be ranked, with five ideas being commonly specified in the literature. Finally, the scores for each idea are summed and presented to the group for discussion. The cycle may or may not repeat depending on whether consensus was achieved via voting and/or discussion.

NGT encourages group discussion and interaction. Whilst prescribed concepts are provided to participants in advance for consideration, the first three NGT steps may result in significant interaction regarding these concepts or generation of novel concepts. This is particularly useful when concepts may not necessarily be presented in their final refined forms or where there is need to explore whether additional concepts not presented to participants should be considered. Given the face-to-face nature of the NGT, sample sizes are generally smaller than for the Delphi technique, thus findings may be less representative of a wider defined population, which is a disadvantage if generalisability is an objective. The face-to-face nature also presents the logistical challenges associated with convening sessions of approximately three hours in duration with geographically diverse participants and thus must be considered in terms of feasibility.

Some NGT studies adopt a modified approach, often borrowing elements of the Delphi technique, such as administration of a pre-NGT survey(256). In this form of modified NGT, participants complete a pre-session consensus survey and the results of which inform the latter face-to-face NGT session. An advantage of this adaptation to NGT is that an early indication of participants' views towards the research problem and the magnitude of consensus is obtained prior to the face-to-face meeting. This allows the NGT facilitator to guide the face-to-face discussion to focus on areas of non-consensus amongst participants, as informed by the survey. Removal of concepts prior to the time and resource intensive face-to-face NGT session if there is clear consensus that the concepts are not relevant to the research questions may occur.

There is a need for a consensus approach to achieve the two objectives of selecting BCTs from the hDIF and characterising the selection for inclusion in a hospital deprescribing intervention. Whilst the Delphi technique may facilitate the former objective, it will not enable the respondent group to generate and agree through discussion, characterisations of how BCTs may be operationalised. NGT would facilitate both selection of BCTs through the voting step and characterisation of BCTs, it is not feasible to discuss all 44 BCTs from the hDIF in a face-to-face NGT session. This modified NGT previously described(256) enables participants to appraise the 44 BCTs before the face-to-face meeting, allowing only those BCTs which may be appropriate for inclusion in the intervention proceeding to the formal NGT. The consensus survey would therefore likely remove a substantial number of BCTs from the process, making the face-to-face NGT session feasible.

Accordingly, an expert panel was convened to select and characterise BCTs for a hospital deprescribing intervention using a modified NGT to facilitate consensus in two stages:

Stage 1: Initial voting round (online survey)

Stage 2: Face-to-face NGT

6.5.1.1 Initial appraisal of Behaviour Change Techniques by the research team

In order to eliminate unnecessary burden on the expert panel, an initial appraisal of the 47 BCTs from the hDIF by the research team was deemed necessary to remove any which were clearly inappropriate for a United Kingdom (UK) hospital deprescribing intervention. This was achieved through an initial discussion between SS and DB which was guided by but not restricted to the APEASE criteria. The 19 BCTs proposed for exclusion plus rationale were presented to the study management group of geriatricians, pharmacists, patient and carer representatives, academic pharmacists and medical statistician, and are provided in table 15. The remaining 28 BCTs were deemed to conservatively meet the APEASE criteria.

Table 15 Behaviour Change Techniques excluded from the study through research team appraisal

Behaviour Change Technique **Definition**(172)	**Rationale for exclusion**
Misconception that patients and carers are resistant to deprescribing (barrier)	
Social support or encouragement (general) Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues,' buddies' or staff) or non-contingent praise or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the behaviour.	General social support/encouragement covered by the BCTs 'Social support emotional' and 'Social support practical'.
Pharmacists' negative beliefs about deprescribing consequences (barrier)	
Anticipated regret Induce or raise awareness of expectations of future regret about performance of the unwanted behaviour.	Pharmacists do not currently perceive failure to deprescribe as an unwanted behaviour (chapter 5) thus will not regret failing to deprescribe. Thus other BCTs require prioritisation above and beyond anticipated regret.
Comparative imagining of future outcomes Prompt or advise the imagining and comparing of future outcomes of changed versus unchanged behaviour.	Pharmacists think that the risks of deprescribing outweigh the benefits (chapter 5), therefore this BCT may reinforce failing to deprescribe.
Threat Inform that future punishment or removal of reward will be a consequence of performance of an unwanted behaviour (may include fear arousal).	Threatening a healthcare practitioner is very unlikely to be deemed acceptable and may precipitate demoralisation if presented to the expert panel in this study. Undesirable consequences may include unmotivated workforce/inappropriate deprescribing for fear of threat.
Covert conditioning Advise to imagine performing the wanted behaviour in a real-life situation followed by imagining a pleasant consequence.	Pharmacists are sceptical about the benefits of deprescribing relative to the risks (chapter 5) thus unlikely to imagine performing the behaviour.

Table 15 (continued)

Behaviour Change Technique **Definition**(172)	**Rationale for exclusion**
Pharmacists' working patterns limits capacity to support deprescribing (barrier)	
Discriminative (learned cue) Identify an environmental stimulus that reliably predicts that reward will follow the behaviour.	Pharmacists' dictated working patterns cannot be altered by pharmacists responding to a cue reward.
Prompts/cues Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.	Pharmacists' dictated working patterns cannot be altered by pharmacists responding to a cue.
Restructuring the social environment Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour (other than prompts/cues, rewards and punishments).	Pharmacists' working patterns e.g. limited or no time allocated to supporting deprescribing cannot be altered by a change in the social environment.
Avoidance/changing exposure to cues for the behaviour Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines.	Pharmacists' working patterns e.g. limited or no time allocated to supporting deprescribing cannot be altered by a change in exposure to deprescribing cues.
Deprescribing is not a hospital priority (barrier)	
Goal setting (outcome) Set or agree on a goal defined in terms of a positive outcome of wanted behaviour.	The target behaviour is deprescribing inappropriate medication; it is not appropriate to set a target of the number of medications deprescribed as this is dependent on several factors external to the prescriber e.g. presence of inappropriate medication, patient willingness to engage etc.

Table 15 (continued)

Behaviour Change Technique **Definition**(172)	**Rationale for exclusion**
Review of outcome goals Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to resetting the same goal, a small change in that goal or setting a new goal instead of, or in addition to the first.	The target behaviour is deprescribing inappropriate medication; it is not appropriate to review a target of the number of medications deprescribed as this is dependent on several factors external to the prescriber e.g. presence of inappropriate medication, patient willingness to engage etc.
Incentivising deprescribing (enabler)	
Threat Inform that future punishment or removal of reward will be a consequence of performance of an unwanted behaviour (may include fear arousal).	Threatening a healthcare practitioner is very unlikely to be deemed acceptable and may precipitate demoralisation if presented to the expert panel in this study. Undesirable consequences may include unmotivated workforce/inappropriate deprescribing for fear of threat.
Differential reinforcement Arrange reward for performance of an alternative to the unwanted behavior.	Not applicable as the target behaviour (deprescribing inappropriate medication) is the only alternative to the undesirable behaviour (failing to stop inappropriate medication).
Discrimination training Arrange for reward following the behavior in one situation but not in another.	There are no situations in which failing to appropriately deprescribe is acceptable.
Social reward Arrange verbal or non-verbal reward if and only if there has been effort and/or progress in performing the behavior.	It cannot be guaranteed that deprescribing will always lead to a positive social response
Non-specific reward Arrange delivery of a reward if and only if there has been effort and/or progress in performing the behavior.	Excluded as generic rewards already covered by material and social rewards.

Table 15 (continued)

Behaviour Change Technique **Definition**(172)	**Rationale for exclusion**
Response cost Arrange for withdrawal of something valued if and only if an unwanted behavior is performed.	This variation of threatening a healthcare practitioner is very unlikely to be deemed acceptable and may precipitate demoralisation if presented to the expert panel in this study. Undesirable consequences may include unmotivated workforce/inappropriate deprescribing for fear of threat.
Anticipation of future rewards or removal of punishment Arrange for future rewards or removal of punishments will be a consequence of undertaking the desired behaviour.	Significant overlap with incentive and threat BCTs
Punishment Arrange for aversive consequence contingent on the performance of the unwanted behavior.	Punishing a healthcare practitioner is very unlikely to be deemed acceptable and may precipitate demoralisation if presented to the expert panel in this study. Undesirable consequences may include unmotivated workforce/inappropriate deprescribing for fear of threat.

A: Affordable, P: Practical, E: Effective/cost-Effective, A: Acceptable, S: Safe, E: Equitable

All proposed BCTs for exclusion were accepted by the wider research team and thus the BCTs indicated in table 15 were excluded from the study.

6.5.1.2 Sample

A purposive sample of senior hospital geriatricians and pharmacists representative of the target audience for the deprescribing behaviour change intervention were eligible and formed the expert panel. Participants were recruited from five acute teaching and district general hospitals across three English counties to represent a range of context and resource provision.

6.5.1.3 Recruitment

An invitation email describing the study was sent to eligible potential participants via nominated gatekeepers at each of the five hospitals. The gatekeepers were members of the University of East Anglia Health Partners Medicines Optimisation Group which has representation from the five hospitals. Participants provided written, informed consent for participation in the two-stage consensus study and provided demographic information including age, gender and professional group (geriatrician or pharmacist) via the stage 1 online survey (initial voting round) described below.

6.5.2 Data collection

6.5.2.1 Stage 1: Initial voting round

6.5.2.1.1 Procedure

A survey was developed by four members of the research team with experience in the field of behavioural science (SS, DB, AD and JT), provided in appendix 15. The survey was designed to facilitate the expert panel's selection of BCTs for inclusion in the deprescribing intervention using the APEASE criteria.

The definitions provided in the Behaviour Change Technique Taxonomy version 1 (BCTTv1)(172) for each of the 28 BCTs from the hDIF retained by the research team (see 6.5.1.1) were used as a foundation for the survey statements. To enable full participation by the expert panel who were not behavioural scientists, the BCT

definitions(172) were modified into plain English statements. Additionally, for the prioritised barriers, enabler and each of the six APEASE criteria, a brief plain English statement was also prepared.

The survey therefore comprised the five sections of four barriers and one enabler, each presenting BCTs requiring a response to statements representing the six APEASE criteria. Participants were asked to rate their level of agreement with each of the APEASE criteria in relation to BCTs on a four-point Likert scale from strongly disagree to strongly agree. An optional extended response answer box was also provided for each BCT section to allow respondents to expand on their answers.

The survey was piloted and refined with the wider research group, which included senior clinical pharmacists and consultant geriatricians representative of the target audience. As the wider research group did not have experience in behavioural science, this piloting/refinement enabled identification of any difficulties with interpreting survey statements and selecting informed responses. The consensus survey was refined iteratively based on the wider research team's feedback until no further adaptations were deemed necessary.

Table 16 illustrates the presentation of the BCT 'Information about others' approval' for APEASE appraisal regarding the barrier of 'misconception that patients and carers are resistant to deprescribing' in the final survey.

Table 16 Example appraisal question for the BCT 'Information about others' approval'

Information about others' approval Tell geriatricians and pharmacists that the vast majority of patients and carers are willing to have one or more of their medications deprescribed if this is proposed by a practitioner				
	Strongly disagree	**Disagree**	**Agree**	**Strongly agree**
Affordable for my hospital				
Practical to deliver as intended				
Likely to be **effective and cost-effective** in addressing the barrier				
Acceptable to patients, carers and practitioners in my hospital				
Likely to be **safe** and free of undesirable consequences				
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender				

The final survey was hosted on the Online surveys® platform and a link to complete emailed to participants by their gatekeeper.

6.5.2.1.2 Data analysis

Descriptive statistics were reported for ratings across the APEASE criteria for each BCT using Microsoft® Excel. Consensus was defined as 80% of the expert panel agreeing or strongly agreeing that a BCT met all six of the APEASE criteria. A systematic review of methodological criteria for consensus studies reported a median threshold of 75% definition for consensus, ranging from 50-97%(254). A stringent threshold of 80% was adopted for the present study due to the anticipated relatively small number of participants and the large number of items requiring a response (six APEASE criteria for 37 BCTs). Additionally, BCTs which fail to meet the consensus threshold would not be retained, thus allowing discussions to focus on the BCTs with the greatest support.

Partial consensus was defined as 80% of experts agreeing or strongly agreeing that a BCT met at least three of the APEASE criteria; these BCTs required consensus discussions by the expert panel in stage 2. All other BCTs not achieving consensus or patient consensus were excluded from the study. Additionally, BCTs achieving partial consensus where one or more other BCTs achieved consensus for the same barrier or enabler were excluded.

Extended responses were collated for each BCT progressing to stage 2 for use during the discussions.

6.5.2.2 Stage 2: Face-to-face NGT

6.5.2.2.1 Procedure

The aims of stage 2 were to facilitate:

1. Discussion regarding BCTs achieving partial consensus during stage 1 and then re-voting to achieve consensus to include or exclude.
2. Discussion regarding characterising BCTs for operationalising in the hospital setting.

Aim 1

One NGT cycle per BCT that achieved partial consensus in stage 1 was undertaken to determine whether to include or exclude in the deprescribing intervention. Quantitative and extended responses to the online survey regarding these BCTs with partial consensus were presented. The voting round mirrored the online survey APEASE criteria appraisal. Turning Point® electronic voting system facilitated the NGT voting stages. All BCTs not achieving consensus were excluded.

Aim 2

One NGT cycle per BCT selected for inclusion in the deprescribing intervention (from stages 1 and 2) was undertaken to characterise BCTs for operationalising in the hospital setting. Participants reached consensus regarding the agreed idea or combination of ideas through the discussion step. SS and DB facilitating the discussions synthesised the agreed BCT characterisation statements in real-time.

6.5.2.2.2 Data analysis

For aim 1, real-time analysis of voting mirrored the online consensus survey analysis, facilitated by the Turning Point platform. For aim 2, generated and agreed BCT characterisation statements were recorded and validated by participants through discussions.

6.6 Results

Four geriatricians and five pharmacists were recruited, six were male and the mean (standard deviation) age of the participants was 40 (9) years.

6.6.1 Stage 1: Initial voting round

Tables 17 and 18 provide the quantitative and extended responses to the initial voting round survey respectively.

Table 17 Expert panel quantitative responses to the initial voting round survey and consensus decision regarding the 28 Behaviour Change Techniques

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	A	P	E	A	S	E	Consensus Decision
			% agreement						
Misconception that patients and carers are resistant to deprescribing (barrier)	Social influence	Social comparison	100.0	88.9	88.9	88.9	100.0	88.9	Include
		Information about others' approval	100.0	88.9	77.8	77.8	100.0	88.9	Partial consensus
		Social support emotional	77.8	33.3	33.3	66.7	100.0	100.0	Reject
		Social support practical	66.7	66.7	88.9	88.9	100.0	100.0	Partial consensus
		Vicarious reinforcement	100.0	88.9	77.8	88.9	100.0	100.0	Partial consensus
		Restructuring the social environment	66.7	44.4	77.8	100.0	100.0	100.0	Partial consensus
		Modelling or demonstrating the behaviour	77.8	66.7	88.9	88.9	100.0	100.0	Partial consensus
		Identification of self as role model	100.0	88.9	77.8	88.9	88.9	100.0	Partial consensus
		Social reward	88.9	77.8	77.8	77.8	100.0	88.9	Partial consensus
Pharmacists' negative beliefs about deprescribing consequences (barrier)	Beliefs about consequences	Emotional consequences	100.0	77.8	100.0	88.9	100.0	100.0	Partial consensus
		Salience of consequences	100.0	88.9	100.0	88.9	100.0	100.0	Include
		Covert sensitisation	77.8	77.8	66.7	77.8	88.9	100.0	Reject

Table 17 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	A	P	E	A	S	E	Consensus Decision
			% agreement						
		Social and environmental consequences	77.8	88.9	88.9	100.0	88.9	100.0	Partial consensus
		Vicarious reinforcement	100.0	77.8	66.7	88.9	100.0	100.0	Partial consensus
		Pros and cons	100.0	88.9	88.9	100.0	100.0	100.0	Include
Pharmacists' working patterns limits capacity to support deprescribing (barrier)	Environmental context and resources	Restructure the physical environment	11.1	22.2	88.9	100.0	88.9	100.0	Partial consensus
Deprescribing is not a hospital priority (barrier)	Goals	Goal setting (behaviour)	66.7	33.3	66.7	66.7	77.8	88.9	Reject
		Review behaviour goals	66.7	44.4	55.6	66.7	77.8	88.9	Reject
		Action planning (implementation intention)	77.8	77.8	100.0	100.0	100.0	100.0	Partial consensus
Incentivising deprescribing (enabler)	Reinforcement	Self-reward	88.9	77.8	66.7	77.8	77.8	77.8	Reject
		Material incentive	22.2	44.4	33.3	44.4	55.6	77.8	Reject
		Thinning	22.2	33.3	55.6	44.4	66.7	66.7	Reject
		Negative reinforcement	77.8	22.2	11.1	11.1	22.2	66.7	Reject
		Shaping	66.7	33.3	66.7	66.7	66.7	77.8	Reject
		Counter conditioning	55.6	44.4	44.4	55.6	55.6	77.8	Reject
		Material reward	0	44.4	22.2	33.3	55.6	77.8	Reject
		Extinction	55.6	44.4	22.2	22.2	44.4	77.8	Reject
		Classical conditioning	66.7	55.6	88.9	88.9	100.0	100.0	Partial consensus

A: Affordable, P: Practical, E: Effective/cost-Effective, A: Acceptable, S: Safe, E: Equitable

Table 18 Expert panel extended responses to the initial voting round survey

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
Misconception that patients and carers are resistant to deprescribing (barrier)	Social influence	Social comparison	Not sure how you'd draw attention to other practitioners and audit what they're actually doing Requires real life examples, with information about follow up as the key is deprescribing safely so its necessary to demonstrate the lack of harm. Ideally at an individual patient level as well as a health economy level. Would be more useful if built on the top of evidence based tools and lists of high risk / low value drugs too target. Perhaps patient stories on how they felt and how to successfully explain this to patients and family. Would like examples from comparable trusts The other practitioners who are successfully deprescribing should work in a comparable environment, within similar constraints of the job as those being shown By inviting successful de prescribers to local education meetings in the trust
		Information about others' approval	Is this true? What's the vast majority? Often some are quite attached to things. This could be published but wouldn't be that effective I feel This presumes we have the evidence to support this statement. Knowing that it's acceptable to patients to initiate the conversation will build confidence in professionals to broach the topic. Real examples and patient stories e.g. videos of patient interviews demonstrating the benefit would be useful, ideally in different clinical / social scenarios. The geriatricians/pharmacists would want to see evidence of this claim

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Social support emotional	What sort of emotional support - not sure this helps in any way Most likely to be achievable through clinical supervision or coaching style sessions. Could be effective if flexible and supported by the organisation to pair up supervisor and supervisee. Time and people's busy days are likely to make this hard to deliver in practice. May need to target who would benefit and at what point, or for what length of time. E.g. is this most effective if provided for the first 3 months of implementing a programmed intervention or change programme? Will be dependent on the nature of the support required I don't feel like a lack of emotional support for potential deprescribers is necessarily a barrier to deprescribing... the term 'emotional support' requires clarification I'm not sure about the practicability , acceptability or cost efficacy of this intervention

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Social support practical	Probably best idea so far - a geriatrician as lead, with a pharmacist as support may help. They need job planning time to lead education, review cases etc. If training and underpinning knowledge is sufficient and toolkit with tools provided I'm not sure what practical help would be required in person. A third person being asked to attend for this discussion may undermine the clinician-patient relationship and risks escalating the concern over why this conversation is being managed in this way. May risk development of deprescribing 'experts' being called upon to support when patients identified rather than a culture spreading through clinical staff that deprescribing is business as usual. Again dependent upon the nature of the support required I feel this is probably the most powerful intervention put forward for this barrier
		Vicarious reinforcement	Not sure how effective this would be - seems very vague Positive reinforcement, particularly if it can be kept local, could be effective. Especially if this take the form of a social movement to promote working towards a joint goal. Good examples - on line learning? Evidence base to be shared.

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Restructuring the social environment	Agree is a good idea but finding the time may be tricky On a wide scale this is likely to be expensive and therefore unaffordable. Perhaps may work for nominated leads in each Trust. Perhaps by creating a inter-Trust network of deprescribing leads. Again would be useful if this provides practical support, is relevant to my trust - could be delivered by e-learning or conference call to make this more practical to deliver They would need to be working in a similar environment to get the best results
		Modelling or demonstrating the behaviour	Acceptability will depend on the experience of practitioners - suspect less likely to be well received by experienced clinicians but could be an effective method for early years practitioners. This would be excellent - within our trust you would need a lead for this who could then set this example with colleagues.

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Identification of self as role model	Again is a bit vague - not sure this would encourage me - seems a bit sycophantic As part of a wider package this might be useful, but not sufficient alone to make an impact.
		Social reward	Gift Vouchers? Not sure this would be effective, could be abused – avoid Sounds like incentives for deprescribing. How would 'successfully engaging' be defined? Could possibly work as an award or recognition for individuals or teams that have implemented good projects or had good results through publishing audit or project writ up.
Pharmacists' negative beliefs about deprescribing consequences (barrier)	Beliefs about consequences	Emotional consequences	Not clear how this would be achieved beyond good mentoring I don't personally agree with this statement, so think it should be effective to provide the evidence of the overall benefits of deprescribing and pharmacists should then be vocal advocates.
		Salience of consequences	Is negative reinforcement better than positive? Probably not in my eyes Include in the training package as part of generating a behaviour change

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Covert sensitisation	Not sure this role pay aspect works in a busy real life situation - maybe in a classroom Happy to support if there's evidence this works as part of the behaviour change training programme. would work well with real life patient stories Real life examples of actual case studies where there was an opportunity to deprescribe that wasn't taken, and harm then occurred - appreciate that these may be difficult to find!
		Social and environmental consequences	More evidenced based may have more effect - making pricing comparisons of drugs on prescription systems (e.g. EPMA) I've always wondered if that makes a difference - would need to be integrated into existing digital systems I'd query including the financial consequences - may prove a disincentive for some if motives appear to be non-clinical I feel like the risk-focused comparison would be more effective than health/financial benefit comparison
		Vicarious reinforcement	Draw attention how? Too vague Would be interested in understanding how this could be achieved

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Pros and cons	Good idea given time - often the best way of deciding but is this practical for multi-drugs? Could be useful as part of a wider training package Pharmacists are aware of the pros of deprescribing, yet still are often averse to it, so I don't necessarily feel like listing them out will improve deprescribing rates

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
Pharmacists' working patterns limits capacity to support deprescribing (barrier)	Environmental context and resources	Restructure the physical environment	Good idea - I'd love more MDT ward rounds and have had pharmacists on ward rounds - is it practical - more time should be given to ward rounds in general - can be intimidating for pharmacists - need experience (perhaps part of training?) Changing what clinical activities pharmacists are working on is not about working patterns as much as about use of resource. Taking time for advising on deprescribing and getting involved in MDTs is a change of focus and existing workload needs to be rearranged or delegated. Needs a whole team approach and agreed model for provision of clinical pharmacy, as well as increased involvement of pharmacy technicians in meds rec etc. This is what we should be doing but currently lack the staffing to do so In my opinion, it not necessary the fact that working patterns can't allow it, but it is purely for reasoning of priority. Pharmacists are on the ward at the time of the ward round, but aren't able to join due to missed doses/discharges/MRs that unfortunately take priority This intervention will require increased number of pharmacists to provide ward pharmacy services and actively support deprescribing Not practical - no where near enough pharmacists for this to work A pharmacist on the ward rounds would be brilliant in terms of working together and deprescribing.

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
Deprescribing is not a hospital priority	Goals	Goal setting (behaviour)	Somewhat arbitrary and who decides the target - can see national guidelines would do anything other than ENCOURAGE prescriptions not DISCOURAGE them. May encourage rogue deprescribing (I've not hit my 50% warfarin deprescribing target) Setting targets may be the wrong approach unless very specific and evidence based. Getting a confirmed indication if a target may become tick box and not as effective as intended. There may not be the appropriate records in secondary care to even answer this question. Needs a whole system approach not setting expectations that this can be solved in any one sector of the NHS. The priority in hospital is medical stabilisation and discharge. Changing meds can result in destabilising the patient - need evidence this is not the case. Or agreement with GPs that they will act on advice to stop certain medicines if deprescribing identified in hospital but not acted upon. There would be a massive data collection/audit burden associated with this which I believe would make it impractical to deliver. Also, during this data collection, if you find a drug without a known indication would it be 'unethical' to leave it? Would be useful is setting aside a number of patients on the ward round that you then select for deprescribing.
		Review behaviour goals	Again who sets the targets - this isn't holistic medicine surely? Likely to be effective if implemented as part of an ongoing implementation and support programme

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Action planning (implementation intention)?	Action plans are always good - more joined up working with pharmacy and geris together has to be a good thing Likely to be effective if implemented as part of an ongoing implementation and support programme. Would like to see this as a team/trust action plan rather than for individuals - joint action and support I think this would work on a targeted basis - like the antibiotic guardian pledge - for example, "*I pledge to look further into any patient prescribed a PPI where there is no clear indication for it, with a view to potentially stopping that medication.*"
Incentivising deprescribing	Reinforcement	Self-reward	Not sure this will work. Not what CPD points are for! The motivation should be for the good of the patient not the good of the doctor! Not convinced this will be effective or there are currently effective systems to measure this Not sure I agree with this approach

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Material incentive	Material incentive? At best QOF points type system. At worst Daily Mail Headline "*Doctors denying drugs for Prizes!*" Wouldn't motivate me - may others! Cost also an issue Would need good evidence that proxy measures result in clinical impact. Would prefer to see specific targets for deprescribing and good system wide measures etc. opiate prescribing, antipsychotics in dementia Difficult. It would have to be clear that the reward was for initiating the conversation, not the actual deprescribing of a drug. Also, although practitioners would welcome this I think patients would not necessarily appreciate knowing a practitioner is getting material reward out of their healthcare.
		Thinning	As long as the measures are sensible and make sense otherwise will be a tick box exercise I wouldn't be convinced that my trust would take this on if we were talking financial incentives

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Negative reinforcement	This is the stick rather than the carrot? Rarely works Eventually the culture may change to such an extent that continuing to prescribe something that is inappropriate is clinically unacceptable and is an 'incident' but I think we are a way off that at the moment. More likely to work on an organisational level if Trusts are required to demonstrate that have training and systems in place to support this work. System wide data on specific clinical targets showing poor performance may also work, just not sure this works on the individual level. Who is going to do this Not a reasonable intervention, and would not be seen positively by practitioners. Potentially unsafe as practitioners essentially forced.
		Shaping	Deprescribing Champions is a good concept but can be lost with all the other champions in a hospital. Again not keen on the reward idea Works well in other areas e.g. CQUIN projects to start with easy goals and gradually make them harder as organisations improve. Not sure how this would work I feel like this would be a more effective intervention than 'thinning'

Table 18 (continued)

Barrier or enabler	Prioritised TDF domain	Behaviour Change Technique	Extended responses
		Counter conditioning	If we can identify the prompts and measure the % acted upon this could work well. These more measured approaches to rewards I feel are likely to be more reasonable and effective than a blanket ‘material incentive/reward’ intervention.
		Material reward	Rife for bad headlines and abuse sorry! If we want deprescribing to be seen as normal behaviour and to be adopted widely, this may disincentives uptake or embedding. Rewards for doing what some patients could be seen as the prescribers 'job' e.g. prescribing safety could be poorly received by the public. Could encourage inappropriate deprescribing
		Extinction	Not holistic - won't work Akin to CQUIN projects as long as measures realistic and were achievable. Rewards have to be worth the effort required to implement or will not be take up Once the promised rewards have been permanently discontinued, there would be no drive to even attempt the remaining targets from a rewards point of view - in fact, it may push deprescribing interventions down afterwards.
		Classical conditioning	Much more interesting - coloured digital prompts perhaps have some merit with a ‘champion’ designing, running and auditing it May not be practical dependant on which digital prescription system is used. The person needs job planned time to do this A mixed approach like this is most likely to be effective Would be interested in this approach

6.6.2 Stage 2: Face-to-face NGT

The following BCTs achieved partial consensus and thus proceeded to stage 2 for consensus discussions and re-voting:

- Restructure the physical environment (Barrier: Pharmacists' working patterns limits capacity to support deprescribing).
- Action planning (Barrier: Deprescribing is not a hospital priority).
- Classical conditioning (Enabler: Incentivising deprescribing).

The following BCTs achieved consensus at stage 1 thus proceeded to stage 2 for discussion regarding characterisation for operationalising in the hospital setting (in addition to any of the three BCTs above achieving consensus at stage 2 regarding inclusion in the intervention):

- Social comparison (Barrier: Misconception that patients and carers are resistant to deprescribing).
- Salience of consequences (Barrier: Pharmacists' negative beliefs about deprescribing consequences).
- Pros and cons (Barrier: Pharmacists' negative beliefs about deprescribing consequences).

NGT cycles for 'Restructure the physical environment' and 'Action planning' resulted in consensus to include these BCTs in the deprescribing intervention. The expert panel failed to achieve the 80% consensus threshold when voting for the practicality criterion for the BCT 'Classical conditioning' to address the enabler of incentivising deprescribing. Following the discussion NGT round, the panel suggested that this enabler would be addressed instead by 'measuring, reporting and sharing levels of deprescribing opportunities between team such as wards or hospitals'. This aligns with the BCT 'social comparison', defined as to 'draw attention to others' performance to allow comparison with the person's own performance'. The panel agreed that this newly proposed BCT met the APEASE criteria to address the aforementioned enabler, and it was selected for inclusion in the deprescribing intervention.

The characterised BCTs are provided in table 19. For the BCTs of 'Social comparison', 'Salience of consequences' and 'Pros and cons', the characterisation

statements are unchanged from the plain English descriptions synthesised by the research team in stage 1.

Table 19 Six Behaviour Change Techniques selected and characterised for operationalisation in a hospital deprescribing intervention

Behaviour Change Technique	Characterisation
Misconception that patients and carers are resistant to deprescribing (barrier)	
Social comparison	Draw attention to practitioners through weekly departmental bulletins who are successfully deprescribing by navigating any challenges of patients and carer resistance to deprescribing
Pharmacists' negative beliefs about deprescribing consequences (barrier)	
Salience of consequences	Emphasise the benefits of deprescribing and harmful consequences of failing to deprescribe in terms which will resonate with pharmacists e.g. a 30 minute online training session
Pros and cons	Advise pharmacists to list and compare the advantages and disadvantages of actively supporting deprescribing of inappropriate medication e.g. a 30 minute online training session
Pharmacists' working patterns limits capacity to support deprescribing (barrier)	
Restructure the physical environment	Pharmacists to attend short multi-disciplinary team meeting e.g. 30 minute geriatrician-led multidisciplinary team meeting to enable them to actively support deprescribing
Deprescribing is not a hospital priority (barrier)	
Action planning	A senior geriatrician and pharmacist to engage with senior managers such as the medical and nursing directors to develop an organisational-level action plan. The action plan is to comprise of setting deprescribing as a high organisational priority goal and specifying locally relevant steps to achieving the goal and specifying who is responsible within the organisation for contributing towards the goal.
Incentivising deprescribing (enabler)	
Social comparison	Measuring, reporting and sharing the proportion of patients screened for deprescribing opportunities between hospital wards, hospitals and regions.

6.7 Discussion

This study demonstrates the methodological approach by which the hDIF is operationalised to develop a theory and evidence-based hospital deprescribing intervention tailored to contextual factors, using the UK setting as an exemplar.

Engagement with the practitioners whose behaviour requires changing has led to selection and characterisation of six BCTs to support implementation of deprescribing in the UK hospital context.

The action plan and training elements of the deprescribing intervention are designed to create an environment that promotes engagement with deprescribing. Restructuring pharmacist working patterns and the sharing of practice are designed to perpetuate deprescribing activity. The dual-nature of the resultant intervention departs from previous trials that report a focus purely on perpetuation of activity, for example by providing a guide for identifying deprescribing opportunities. The absence of components within these interventions to support initial engagement with deprescribing may provide some explanation for their lack of efficacy, even within a resource intensive trial environment which may in itself support perpetuation(84).

Selection of 'Action planning' at the organisational level aims to establish deprescribing as a priority through specifying where, when and how the hospital's deprescribing goals will be achieved. "*Action plans specify where, when and how a goal will be implemented and help individuals plan the specific actions they will take to achieve their overarching goal"*(257). Action plans have been frequently used to promote behaviour change in the healthcare setting. An intervention comprising action planning alone resulted in 53% of patients with coronary heart disease adopting healthier health related behaviours such as improvements in diet and increasing regular exercise(258).

The two BCTs selected to address the barrier of pharmacists' beliefs about negative deprescribing consequences recognise the findings from Chapter 5 that senior pharmacists have appropriate knowledge regarding the risks and benefits of prescribing and not deprescribing. The 'Salience of consequences' and 'Pros and cons' BCTs therefore request pharmacists to cognitively appraise deprescribing opportunities, focussing on the likelihood and evaluation of the consequences of deprescribing versus failing to deprescribe(259). These BCTs may be delivered through training, which could be online or face-to-face. It may be possible to combine these BCTs with a recently developed survey to measure practitioners' deprescribing self-efficacy (240). The survey may serve as a 'readiness test' undertaken after training to ensure pharmacists are prepared for deprescribing activities.

The ‘Social comparison’ BCT was selected to address both the barrier of misconception that patients and carers are resistant to deprescribing and enabler of deprescribing incentivisation, with distinct characterisations for both. For the barrier, selection of alternative BCTs such as providing evidence to align practitioners’ views with the evidence that patients/family endorse deprescribing in hospital(260), via the BCT ‘Information about others’ approval’, may have been expected. However, practitioners rated ‘Social comparison’ more favourably in terms of effectiveness, suggesting that observing a peer successfully agreeing deprescribing with a patient/family member resonates more with practitioners than simply being told this is possible.

The expert panel’s decision to address the enabler of reinforcing deprescribing with a BCT not presented in the implementation framework is of interest. Given that the BCTs for reinforcement in the implementation framework relate either to incentivisation or punishment, it is likely that neither were acceptable due to both being perceived as unethical. This is supported by the extended responses and low agreement with the ‘acceptability’ criterion regarding reward BCTs. Whilst incentivisation to change practitioners’ prescribing behaviour is common practice, for example promoting appropriate antimicrobial prescribing(241), rewards are usually provided to the organisation and not practitioner(241). The hDIF does not stipulate that rewards should be at the practitioner level, however, the plain English description of each linked BCT provided in the online survey did contextualise reward BCTs at the practitioner level to aid interpretation. This may have influenced the panel’s decision-making, and future applications of the hDIF should therefore avoid prescribing BCTs with this degree of specificity where possible. Alternatively, practitioners may have simply perceived ‘Social comparison’ which they proposed in preference to incentives and punishments as a superior BCT for reinforcing deprescribing behaviour.

This study has applied a modification of a structured and widely used consensus method in order to support an expert panel of geriatricians and pharmacists to select BCTs for inclusion in a novel deprescribing intervention. The modified NGT drew on key elements of the Delphi technique in terms of the initial voting round, which informed a traditional NGT. This hybrid approach ensured that appraisal of a large number of BCTs by an expert panel was feasible, whilst also enabling the panel to focus on certain BCTs for further discussion and characterisation.

Initial appraisal of the 44 BCTs included in the hDIF by two members of the research team resulted in the exclusion of BCTs which were deemed inappropriate for a UK hospital deprescribing intervention. This was undertaken in order to increase the feasibility of the study by removing BCTs which experts clearly did not need to spend time appraising. However, there is a risk that this process resulted in the removal of BCTs that the expert panel may have deemed appropriate for the deprescribing intervention. Efforts were made to minimise this risk, including the initial appraisal being undertaken by two pharmacists with an understanding of the UK hospital context and subsequent validation of the decision-making by the wider research team, which included geriatricians and pharmacists representative of the expert panel members.

Whilst the number of expert panel members was relatively small for a survey study, a high consensus threshold of 80% across all six APEASE criteria was set in order to minimise the uncertainty introduced by the small sample size. The aim of this study was to develop an intervention bespoke to the English setting and thus international transferability was not intended. However limiting the study to geriatricians and pharmacists representing hospitals from three East of England counties may limit transferability of the resultant intervention nationally, particularly to hospital contexts differing significantly to the included sample. Efforts were made to minimise this, such as representation of both district general and teaching hospitals which differ in terms of resources and patient acuity(222–224). During the NGT BCT characterisation discussions, the panel alluded to some of these differences at their own hospitals such as whether medicines were prescribed using electronic or paper-based systems.

Engagement from the target audience of a behaviour change intervention in the development process is pivotal to intervention success(96,97). The development of the hDIF was informed by the barriers and enablers to deprescribing in hospital from the perspectives of geriatricians and pharmacists, as described in Chapter 5. The present study adds a further layer of engagement to the development of a novel deprescribing intervention by going back to the target audience for selection of BCTs from the hDIF.

Five of the six BCTs selected by the expert panel were options provided by the hDIF for the prioritised TDF domains and related barriers to deprescribing. This triangulation between BCTs provided by the hDIF and what the expert panel perceive as appropriate for inclusion in a deprescribing intervention affords some

confidence that the hDIFs is a valid framework for application for this purpose. However, further exploration regarding selection of a non-mapped BCT to address the enabler of 'Incentivising deprescribing' in warranted. As discussed above, this may be a limitation of the stage 1 plain English descriptions synthesised for the online survey unduly influencing the expert panel's interpretation of relevant BCTs. Whist the online survey was informally piloted with non-experts in behavioural science and no issues were identified, these were members of the research team who may not have been sufficiently naïve to the programme of work. Accordingly, future studies applying the hDIF using a similar methodological approach should consider formal piloting using appropriate methods such as the 'think aloud' applied in Chapter 4.

Hospital deprescribing interventions should attend both to the barriers of initiating deprescribing activity and strategies to perpetuate. The hDIF has been successfully applied in a consensus study with the practitioners whose behaviour requires changing to select six intervention components to address the barriers and enabler to deprescribing in hospital. The selected intervention components have been characterised and are the active ingredients of a novel deprescribing intervention for the UK context.

Chapter 7 Discussion

7.1 Overall thesis discussion

This is the first programme of work developed using behaviour change theory to develop a deprescribing intervention to address inappropriate polypharmacy in the hospital setting. Reactive and proactive deprescribing have been conceptualised and it was identified that the latter does not routinely occur in the hospital setting. Older patients and their carers expressed that deprescribing in the hospital setting was acceptable to them. Patients and carers were also clear that deprescribing must be initiated by their doctor thus it was established geriatricians are the target audience for behaviour change. Furthermore, the availability of pharmacists in the hospital setting provides a unique opportunity to identify inappropriate medicines and make deprescribing suggestions to geriatricians caring for older people. Accordingly, pharmacists were also established as the target audience for behaviour change. Unlike GPs, geriatricians and pharmacists identify that they have the required knowledge and skills to undertake their defined roles. Moreover, the hospital setting offers existing enablers to deprescribing such as provision of routine patient monitoring and access to the wider multidisciplinary team of healthcare practitioners. However, several barriers to deprescribing by geriatricians and pharmacists were identified which required addressing including it being a low organisational priority, a misconception that patients and carers are resistant to deprescribing and a negative belief about the consequences of deprescribing. Finally, the Behaviour Change Techniques (BCTs) to address the barriers and enablers to deprescribing in the hospital setting which are most likely to be acceptable, effective and practical to implement in this environment have been identified and are the active ingredients for a novel intervention.

During the course of this PhD, there have been significant developments to the wider deprescribing landscape globally. 'Deprescribing networks' have evolved through bringing together healthcare professionals, researchers and policy makers to collaboratively formulate strategies to address inappropriate polypharmacy. As of 2019, five networks have been established: United States National Network on Deprescribing; Canadian Deprescribing Network; English Deprescribing Network; Northern European Researchers in Deprescribing; Australian Deprescribing Network. A key objective of the English Deprescribing Network is to "*improve communication between patients and clinicians and shape the national strategy around appropriate prescribing and the avoidance of medicines-related harm.*" The network hopes to achieve this through facilitating work which will "*support the… behavioural change required to ensure people are taking the right medicines*"(261).

Whilst deprescribing networks have led to the development of evidence-based deprescribing guidelines(65,66,71,72) which support decision making, particularly where knowledge and skills deficits are a barrier to deprescribing, they do not consider how to operationalise deprescribing. The research in this thesis provides the evidence-base and theory required to operationalise deprescribing in the hospital setting.

Prior to commencing this PhD, the existing body of research had focussed on practitioners and patients in the primary care setting; a 2014 systematic review of prescribers' barriers and enablers to deprescribing demonstrated this trend, with 20 out of the 21 eligible studies being in primary care(116). This focus is understandable given that the vast majority of medicines are prescribed by primary care practitioners. For example, in England 98% of prescriptions are generated by general practitioners (GPs). There is therefore a clear need for primary care interventions targeting GPs' deprescribing behaviour. Accordingly, in May 2018 the UK National Institute for Health Research funded the 'Improving Medicines use in People with Polypharmacy in Primary Care' project through its Health Services and Delivery Research programme(262). The project aims to develop and test an intervention to improve how polypharmacy is managed, including deprescribing, through the development of a novel intervention.

There is acknowledgement that tackling inappropriate polypharmacy requires interventions in primary care, hospital and at the interface between the two settings(38). This is reinforced by Health Education England through its 'Making Every Contact Count' initiative, which encourages practitioners to use every opportunity arising from interactions with patients to make positive improvements on health and wellbeing(263). Over half of older people in hospital are prescribed at least one pre-admission medicine that is potentially inappropriate and thus requires review to determine suitability for deprescribing(34). An admission to hospital is an opportunity for a holistic review of a patient's medication, which has led to calls for practitioners to undertake a generalist review of patients' medications(38) to tackle inappropriate polypharmacy. However, the evaluation of deprescribing in Chapter 3 identified that this rarely happens in the one hospital where activity was explored(190). Whilst there are deprescribing networks and guidelines rapidly being generated and tools available to inform the process, they do not seem to have translated into hospital deprescribing practice locally. There is no reason to suggest that this is likely to be different elsewhere. Contrary to the calls for addressing inappropriate polypharmacy in hospital, an Irish longitudinal study including 38,299

older patients found that for patients admitted to hospital, the likelihood of being prescribed a PIM at discharge was higher than before the admission (adjusted odds=1.72 (95% confidence interval 1.63 to 1.84) (37). It is unsurprising therefore that GPs are amongst those leading calls for the hospital setting to assume a role in deprescribing(264). The resounding acceptability of deprescribing in hospital indicated by the patients and carers surveyed in Chapter 4 further endorses a research focus on hospital deprescribing(260). Finally, the exploratory focus groups undertaken with hospital practitioners in Chapter 5 confirmed that several of the key components for safe and effective deprescribing such as medication history and routine monitoring were already available to them in hospital(60).

Polypharmacy often spans multiple therapeutic areas therefore requires generalist strategies to address the problem at scale. Generalist practitioners such as pharmacists and geriatricians are described by GPs as best placed to provide a generalist review of polypharmacy and deprescribe accordingly(264). Conversely, specialists in hospitals with a restricted therapeutic focus may not feel able to provide this generalist review, particularly those who's prescribing is driven by guidelines which rarely advise on deprescribing(50,52).

Successful deprescribing within a restricted therapeutic focus has been demonstrated to be safe and feasible in the ECSTATIC cluster randomised non-inferiority trial of deprescribing preventative cardiovascular medication in primary care(265). Whilst the development of the ECSTATIC intervention has not been comprehensively reported, it appears to have been designed cognisant of the known barriers to deprescribing in the primary care context. Briefly, the intervention comprises providing knowledge to GPs and nurses in a two hour workshop led by a GP with a special interest in cardiology. The difference in the primary outcome of predicted cardiovascular risk between the intervention and control groups fell within the non-inferiority margin, and the authors concluded that deprescribing preventative cardiovascular medication is safe. ECSTATIC has clearly made a valuable contribution to the literature by establishing the safety and feasibility of deprescribing with a restricted therapeutic focus in primary care. As intervention efficacy is specific to both the setting and the nature of the behaviour(249), the ECSTATIC intervention is unlikely to be directly transferable to the hospital polypharmacy context.

Akin to prescribing, deprescribing is a patient-centred process(60) and the importance of understanding the views of patients and carers has been emphasised

in the literature(98) and is reflected in the patient and public involvement from inception to completion of the programme of research included in this thesis(260).

In addition to the primary care focussed practitioner literature, there has been substantial research internationally exploring the views of patients towards deprescribing. For example, the rPATD has been used in studies across several countries and in various care settings including the United States of America(266), Australia(267) and Malaysia(207), all reporting similar results to those in Chapter 4. This high agreement with deprescribing has led researchers and practitioners to focus on targeting patients' behaviour in order to increase deprescribing activity.

The EMPOWER (Eliminating Medications through Patient Ownership of End Results) is a patient-educational intervention booklet providing knowledge about benzodiazepine deprescribing which aims to encourage patients to initiate deprescribing discussions with practitioners. The EMPOWER booklet was tested in 2019 in a feasibility study of a randomised controlled trial (RCT) in the Australian hospital setting(245). Delivering the booklet to patients was feasible, however there did not appear to be a trend towards more deprescribing discussions being initiated by intervention participants and the rates of deprescribing at one-month post discharge were comparable. This was a feasibility study and therefore not designed to detect a difference, the authors concluded that definitive trials were indicated in order to determine whether EMPOWER is effective in the hospital setting.

Whilst the delivery of a patient-centred deprescribing intervention may be desirable under certain circumstances(245), two key considerations mean that it deviates from the programme of work described in this thesis. Firstly, as described above, a focus on polypharmacy, rather than medicines within a specific therapeutic area may yield greater benefits(268). Secondly, the results presented in Chapter 4 suggest that patients and carers in the hospital context want practitioners to initiate deprescribing discussions, rather than this being their responsibility. This finding was replicated in a recent administration of the rPATD in the Australian primary care context(267). The gap in the literature addressed by this thesis was therefore the development of a hospital intervention targeting the behaviour of geriatricians and pharmacists.

The majority of existing deprescribing intervention studies report deprescribing of PIMs as defined by criteria such as STOPP(84). The Chapter 3 evaluation of existing deprescribing activity in hospital identified that deprescribing in response to an adverse clinical trigger such as suspected medication related kidney damage,

dominated deprescribing activity(190). In contrast, deprescribing medicines if future gains were unlikely to outweigh future harms was infrequent. This led to coining of the terms ‘reactive deprescribing’ and ‘proactive deprescribing’. This characterisation of the observed deprescribing activity in the hospital setting indicates that these are two discrete behaviours with different behavioural determinants and therefore likely different intervention components to effect behaviour change and therefore should not be reported as an amalgam.

The Medical Research Council’s (MRC) guidance on developing and evaluating complex interventions emphasises the importance of ‘Identifying the evidence base’ and ‘Identifying/developing theory’(96). The Theoretical Domains Framework (TDF) underpinned focus groups with geriatricians and pharmacists in Chapter 5 fulfilled both the requirement of ‘Identifying the evidence base’ and ‘Identifying/developing theory’. The existing work by Cane *et al*. which maps each TDF domain to a taxonomy of 96 Behaviour Change techniques (BCTs)(220) enabled progression from characterising deprescribing behavioural determinants in Chapter 5 to selecting BCTs in Chapter 6.

The richness of data generated from the qualitative approach adopted was essential to the application of the TDF for understanding behaviour change mechanisms. Mapping of qualitative data to the TDF often results in the full range of domains being ‘active’ in the data(159). This is unsurprising given that researchers undertaking qualitative studies using the TDF aim to explore all potential barriers and enablers within each domain, therefore topic guides and interview schedules are structured accordingly. Previous studies have then reported that most or all TDF domains should be targeted for behaviour change in a subsequent intervention, with all 96 BCTs being intervention candidates(159). Reporting most or all TDF domains as requiring targeting in an intervention indicates that the precise mechanism by which behaviour change may occur has not been established. Instead, TDF domains which may be of little relevance are likely to have been captured and proceed to be targeted using BCTs within an intervention. This inefficiency adds unnecessary complexity to what is already a complex intervention. For interventions intended for implementation in contexts with scope for provision of limited or no additional resources, inclusion of BCTs that are not necessary is counterproductive and limits the likely feasibility and potential efficacy of the intervention(269). There should therefore be a focus on targeting TDF domains that are essential for behaviour change. Accordingly, there was a need in this thesis to prioritise TDF

domains in terms of their relative importance to geriatricians' and pharmacists' deprescribing behaviour.

New guidance for using the TDF emerged in 2017, which included references to more recent studies which have attempted to prioritise TDF domains(159). Unlike the novel approach adopted in Chapter 6, the majority of these studies resorted to counting utterances of qualitative data mapped to TDF domains, with domains containing more mapped data being prioritised. The limitation of this approach is that it does not accurately capture the extent to which participants express the relative importance of a barrier or enabler within the mapped text. It may be that participants spent little time discussing a fundamental barrier, for example because they felt it could not be addressed. In contrast, inductive thematic analysis enabled barriers and enablers expressed by the collective as having a strong impact on deprescribing behaviour in the absence of conflicting views to be identified and the TDF domains prioritised.

Chapter 5 demonstrated that some of the barriers and enablers to deprescribing span both the primary care and hospital settings. The barrier of practitioner perception that patients are resistant to deprescribing cited by GPs(116) was echoed by geriatricians and pharmacists in Chapter 5. The conclusion from Chapter 4 that patients and carers are amenable to deprescribing in hospital suggests that the aforementioned barrier is in fact a misconception by geriatricians and pharmacists in the UK hospital context. The extent to which this barrier is a misconception by GPs, rather than genuine patient resistance in the primary care context, is unclear given that the revised Patients' Attitudes Towards Deprescribing (rPATD) questionnaire has not been used in the UK primary care setting. Research in the primary care setting to establish patient attitude towards practitioner initiated deprescribing discussions is therefore warranted. Such research will guide selection of intervention components according to whether or not perceived patient and carer resistance is a misconception by GPs or whether it is an accurate representation of patient and carer attitudes towards deprescribing in the primary care setting. Clear distinctions were also identified in Chapter 5 between the primary care and hospital settings in terms of the barriers and enablers to deprescribing. This reinforces the need to develop deprescribing interventions which are context specific and endorses the methodological approach adopted for the research in this thesis.

Given the global appetite for all care settings to contribute to deprescribing(38,270), the findings from this thesis demonstrate a need to develop interventions that are

tailored to the barriers and enablers of specific contexts. The 'Improving Medicines use in People with Polypharmacy in Primary Care' programme of work is focussing on developing an intervention which achieves this for the primary care context, for example the intervention is likely to include training to address the barrier of lack of knowledge and skills regarding how and when to deprescribe(116,271).

The limited success of previously reported hospital interventions may be attributable to their incorrect focus on addressing lack of knowledge and skills through providing PIM screening tools such as FORTA(69) and STOPP(31). This is unsurprising given that the literature available prior to this thesis designated a lack of knowledge and skills as a key barrier, notwithstanding that this is derived from a primary care perspective. However, this contradicts the hospital context work undertaken in Chapter 5, which identified that geriatricians and pharmacists perceive themselves to already have the required knowledge and skills to deprescribe. Failure to identify and address a gap in the evidence base has led to previous hospital deprescribing interventions not addressing the determinants of deprescribing identified in Chapter 5. Moreover, previous intervention have included components which are redundant via targeting a barrier that does not apply to the hospital setting. As discussed earlier in this chapter, redundant components may impede the feasibility and potential efficacy of interventions by detracting from target audience engagement with components which are essential(269). Nonetheless, PIM screening tools are likely to be useful in trials of hospital deprescribing interventions for research purposes to evaluate the extent to which deprescribing opportunities are addressed, or where BCTs involving monitoring and/or feedback on behaviour are indicated.

The hospital Deprescribing Implementation Framework (hDIF) introduced in Chapter 6, provided a framework of 44 BCTs corresponding to five prioritised TDF domains for developing a hospital deprescribing intervention. Selecting BCTs from the hDIF should be informed by the context in which the intervention is intended to be delivered. For example, whilst the barrier of misconception of patient and carer resistance to deprescribing may apply to both primary care and hospital practitioners, the most appropriate BCT is likely to differ. There is variation in practice for selecting BCTs for inclusion in an intervention. Historically, BCTs have been selected by the research team developing the intervention(175,272,273). This may be due to researchers considering that context has been fully considered by engaging with the target audience during the process of exploring the barriers and enablers to the behaviour in a similar manner to Chapter 5. The limitation of this methodological approach is that the research team may have less contextual insight

than the target audience in terms of a BCT's affordability, practicability, effectiveness, acceptability, safety and equity (APEASE)(97).

The added value of working with the target audience to select BCTs was demonstrated in Chapter 6 for the enabler of 'incentivising deprescribing'. The target audience emphatically rejected 'reward' related BCTs, describing these as incompatible with the behaviour of deprescribing. Since rewards have been successfully used in the hospital setting previously to change antimicrobial prescribing behaviour, it is possible that researcher-led selection of BCTs may have resulted in inclusion of similar BCTs in a hospital deprescribing intervention(241). The resultant intervention would likely have been highly unacceptable to the target audience.

Whilst the barriers and enablers and TDF domains included in the hDIF were derived from empirical work in the English hospital context, there are several BCTs available for each prioritised TDF domain which may be selected from. The implications of this is that the hDIF may be appropriate for developing practitioner behaviour change interventions for hospitals beyond the English context, providing the barriers and enabler that require addressing align with those included in the hDIF. Contextual factors will then influence which BCTs are selected to include in the intervention to address the barriers and enabler.

The evidence base, underpinning theory and intervention components (i.e. BCTs) relating to the development of complex interventions are often represented as logic models(96). These describe an intervention, its causal assumptions and the process and clinical outcomes. This provides a diagrammatic representation of the hypothesised mechanism by which an intervention is intended to produce its effects(274). Arrows are used to represent the causal mechanisms between key aspects of the logic model. Figure 14 provides a logic model for the behaviour change intervention developed in this thesis. The 'problem' and 'context' components of the logic model have been informed through identifying the evidence base via the empirical work undertaken in Chapters 3, 4 and 5. Chapter 2 identified the most appropriate theory to underpin the programme of research whilst Chapters 5 and 6 populated the theoretical determinants and behaviour change techniques respectively. Figure 14 does not provide the intended outcomes for the intervention, as defining definitive trial outcomes was beyond the scope of the early developmental work undertaken in this thesis. Section 7.3 Implications for research and future research plans provides recommendations accordingly.

Logic models are useful because they inform the evaluation of complex interventions by informing the structure and prioritisation of data collection. The causal mechanisms described in a logic model should be tested prior to a definitive trial to determine whether the intervention works as intended, with potential refinements made to the logic model as necessary. Recommendations for refinement and testing of the intervention developed in this thesis are discussed in section 7.3 Implications for research and future research plans.

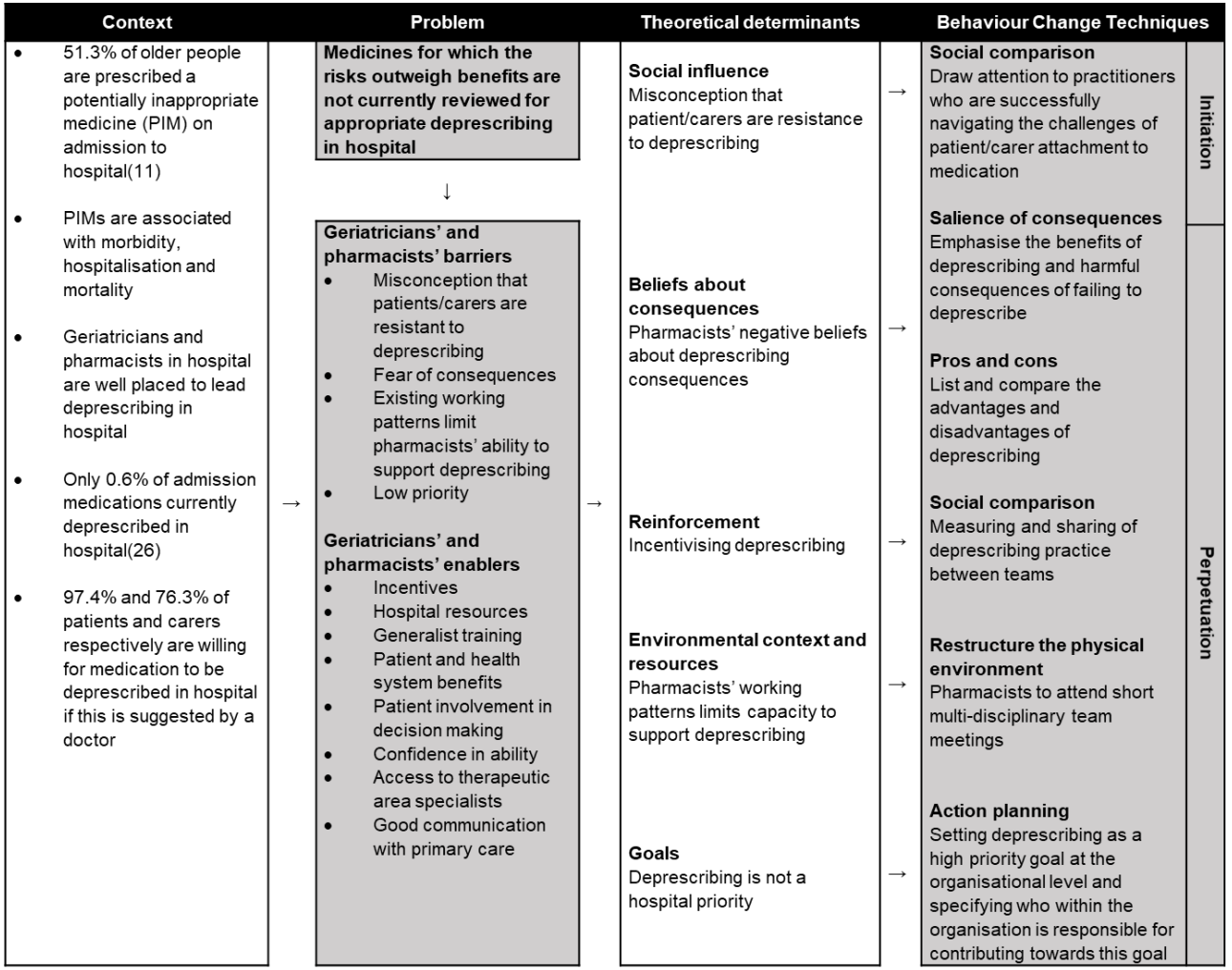

Figure 14 Logic model for the development of a practitioner behaviour change intervention for deprescribing in the hospital setting

7.2 Implications for practice

A hospital deprescribing intervention should therefore include components to address the barriers of a misconception that patients and carers are resistant to deprescribing, pharmacists' negative beliefs about deprescribing consequences, pharmacists' working patterns limits capacity to support deprescribing and deprescribing is not being a hospital priority. A component(s) should also be included which addresses the enabler of incentivising deprescribing. The most appropriate configuration for the intervention is inclusion of the following BCTs:

- Social comparison: Draw attention to practitioners who are successfully navigating the challenges of patient/carer attachment to medication
- Salience of consequences: Emphasise the benefits of deprescribing and harmful consequences of failing to deprescribe
- Pros and cons: List and compare the advantages and disadvantages of deprescribing
- Social comparison: Measuring and sharing of deprescribing practice between teams
- Restructure the physical environment: Pharmacists to attend short multi-disciplinary team meetings
- Action planning: Setting deprescribing as a high priority goal at the organisational level and specifying who within the organisation is responsible for contributing towards this goal

Chapter 6 described selection and characterisation of these BCTs according to the English hospital setting. Granular detail regarding the characterisation is intentionally not provided for the BCTs in terms of how they will be operationalised in practice. This scope for adaptation is necessary when developing behaviour change interventions in terms of implementation at scale, as it provides scope for local adaptation at the individual hospital or ward level. Adaptation is an essential process to align the intervention with the needs of the target audience, organisation resources and to gain trust and ownership by the target audience(275). Adaptation of the intervention to 'fit' the local context facilitates successful implementation and sustainability(275).

Positive results from a definitive trial testing the practitioner behaviour change intervention will have significant implications for practice. Widespread implementation across English hospitals will hopefully lead to an increase in

deprescribing of inappropriate medication and associated positive outcomes for patients, practitioners and the NHS(190). There are, however, further indirect implications for practice arising from this programme of work.

The focus groups in Chapter 5 identified the barrier of insufficient deprescribing education for trainee doctors and pharmacists. Whilst the geriatrician and pharmacist participants were able to circumvent this barrier through post qualification education, and peer and experiential learning, this lack of education and training precluded junior practitioners from actively participating in deprescribing. This same barrier has been expressed by GPs(116), and may also extend to therapeutic area specialists in hospital who may not have the enabling knowledge and experience described by the focus group participants. Ultimately, medicines optimisation(7) and good prescribing practice(20) is the responsibility of all practitioners involved in medicines management for patients. With deprescribing being a core component of both, practitioners beyond those specialising in geriatrics and pharmacy should contribute to deprescribing. Accordingly, deprescribing should be included in the education and training of healthcare practitioners in order to equip the healthcare workforce to routinely support deprescribing.

The calls from GPs for hospitals to assume a greater role in deprescribing are contingent on effective communication of deprescribing decisions by hospitals to primary care(264). This includes conveying why a medication has been discontinued and clear instructions regarding the monitoring GPs are expected to undertake. Whilst not prioritised as a key barrier in Chapter 5 as it does not independently hinder hospital deprescribing, poor communication between hospitals and primary care was acknowledged as requiring improvement to ensure that deprescribing is safely monitored long-term post-discharge. A key requirement to comprehensive communication of medication changes at discharge is effective recording of the changes during the admission. The data form the evaluation of deprescribing activity in hospital from Chapter 3 suggests that this requirement is not met for a substantial proportion of medication discontinuations in hospital(190). Hospitals need to develop strategies to effectively document medication changes, preferably in real time. Systems for automatic transfer of this information into discharge letters may help address the concerns regarding poor communication of deprescribing between hospital and primary care.

The government-commissioned independent review of ‘Operational productivity and performance in English NHS acute hospitals’ by Lord Carter of Coles published in

2016 made several key recommendations relating to the role of pharmacists(230). Pharmacists' time being spent undertaking clinical rather than operational services has a positive impact on medicine optimisation(230). Lord Carter reported significant variation in the average proportion of pharmacists' time undertaking clinical services (2.5-71%), and recommended that "*80% of pharmacist resource is utilised for direct medicines optimisation activities*"(230), of which deprescribing is a core component(7). How hospitals are performing against this benchmark has yet to be evaluated.

Pharmacists recruited into the Chapter 5 focus group study identified as having a principally clinical role at recruitment and the discussions regarding their activities supported this. However, both geriatricians and pharmacists identified that pharmacists' lack of integration into the multi-disciplinary team was a barrier to deprescribing. Pharmacists explained that their activities focussed on medication histories and processing discharge prescriptions across several wards, limiting their capacity to integrate into the multi-disciplinary team. In turn, this limited their capacity to support deprescribing. Whilst pharmacists appear to be spending a substantial proportion of their time working on hospital wards, the activities they are performing are not necessarily contributing to medicines optimisation as Lord Carter suggests. Pharmacists' lack of integration into the multi-disciplinary team is a long established challenge and it is unlikely that the profession will be able to contribute to medicines optimisation to its full potential without addressing this(235,236). The intervention developed in this programme of work includes a component to restructure the physical environment to facilitate pharmacists attending multi-disciplinary meetings to support deprescribing. This change in working patterns is on a relatively small scale (attending short meetings e.g. attending a geriatrician-led multidisciplinary team meeting for 30 minutes), however it was deemed appropriate to support deprescribing by the expert panel in Chapter 6. The precedent set by Lord Carter's review(230) and the results from this thesis indicate a clear need for further work to embed pharmacists into multi-disciplinary teams. Whilst research is required to identify and address the barriers and enablers to pharmacist multi-disciplinary team working, this is firstly and foremost an implication for the profession itself and NHS organisations, both of which should provide leadership in order to address the issue.

7.3 Implications for research and future research plans

The implications for research closely associated with each empirical project are discussed within the relevant chapters of this thesis (Chapters 3-6). Implications associated with the overall programme of work are discussed below.

Coining of the terms ‘reactive deprescribing’ and ‘proactive deprescribing’ has implications for future studies which aim to characterise deprescribing practice, including those applying PIM screening tools such as FORTA(69) and STOPP(31). Researchers should apply the published definitions(190) in studies characterising existing deprescribing practice and those testing new interventions to determine which deprescribing behaviour is being changed.

The evaluation of hospital deprescribing activity undertaken in Chapter 3 aimed to identify the scope for developing a novel intervention. An evaluation of deprescribing activity in the primary care setting is also warranted to fulfil the same aim. Characterisation of this activity into reactive and proactive deprescribing should also be included in the evaluation to determine the nature of the change in deprescribing behaviour to be targeted by primary care interventions.

The programme of work described in this thesis to develop a practitioner behaviour change intervention for deprescribing in the hospital setting has completed the ‘Identifying the evidence base’ and ‘Identifying/developing theory’ components of the MRC complex intervention ‘Development’ phase(96). The final goal for a behaviour change intervention is evaluation of efficacy within a definitive trial, which then informs whether wide scale implementation into practice is appropriate. However, according to MRC guidance, prior to evaluation there remains a need to complete the ‘Development’ phase and undertake the ‘Feasibility/piloting’ phase(96).

Future research plan 1: Development of a Core Outcome Set for hospital deprescribing trials

As discussed earlier in this chapter, intervention outcomes are an important component of intervention logic models which have not been included in figure 14. As a behaviour change intervention, an essential process outcome measure is the extent to which the target behaviour (deprescribing) has changed(249), thus *a priori* the number of pre-admission medicines discontinued will likely be a primary outcome. However, suitable patient, practitioner and commissioner orientated

outcome measures are also important. There are currently no universally accepted outcomes for hospital deprescribing trials (Core Outcome Set (COS)).

This developmental work may be facilitated by building on the foundations of a primary care COS for appropriate polypharmacy trials(276) and a medication review trials COS(277). Both existing COSs are pertinent to deprescribing in hospital but neither can be adopted for testing the intervention developed in this thesis in a trial without refinement. The former COS(276) omits relevant hospital specific outcomes such as readmissions, despite patients prescribed inappropriate medications being significantly more likely to be readmitted relative to those with no inappropriate medications(278). The broad focus of the latter COS(277) to include all aspects of medication review such as prescribing, deprescribing, dose and formulation changes was not intended to prioritise deprescribing related outcomes. For example, it considers prescribing related outcomes such as improved pain control but not potentially relevant deprescribing outcomes such as frailty. A longitudinal non-randomised, researcher delivered deprescribing intervention reported "*less deterioration in functional, mental and cognitive status, sleep quality, appetite and sphincter control*"(279). These effects were observed within 3 months after de-prescribing and are therefore potentially appropriate co-primary outcome measures for a hospital deprescribing trial. Prioritisation of outcomes from a future hospital deprescribing COS may then be added to the logic model (figure 14).

Future research plan 2: Modelling intervention processes and outcomes

The design and testing of complex interventions is time and resource intensive, thus there has been a call for efficient trial design(96). 'Modelling processes and outcomes' is the final step of the MRC's 'Development' phase(96), and evaluates how core intervention components, such as BCTs, perform individually and when combined to determine which are active or inactive within the intervention and at what level ('dose') best outcomes are achieved(143,280). The best performing components and their optimal doses can then be combined to generate the optimal intervention deliverable within predetermined constraints such as time allowed. Modelling also enables testing of the causal assumptions described in the logic model (figure 14). This is achieved by selecting an outcome which measures the proposed mechanism by which a BCT being tested is hypothesised to act, rather than a global outcome measure such as change in deprescribing practice which would be appropriate for a definitive trial. The Multiphase Optimization Strategy

(MOST) is one such approach to modelling which involves undertaking a series of fractional factorial experiments which has been successfully applied to the development of complex behaviour change interventions including smoking cessation(143) and weight loss(281). Modelling the practitioner behaviour change intervention for deprescribing in hospital developed in this thesis using a methodological approach such as MOST should therefore follow in order to refine the intervention.

Future research plan 4: Feasibility trial of the intervention

After modelling and incorporating any refinements necessary, the intervention may proceed to 'Piloting/feasibility testing' in order to test the intervention and trial procedures in terms of acceptability, recruitment and retention of participants and selection of an appropriate primary outcome and inform the subsequent sample size calculation(96). The feasibility testing is also an opportunity to evaluate the reliability and validity of intervention implementation, termed intervention fidelity. This may include evaluating whether the intervention was delivered to the target audience as intended, whether it was received by the target audience as intended and whether the target audience enacted elements of the intervention (i.e. BCTs) as intended(282). Assessing intervention fidelity is an essential component of a feasibility study because it allows for adaptations to address poor intervention implementation prior to conducting a time and resource intensive definitive trial.

Future research plan 5: Definitive trial of the intervention

Post-successful feasibility testing, a definitive trial may proceed in order to determine whether the intervention changes practitioner behaviour and results in an increase in the number of patients receiving deprescribing on Older People's Medicine wards in hospital(190). Moreover, as discussed above, the intervention will also need to demonstrate that it leads to improvements in other outcomes such as those which are patient orientated.

Testing of any intervention requires a trial design which ensures a robust assessment of the intervention(96). Randomisation within the trial design is recommended because it is the most robust method of preventing selection bias. This arises when participants who receive the intervention (intervention group) differ

significantly from participants who do not receive the intervention (control group)(96).

A randomised-controlled trial (RCT) is the preferred method to test healthcare interventions such as the efficacy of a medication(96). An RCT involves participants being individually randomised to either the intervention or control group. A conventional RCT is not an appropriate trial design to test a behaviour change intervention due to the high probability of contamination between the care received by intervention and control group patients(96). This is because once practitioners receive the intervention, they are not suitable to deliver 'usual care' to control group patients, because their deprescribing behaviour is likely to have changed as a result. Accordingly, there is a need to select a trial design which avoids contamination between groups.

A cluster randomised trial is a potential solution to contamination of interventions to change behaviour and are widely used in health services research(96). In these trials, groups of patients (clusters), rather than individual patients, are randomised to receive either the intervention or control. For the intervention developed in this thesis, the cluster could be the hospital itself. This would significantly reduce the likelihood of contamination given that the practitioners who receive the intervention will be in contact only with patients in the intervention group, and vice versa(96).

An alternative to the cluster randomised trial is a stepped wedge design, which involves "*random and sequential crossover of clusters from control to intervention until all clusters are exposed"*(283). Accordingly, in a stepped wedge design, all patients eventually receive care delivered as a result of phased implementation of the deprescribing behaviour change intervention(96). One advantage of a stepped wedge design over a cluster randomised trial is there are a greater number of clusters exposed to the intervention in the former (i.e. all clusters are exposed eventually)(283). This results in a smaller sample size being required to test the intervention which means a trial may be more feasible. Moreover, stepped wedge trials are advantageous where not offering the intervention to a group of participants may be deemed unethical(283). However, a disadvantage of the stepped wedge design relates to the phased implementation. Because more clusters are exposed to the intervention towards the end of the trial, the effect of the intervention may be confounded by any temporal effects(283).

Given the unpredictable nature of interventions to change behaviour(97,148), a cluster randomised trial which is not vulnerable to temporal confounding is the most

appropriate trial design to test the intervention developed in this thesis. The sample size required to test the intervention in the definitive trial will depend on the primary outcome selected.

Future research plan 6: Widespread intervention implementation

Finally, if the intervention is deemed effective, the process of widespread implementation can commence. Whilst this will be heavily informed by the learning from the aforementioned phases, an implementation theory, such as Normalisation Process Theory (NPT)(284), which was discussed in Chapter 2, may support this process.

Engagement with a wide group of stakeholders in future research

The future research recommendations outlined above should also involve engagement with stakeholders beyond those included in the programme of work described in this thesis. For example, other members of the OPM multi-disciplinary team such as nurses, physiotherapists and occupational therapists who are likely to be working with geriatricians and pharmacists whilst they are deprescribing. This will provide an opportunity to evaluate the acceptability of the intervention to these stakeholders and address any barriers through refinement as necessary. Similarly, GPs and primary care pharmacists should be invited to comment on the intervention, particularly as communication with primary care to facilitate ongoing monitoring of deprescribing was identified in Chapter 5 as important by geriatricians and pharmacists. Engaging with these stakeholders will also provide an opportunity to address some the limitations discussed earlier in this chapter as a result of focussing on geriatricians and pharmacists only in this programme of work.

7.4 Strengths and limitations

The strengths and limitations associated with each empirical project are discussed within the relevant chapters of this thesis (Chapters 3-6). The strengths and limitations associated with the overall programme of work are discussed below.

The collaborative nature of the programme of work underpinning the intervention has enhanced the transparency of findings and maximised the feasibility of both the studies undertaken and likely implementation of the intervention. Engaging with key

stakeholders is a core requirement in the development of strategies to change behaviour because it enables tailoring of intervention components to address the key barrier. Securing external funding from Pharmacy Research UK made the studies in Chapters 4 and 5 eligible for adoption on to the national portfolio of the National Institute for Health Research. The portfolio adoption provided access to support from the Ageing Clinical Research Network which enabled recruitment of patient, carer and practitioner participants across multiple hospital sites. The Pharmacy Research UK funding also facilitated meaningful patient and carer involvement throughout the programme of work through funding NN (patient prescribed polypharmacy) and JG (carer of a patient prescribed polypharmacy) to join the research management group described in Chapter 3. NN and JG had significant impact on key decision taken throughout the studies described in this thesis. For example, NN and JG provided leadership in the interpretations of the views of patients' and carers' towards deprescribing captured in Chapter 4(260) which was highly influential in aligning the programme of work with the development of a practitioner-focussed intervention. NN and JG continued to ensure that the voices of patients and carers shaped the resultant deprescribing intervention through guiding our interpretation of the subsequent intervention developmental work with geriatricians and pharmacists.

Furthermore, application of behavioural science theory to understand the barriers and enablers to deprescribing in hospital from the perspectives of geriatricians and pharmacists enabled an understanding of the likely mechanism by which behaviour change may occur in terms of increasing deprescribing activity(96). This was a key distinguishing characteristic of this programme of work versus the atheoretical approach taken to develop previously reported hospital deprescribing interventions, achieving little or no effect on deprescribing activity(84). Additionally, undertaking the empirical work described in Chapters 5 and 6 enabled exploration of the barriers and enablers to deprescribing which provided an understanding of what was missing from the existing interventions in terms of content which may have been responsible for the limited efficacies achieved. This in turn enabled identification and selection of BCTs by the target audience of geriatricians and pharmacists. Successful selection of BCTs by the target audience via the modified Nominal Group Technique study in Chapter 6 validates the exploratory work in the focus group study in Chapter 5, importantly the outcome of TDF domain prioritisation and the associated novel approach adopted.

When developing interventions to change behaviour, there is a need for high specificity in terms of what the behaviour is and who is the target(249). Lack of specificity in terms of the practitioner group an intervention targets may result in an insurmountable number of key barriers and enablers pertinent to each practitioner group of interest being identified as requiring addressing. This adds further complexity to a system which by its very nature of targeting human behaviour is already complex. It is therefore impractical to develop a hospital deprescribing intervention targeting all practitioners. Rather than developing an intervention to target the behaviours of all practitioner groups within the multidisciplinary team, resources should focus on changing the behaviour(s) of a small number of practitioner groups who are most likely to deprescribe with the support of an intervention. The programme of work described in this thesis specified geriatricians and pharmacists as the target audience of a behaviour change intervention. The research then focussed on developing an intervention tailored to the determinants of these professional groups' deprescribing behaviour(249).

The mixed method approach to the programme of work in this thesis provided a broad lens for generating evidence and developing the intervention, which is also a strength. This allowed triangulation of key findings between empirical research projects and their associated differences in terms of methods, context and participants. This provides assurances in terms of validity, strength and the interpretative potential of the overall programme of work(285). For example, the finding from the retrospective quantitative analysis described in Chapter 3 that proactive deprescribing practice in hospital was limited was validated by geriatrician and pharmacist focus group participants in Chapter 5.

The peer review process afforded by the Pharmacy Research UK and publication of Chapter 3(190), 4(260) and 5(251) enabled refinement of the research methods, analysis and interpretation of key findings and is a core strength in the work included in this thesis.

There are two key limitations associated with the programme as a whole.

The first is the focus on exploring barriers and enablers to deprescribing from the perspectives of geriatricians and pharmacists at the expense of other professional groups working on OPM wards as discussed earlier in this chapter. Related to this is that the acceptability of deprescribing and the intervention developed here has not been evaluated from the perspectives of other professional groups. The significance of this is that even if an intervention is not intended to target a group of professions,

its implementation should nonetheless be acceptable to all actors within a community of practice(286). This is of particular significance because both geriatricians and pharmacists cited access to other professional groups in hospital for advice as a deprescribing enabler. Moreover, any resistance the intervention content or a change in geriatricians' and pharmacists' behaviour could introduce a new barrier within the social influence TDF domain(157).

A related limitation is the absence of engagement with primary care practitioners, particularly General Practitioners (GPs). Any hospital initiated deprescribing will inevitably require colleagues in primary care to assume ongoing monitoring. This was described by geriatricians and pharmacists in Chapter 5 as an enabler. GPs have expressed that geriatricians and pharmacists are well suited to initiate deprescribing in hospital(116) and that there is an expectation that patients' medicines are reviewed and appropriate deprescribing is initiated during the admission where necessary(264). Accordingly, there is evidence that the concept of deprescribing in hospital is acceptable to GPs. However, as discussed above, the extent to which the intervention content and the manner by which it promotes deprescribing is acceptable to GPs remains unknown.

The second limitation associated with the programme of work as a whole is the likely limited generalisability of the findings and thus potentially the intervention. The empirical studies described in Chapters 3 to 6 were undertaken in hospitals across the East of England only (n=1 to 5 hospitals across the studies). Whilst district general and larger teaching hospitals were included to capture any variation arising from difference resources and patient populations(222–224), there may be differences between hospitals in English regions which were not captured and thus reflected in the intervention. These factors are also likely to impact on the international generalisability of the findings and intervention, particularly in countries where geriatricians and pharmacists are unlikely to be the professional groups assuming responsibility for deprescribing. For example, a reviewer for the manuscript corresponding to Chapter 5(251) commented that a shortage of geriatricians in Canada may limit widespread adoption of the intervention.

Similarly, there is much debate regarding the generalisability of qualitative research, and it is often cited as a limitation. This is of particular relevance to this programme of work given that the findings from the focus group study (Chapter 5) form the foundation of the intervention. Smith suggests that judging generalisability from a statistical perspective is inappropriate for judging the value of qualitative

research(248). Moreover, Smith argues that qualitative research can be generalisable but from a different perspective to quantitative research. For example, in Chapter 5 we discuss the transferability of barriers and enablers between district general and teaching hospitals, which is generalisability from case-to-case within a study. Smith also discusses the concept of theoretical generalisation, which is where qualitative findings are used to establish a concept of theory(248). By underpinning the qualitative data analysis (Chapter 5) with the TDF and thus establishing the theoretical determinants of geriatricians' and pharmacists' deprescribing behaviour, we have achieved theoretical generalisation as described by Smith(248). Accordingly, whilst there are some limitations to the qualitative methodological approach underpinning the intervention development process, there are also key strengths to acknowledge. Moreover, given the absence of exploration of the barriers and enablers to deprescribing in hospital captured in the existing literature(116) to develop a survey, an alternative quantitative approach was not possible.

7.5 Conclusion

- Studies evaluating deprescribing practice should characterise any activity identified according to whether it was reactive or proactive in nature.
- The hospital deprescribing intervention developed in this thesis requires optimisation through modelling the selected Behaviour Change Techniques. This will enable determination of whether all of the selected Behaviour Change Techniques are active and at what 'dose' the optimal outcome is achieved.
- A Core Outcome Set for hospital deprescribing trials requires development to enable selection of appropriate outcomes when testing deprescribing interventions.
- The optimised intervention requires testing in a feasibility study and then definitive trial to ultimately determine whether it is effective and cost-effective in changing practitioner deprescribing behaviour.
- Large-scale implementation of the intervention may follow if the intervention is found to be effective in a definitive trial. This will require adaptation of the intervention to support implementation and sustainability at the local context level.

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Appendices

Appendix 1 Study protocol for Chapter 3

University of East Anglia

Norfolk and Norwich University Hospitals NHS Foundation Trust

Determining the extent of medication discontinuation practice in secondary care

Ethical protocol

Researcher: Sion Scott

Supervisors: Dr Debi Bhattacharya
Dr Allan Clark
Professor David Wright
Dr Michael Twigg

Background

Advances in healthcare over the last century have contributed to reductions in death rates, particularly of older people, resulting in a rapidly expanding and ageing population[1-3]. In developed countries the average life expectancy is 80 years compared with 50 years for those born in 1990[4]. Consequently, most diseases present are age-associated chronic conditions such as hypertension. Accordingly, the prevalence of people living with multiple conditions is increasing as the population continues to age[5].

Developing a morbidity often results in contact with a healthcare provider; prescribing a new medicine is the most likely outcome of this contact. Consequently, a large proportion of older people are taking multiple medicines to manage co-morbidities[5,6]. A study in the United States of America investigated medication use in older veterans and recorded a mean 8.1 medicines per person[7]. The term 'polypharmacy' has emerged to describe the use of multiple medicines. When used appropriately, polypharmacy controls diseases, alleviates symptoms and prolongs life. If the benefits of concomitant medication use outweigh the risks and prescribing is directed by evidence and guidance; the medication regime is described as 'appropriate polypharmacy'[8,9]. Conversely, the use of multiple medicines presenting more risks than benefits is deemed 'inappropriate polypharmacy'[10]. Inappropriate use of multiple medicines in older persons may lead to adverse drug events (toxicity, side effects, drug interactions), hospital admission and medication non-adherence[11-14].

Increased medication use is a predictor for inappropriate polypharmacy[7] thus older persons are most likely to experience the ensuing adverse effects. A cross-sectional study reported 65% of older persons were taking one or more inappropriate medicines. Decreased physical reserve and underrepresentation in drug safety trials place older persons at particular risk of adverse events when taking multiple medicines[15,16].

Efforts to address inappropriate polypharmacy have led to the emergency of a 'deprescribing' concept. Defined as a systematic process of discontinuing inappropriate and/or unnecessary medicines, deprescribing requires patient and practitioner involvement. The process should be carefully planned, incorporating withdrawal regimes where necessary and be accompanied by stringent monitoring of patient response to detect possible adverse withdrawal events. Simply discontinuing a medicine without clear rationale, patient engagement or an agreed work plan does not fulfil the above criteria, hence cannot be considered deprescribing[17]. The former most likely resembles current practice and therefore there is a need to guide practitioners toward deprescribing by developing bespoke interventions[18]

Research has explored the barriers and enablers to deprescribing from patient and practitioner perspectives; a validated questionnaire has determined that patients are willing to engage[19-21]. Feasibility studies and randomised controlled trials primarily undertaken in primary care have demonstrated success in reducing medication burden safely [22].

Given the requirements for close monitoring of patients when deprescribing medicines, an admission to secondary care where physiological and biochemical parameters are routinely observed may be an appropriate environment for developing a deprescribing intervention.

Qualitative research describing primary care practitioner reported deprescribing behaviour has been undertaken. However, no independent quantification of current medication discontinuation practice has been reported. Development of new deprescribing interventions should be informed by current medication discontinuation practice if to address deficits in deprescribing process criteria and promote improvements in uptake. Thus, there is a need to establish current deprescribing practice in secondary care to inform intervention design.

Aim

To determine the extent to which practitioners in secondary care engage with the process of medication discontinuation.

Objectives

- Ascertain the number of medicines discontinued in secondary care
- Determine the medicines and classes of medicines most frequently discontinued
- Establish the secondary care clinical speciality undertaking most medication discontinuation
- Define the patient group where medication discontinuation is most prevalent

Methods

Prior to study commencement, ethical approval will be sought from the ethical committees of the Norfolk and Norwich University Hospitals NHS Foundation Trust and Faculty of Medicine and Health, University of East Anglia.

Data collection

All data pertaining to medicines discontinued during an inpatient stay at the Norfolk and Norwich University Hospital (NNUH) will be extracted from the Electronic Prescribing and Medicines Administration (EPMA) programme (JAC EPMA™) database. The Trust's EPMA pharmacists will construct an algorithm within a JAC EPMA compatible data extraction programme (Crystal Reports™) instructing the system to record the required data and export to Microsoft Excel for data analysis. Data will be handled and interpreted by the researcher who is an NNUH Trust employee clinical pharmacist.

Data will be sent automatically in a Microsoft Excel file by email to the researcher's secure Trust email account by the data extraction programme daily at the end of 24-hour intervals for one calendar month in February 2017.

There are no patient exclusion criteria for this study.

The algorithm will instruct extraction of the following data from EPMA prospectively for all medicines discontinued at the NNUH in one calendar month:

- Local patient identifying number
- Sex
- Date of birth
- Whether the patient was taking the medicine prior to admission
- Reason statement for discontinuing medicine
- Whether the medicine was added to the patients discharge prescription

Data analysis

Initial data analysis will be undertaken at the NNUH on the Trust's secure IT system by the researcher. Daily datasets will be combined to form one dataset containing all medicines

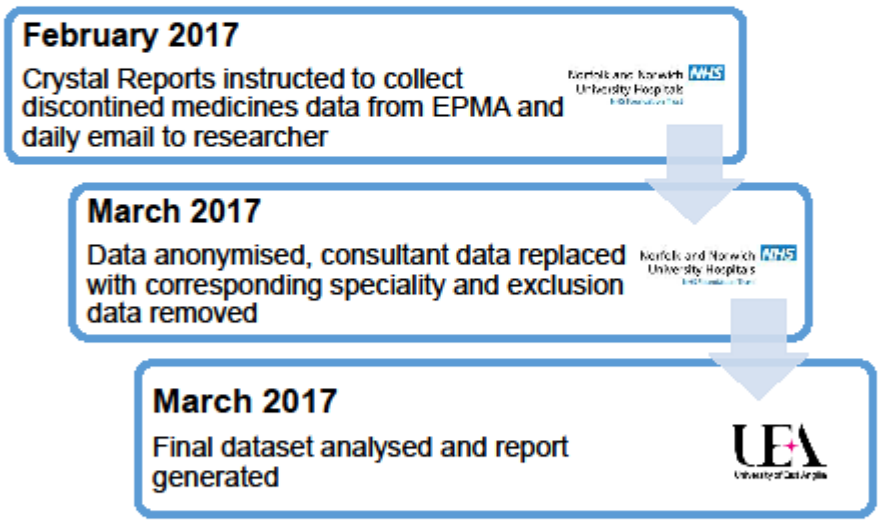
discontinued at the NNUH in one calendar month. Data will be anonymised through replacing local patient identifying numbers with a reference number. Discontinued medicine entries will be removed by the researcher when the following conditions are met:

- Patient not admitted on the medicine
- Discontinued medicine reason statement = 'prescribed in error', 'change in form/strength/route', 'pharmacist amendment'
- Medicine selected for inclusion on discharge prescription (medicine restarted)

The resultant dataset will contain entries for medicines taken by patients prior to admission which were discontinued by NNUH practitioners during the admission and not prescribed on discharge. The anonymised data will be analysed on a University of East Anglia computer by the researcher and may be accessed by the supervisory team. The following data will be reported:

- Number of medicines discontinued

Process flow chart



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Appendix 2 Ethical and governance approval letters for Chapter 3

Faculty of Medicine and Health Sciences Research Ethics Committee

Sion Scott
PHA

Research & Enterprise Services
West Office (Science Building)
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Telephone: +44 (0) 1603 591490
Email: fmh.ethics@uea.ac.uk

Web: http://www.uea.ac.uk/fmh/research/ethics-committee

3rd February 2017

Dear Sion,

Project Title: Determining the extent of medication discontinuation practice in secondary care.
Reference: 2016/2017 - 52 SE

I have reviewed the submission of your above proposal and I can confirm that it is considered to be a Service Evaluation. There are no issues of confidentiality or harm to participants and I am happy to approve the study by light touch review.

Please could you ensure that any 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.

I would like to wish you good luck with your project.

Yours sincerely,

Mark Wilkinson
Chair
FMH Ethics Committee

cc Debi Bhattacharya

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Norwich Radiology Academy
Cotman Centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
NR4 7UB
Direct dial: 01603 286154
Direct fax: 01603 286146
email: stuart.williams@nnuh.nhs.uk

Our Ref: SW/ms

Date: 31 January 2017
Date dictated: 30 January 2017

Mr S Scott
Research Pharmacist
School of Pharmacy Faculty of Science
University of East Anglia
Norwich Research Park
NORWICH
Norfolk NR4 7TJ

Dear Sion

Re: Project determining the extent of medication discontinuation practices secondary care

This is to confirm that I have read the ethical protocol of the project and that I am happy to support the research within the Norfolk and Norwich University Hospital as part of service evaluation and review within the Trust.

Yours sincerely

Stuart Williams MA MRCP FRCR
Consultant Radiologist
Trust Clinical Lead for Audit and Improvement
Honorary Senior Lecturer Norwich Medical School

Appendix 3 Data extrapolation calculations for Chapter 3

		Sampled												Extrapolation									
e-Prescribing reason for medication discontinuation	**All data**	**Sampled**	**% sampled**	**Proactive**	**% proactive**	**Reactive**	**% reactive**	**Neither**	**% neither**	**Unclear**	**% unclear**	**Not stopped**	**% not stopped**	**Total proactive**	**% total proactive**	**Total reactive**	**% total reactive**	**Total neither**	**% total neither**	**Total unclear**	**% total unclear**	**Total not stopped**	**% total not stopped**
Acute kidney injury	2	2	100	0	0	2	100	0	0	0	0	0	0	0	0	2	100	0	0	0	0	0	0
Biochemistry derranged	14	2	14.28571429	0	0	2	100	0	0	0	0	0	0	0	0	14	100	0	0	0	0	0	0
Blood dyscrasia	3	3	100	0	0	2	66.66666667	1	33.33333333	0	0	0	0	0	0	2	66.66666667	1	33.33333333	0	0	0	0
Drowsy	2	2	100	0	0	0	0	1	50	0	0	1	50	0	0	0	0	1	50	0	0	1	50
Formulation no longer appropriate	64	11	17.1875	0	0	1	9.090909091	0	0	0	0	10	90.90909091	0	0	5.818181818	9.090909091	0	0	0	0	58.18181818	90.90909091
Haemodynamically unstable	6	1	16.66666667	0	0	0	0	1	100	0	0	0	0	0	0	0	0	6	100	0	0	0	0
Interaction with other treatment	20	3	15	0	0	1	33.33333333	0	0	0	0	2	66.66666667	0	0	6.666666667	33.33333333	0	0	0	0	13.33333333	66.66666667
No longer clinically necessary	328	79	24.08536585	7	8.860759494	12	15.18987342	17	21.51898734	7	8.860759494	36	45.56962025	29.06329114	8.860759494	49.82278481	15.18987342	70.58227848	21.51898734	29.06329114	8.860759494	149.4683544	45.56962025
No reason documented	138	79	57.24637681	0	0	14	17.72151899	24	30.37974684	5	6.329113924	36	45.56962025	0	0	24.4556962	17.72151899	41.92405063	30.37974684	8.734177215	6.329113924	62.88607595	45.56962025
Patient refusing to take	7	1	14.28571429	0	0	0	0	0	0	1	100	0	0	0	0	0	0	0	0	0	7	100	0	0
Renal impairment	7	1	14.28571429	0	0	1	100	0	0	0	0	0	0	0	0	7	100	0	0	0	0	0	0
Route no longer appropriate	87	15	17.24137931	0	0	1	6.666666667	6	40	0	0	8	53.33333333	0	0	5.8	6.666666667	34.8	40	0	0	46.4	53.33333333
Suspected toxicity/high levels	4	1	25	0	0	1	100	0	0	0	0	0	0	0	0	4	100	0	0	0	0	0	0
Total	**682**	**200**	**29.3255132**	**7**		**37**		**50**		**13**		**93**											

Sampled	No	%
Reactive	37	84.09090909
Proactve	7	15.90909091
Total	**44**	100

Extrapolation	No	% of all discontinued
Reactive	121.5633295	17.82453512
Proactive	29.06329114	4.261479639
Neither	155.3063291	22.77218902
Not stopped	331.2695819	48.57325248
Unclear	44.79746835	6.568543747
Total	**682**	**100**

Overall totals	N	% of confirmed deprescribing
Reactive	121.5633295	80.70507656
Proactive	29.06329114	19.29492344

Appendix 4 Data extrapolation calculations formulae for Chapter 3

		Sampled											Extrapolation									
e-Prescribing reason for medication discontinuation	All data	Sampled	% sampled	Proactive	% proactive	Reactive	% reactive	Neither	% neither	Unclear	% unclear	Not stopped	% not stopped	Total proactive	% total proactive	Total reactive	% total reactive	Total neither	% total neither	Total unclear	% total unclear	Total not stopped	% total not stopped
Acute kidney injury	2	2	=SUM(C3/B3)*100	0	=SUM(E3/C3)*100	2	=SUM(G3/C3)*100	0	=SUM(I3/C3)*100	0	=SUM(K3/C3)*100	0	=SUM(M3/C3)*100	=SUM(B3*(F3/100))	=SUM(O3/B3)*100)	=SUM(B3*(H3/100))	=SUM((Q3/B3)*100)	=SUM(B3*(J3/100))	=SUM((S3/B3)*100)	=SUM(B3*(L3/100))	=SUM((U3/B3)*100)	=SUM(B3*(N3/100))	=SUM(W3/B3)*100
Biochemistry derranged	14	2	=SUM(C4/B4)*100	0	=SUM(E4/C4)*100	2	=SUM(G4/C4)*100	0	=SUM(I4/C4)*100	0	=SUM(K4/C4)*100	0	=SUM(M4/C4)*100	=SUM(B4*(F4/100))	=SUM((O4/B4)*100)	=SUM(B4*(H4/100))	=SUM((Q4/B4)*100)	=SUM(B4*(J4/100))	=SUM((S4/B4)*100)	=SUM(B4*(L4/100))	=SUM((U4/B4)*100)	=SUM(B4*(N4/100))	=SUM(W4/B4)*100
Blood dyscrasia	3	3	=SUM(C5/B5)*100	0	=SUM(E5/C5)*100	2	=SUM(G5/C5)*100	1	=SUM(I5/C5)*100	0	=SUM(K5/C5)*100	0	=SUM(M5/C5)*100	=SUM(B5*(F5/100))	=SUM((O5/B5)*100)	=SUM(B5*(H5/100))	=SUM((Q5/B5)*100)	=SUM(B5*(J5/100))	=SUM((S5/B5)*100)	=SUM(B5*(L5/100))	=SUM((U5/B5)*100)	=SUM(B5*(N5/100))	=SUM(W5/B5)*100
Drowsy	2	2	=SUM(C6/B6)*100	0	=SUM(E6/C6)*100	0	=SUM(G6/C6)*100	1	=SUM(I6/C6)*100	0	=SUM(K6/C6)*100	1	=SUM(M6/C6)*100	=SUM(B6*(F6/100))	=SUM((O6/B6)*100)	=SUM(B6*(H6/100))	=SUM((Q6/B6)*100)	=SUM(B6*(J6/100))	=SUM((S6/B6)*100)	=SUM(B6*(L6/100))	=SUM((U6/B6)*100)	=SUM(B6*(N6/100))	=SUM(W6/B6)*100
Formulation no longer appropriate	64	11	=SUM(C7/B7)*100	0	=SUM(E7/C7)*100	1	=SUM(G7/C7)*100	0	=SUM(I7/C7)*100	0	=SUM(K7/C7)*100	10	=SUM(M7/C7)*100	=SUM(B7*(F7/100))	=SUM((O7/B7)*100)	=SUM(B7*(H7/100))	=SUM((Q7/B7)*100)	=SUM(B7*(J7/100))	=SUM((S7/B7)*100)	=SUM(B7*(L7/100))	=SUM((U7/B7)*100)	=SUM(B7*(N7/100))	=SUM(W7/B7)*100
Haemodynamically unstable	6	1	=SUM(C8/B8)*100	0	=SUM(E8/C8)*100	0	=SUM(G8/C8)*100	1	=SUM(I8/C8)*100	0	=SUM(K8/C8)*100	0	=SUM(M8/C8)*100	=SUM(B8*(F8/100))	=SUM((O8/B8)*100)	=SUM(B8*(H8/100))	=SUM((Q8/B8)*100)	=SUM(B8*(J8/100))	=SUM((S8/B8)*100)	=SUM(B8*(L8/100))	=SUM((U8/B8)*100)	=SUM(B8*(N8/100))	=SUM(W8/B8)*100
Interaction with other treatment	20	3	=SUM(C9/B9)*100	0	=SUM(E9/C9)*100	1	=SUM(G9/C9)*100	0	=SUM(I9/C9)*100	0	=SUM(K9/C9)*100	2	=SUM(M9/C9)*100	=SUM(B9*(F9/100))	=SUM((O9/B9)*100)	=SUM(B9*(H9/100))	=SUM((Q9/B9)*100)	=SUM(B9*(J9/100))	=SUM((S9/B9)*100)	=SUM(B9*(L9/100))	=SUM((U9/B9)*100)	=SUM(B9*(N9/100))	=SUM(W9/B9)*100
No longer clinically necessary	328	79	=SUM(C10/B10)*100	7	=SUM(E10/C10)*100	12	=SUM(G10/C10)*100	17	=SUM(I10/C10)*100	7	=SUM(K10/C10)*100	36	=SUM(M10/C10)*100	=SUM(B10*(F10/100))	=SUM((O10/B10)*100)	=SUM(B10*(H10/100))	=SUM((Q10/B10)*100)	=SUM(B10*(J10/100))	=SUM((S10/B10)*100)	=SUM(B10*(L10/100))	=SUM((U10/B10)*100)	=SUM(B10*(N10/100))	=SUM(W10/B10)*100
No reason documented	138	79	=SUM(C11/B11)*100	0	=SUM(E11/C11)*100	14	=SUM(G11/C11)*100	24	=SUM(I11/C11)*100	5	=SUM(K11/C11)*100	36	=SUM(M11/C11)*100	=SUM(B11*(F11/100))	=SUM((O11/B11)*100)	=SUM(B11*(H11/100))	=SUM((Q11/B11)*100)	=SUM(B11*(J11/100))	=SUM((S11/B11)*100)	=SUM(B11*(L11/100))	=SUM((U11/B11)*100)	=SUM(B11*(N11/100))	=SUM(W11/B11)*100
Patient refusing to take	7	1	=SUM(C12/B12)*100	0	=SUM(E12/C12)*100	0	=SUM(G12/C12)*100	0	=SUM(I12/C12)*100	1	=SUM(K12/C12)*100	0	=SUM(M12/C12)*100	=SUM(B12*(F12/100))	=SUM((O12/B12)*100)	=SUM(B12*(H12/100))	=SUM((Q12/B12)*100)	=SUM(B12*(J12/100))	=SUM((S12/B12)*100)	=SUM(B12*(L12/100))	=SUM((U12/B12)*100)	=SUM(B12*(N12/100))	=SUM(W12/B12)*100
Renal impairment	7	1	=SUM(C13/B13)*100	0	=SUM(E13/C13)*100	1	=SUM(G13/C13)*100	0	=SUM(I13/C13)*100	0	=SUM(K13/C13)*100	0	=SUM(M13/C13)*100	=SUM(B13*(F13/100))	=SUM((O13/B13)*100)	=SUM(B13*(H13/100))	=SUM((Q13/B13)*100)	=SUM(B13*(J13/100))	=SUM((S13/B13)*100)	=SUM(B13*(L13/100))	=SUM((U13/B13)*100)	=SUM(B13*(N13/100))	=SUM(W13/B13)*100
Route no longer appropriate	87	15	=SUM(C14/B14)*100	0	=SUM(E14/C14)*100	1	=SUM(G14/C14)*100	6	=SUM(I14/C14)*100	0	=SUM(K14/C14)*100	8	=SUM(M14/C14)*100	=SUM(B14*(F14/100))	=SUM((O14/B14)*100)	=SUM(B14*(H14/100))	=SUM((Q14/B14)*100)	=SUM(B14*(J14/100))	=SUM((S14/B14)*100)	=SUM(B14*(L14/100))	=SUM((U14/B14)*100)	=SUM(B14*(N14/100))	=SUM(W14/B14)*100
Suspected toxicity/high levels	4	1	=SUM(C15/B15)*100	0	=SUM(E15/C15)*100	1	=SUM(G15/C15)*100	0	=SUM(I15/C15)*100	0	=SUM(K15/C15)*100	0	=SUM(M15/C15)*100	=SUM(B15*(F15/100))	=SUM((O15/B15)*100)	=SUM(B15*(H15/100))	=SUM((Q15/B15)*100)	=SUM(B15*(J15/100))	=SUM((S15/B15)*100)	=SUM(B15*(L15/100))	=SUM((U15/B15)*100)	=SUM(B15*(N15/100))	=SUM(W15/B15)*100
Total	**682**	**200**	**=SUM(C16/B16)*100**	**=SUM(E3:E15)**		**=SUM(G3:G15)**		**=SUM(I3:I15)**		**=SUM(K3:K15)**		**=SUM(M3:M15)**											

Sampled	No	%
Reactive	=SUM(G3:G15)	=SUM(B19/B21)*100
Proactive	=SUM(E3:E15)	=SUM(B20/B21)*100
Total	**=SUM(B19:B20)**	=SUM(C19:C20)

Extrapolation	No	% of all discontinued
Reactive	=SUM(Q3:Q16)	=SUM(B24/$B$29)*100)
Proactive	=SUM(O3:O16)	=SUM(B25/$B$29)*100)
Neither	=SUM(S3:S15)	=SUM(B26/$B$29)*100)
Not stopped	=SUM(W3:W15)	=SUM(B27/$B$29)*100)
Unclear	=SUM(U3:U15)	=SUM(B28/$B$29)*100)
Total	**=SUM(B24:B28)**	**=SUM(C24:C28)**

Total confirmed deprescribing	=SUM(B24:B25)
% of all recorded stopped medicines deprescribed	=SUM(B31/B16)*100
% prescribed meds deprescribed	=SUM(B31/24552)*100

Overall totals	N	% of confirmed deprescribing
Reactive	=B24	=SUM(B36/B31)*100
Proactive	=B25	=SUM(B37/B31)*100

Appendix 5 Study protocol for Chapter 4

University of East Anglia

Norfolk and Norwich University Hospitals NHS Foundation Trust

The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust

STOPPED

STOpping Potentially Problematic mEDicines Your views

Patients and informal caregivers
A questionnaire study

Protocol
Version 1

Study start date: 16/10/2017
Study end date: 12/10/2018

Researcher Sion Scott (PhD student, University of East Anglia)

Research team Dr Debi Bhattacharya (Senior Lecturer, University of East Anglia)
Dr Allan Clark (Senior Lecturer, University of East Anglia)
Dr Michael Twigg (Lecturer, University of East Anglia)
Professor David Wright (Professor, University of East Anglia)
Dr Helen May (Consultant, NNUH NHS Foundation Trust)
Dr Martyn Patel (Consultant, NNUH NHS Foundation Trust)
Professor Carol Farrow (Director of Pharmacy, NNUH NHS Foundation Trust)

Protocol No.	Revision	Date	Investigator Sig.	Sponsor Sig.
12	1	31.08.2017	SS	SH

1.0 Background

The use of multiple medicines, referred to as polypharmacy, is becoming increasingly common. The average number of medicines dispensed per person in England increased by 66% between 2002 and 2012[1]. A large Scottish study reported an increase in the proportion of people prescribed between five and nine medicines from 9.7% in 1995 to 16.3% in 2010[2]. The proportion of people prescribed between 10 and 14 medicines more than trebled over the same period from 1.5% to 4.7%.

Developing age associated chronic conditions such as hypertension are often accompanied by one or more prescription medicines for treatment. Approximately 15 million people in England are living with at least one chronic condition, of which 2 million are living with co-morbidities (>1 chronic condition)[3]. It is therefore unsurprising that older people, who are more likely to develop co-morbidities, represent the majority of polypharmacy recipients, with one fifth of people aged ≥80 years prescribed prescribed10 or more medicines[4].

Medicines optimisation is a concept which defines the principles of ensuring polypharmacy is safe, effective and aligned with a patient's heath goals. Medicines optimisation includes recommendations on commencing new indicated therapies and discontinuing inappropriate medicines[5]

The terms 'appropriate' and 'inappropriate' polypharmacy have emerged[6,7]. Distinguishing between these two extremes is important in order to acknowledge the value of safe and effective polypharmacy and develop strategies to identify and minimise unsafe use of multiple medicines. Appropriate polypharmacy refers to clinically indicated medicines that provide benefits to patients which outweigh potential harms[6,8]. Conversely, inappropriate polypharmacy describes medication regimes containing potentially inappropriate medicines (PIMs)[7] and/or medicines that are not clinically necessary[4], leading to an unfavourable risk-benefit balance[9]. Inappropriate polypharmacy is associated with adverse drug reactions, hospitalisation and impaired quality of life[10].

Data from two cross-sectional studies investigating predictors of inappropriate polypharmacy have suggested the number of medicines prescribed is the largest independent risk-factor[10,11]. It is therefore unsurprising that older people are most exposed to inappropriate polypharmacy, with studies reporting between 51% and 65% prevalence[11,12].

Akin to prescribing, the process of stopping inappropriate medicines is complex and encompasses more than the capability to detect inappropriate prescribing. Factors to consider include adverse drug withdrawal events, return of the condition for which the medicine was indicated and the prescriber:patient relationship. Deprescribing is the rational withdrawal of inappropriate medicines where existing or potential harms outweigh the intended benefits[13]. Crucial to this process is establishing an accurate account of a patient's prescribed medicines

and provision of adequate physiological monitoring in order to observe response to medication withdrawal[14]. Given these requirements, an admission to hospital where medicines reconciliation is routinely undertaken and physiological and biochemical parameters are monitored, may provide an appropriate opportunity for deprescribing. An audit of hospital deprescribing prevalence reported activity to be sparse and dominated by reactive deprescribing in response to present observed harm from a medicine with limited proactive deprescribing to prevent potential future harm or because a medicine is unlikely to provide future benefits. This is supported by qualitative reports with hospital practitioners suggesting medication reviews are driven by acute considerations (i.e. reactive) with little or no stimuli to initiating proactive deprescribing[15].

The complexities presented by deprescribing and emphasis on delivering person-centred healthcare[5,14,16] have directed research towards exploring patient's views towards deprescribing. A systematic review of such studies identified a number of barriers and facilitators to deprescribing[17]. Barriers include disagreement with the appropriateness of deprescribing, apprehension of the medication withdrawal process and fear of negative consequences. A dislike of taking medicines, patient agreement with a deprescribing proposition and a comprehensive medication withdrawal strategy are among patient facilitators of deprescribing. Informal caregivers such as friends and family members, defined here as having any role in a patient's health or medicines management[18], were identified as having substantial influence on deprescribing decisions. The views of informal caregivers towards deprescribing are therefore similarly important and should be considered[17].

The Patients' Attitudes Towards Deprescribing (PATD) questionnaire was developed and validated in Australia to quantify patients' views of deprescribing. The PATD was first administered to older people attending an outpatient clinic and reported 92% of respondents were willing to consider deprescribing[19]. The PATD has since been administered in care homes[20] and hospitals[21]. The PATD has been adapted for an Italian population by removal of irrelevant questions and translation, demonstrating similar patient willingness to engage with deprescribing[22].

Since conceptualisation, the PATD has been revised to include scoring of participant' responses and a second version exploring the views of informal caregivers. The revised Patients' Attitudes Towards Deprescribing (rPATD) questionnaire comprises questions grouped under four factors associated the views of patients and informal caregivers towards deprescribing[18]:

1. Burden (burden of medication taking)
2. Appropriateness (perceived benefits and harms of medicines)
3. Concerns about stopping (concerns expressed in relation to stopping medicines)
4. Involvement (knowledge about medicines and involvement in making decisions)

Provision of a version for informal caregivers is an important development given their increasing involvement in the care of older people and influence on decisions about medicines[17,23]. The rPATD was validated in a study which disseminated the questionnaire through charitable organisations, community pharmacies, outpatient clinics and residential care homes in Australia[18]. Responses to the rPATD are not yet published and administration to older people and informal caregivers in hospital has not been undertaken.

Given the high prevalence of inappropriate polypharmacy in older people, the potential suitability of a hospital admission for identifying and deprescribing inappropriate medicines and the limited deprescribing currently occurring as routine practice in hospital, there may be potential for health gain from developing an intervention to support practitioners, patients and carers to engage with deprescribing in hospital. Before embarking on a programme of work to develop such an intervention, there is a need to first estimate the attitudes of older people and informal caregivers towards deprescribing in this setting.

2.0 Aim and objectives

2.1 Aim

- Describe the views of older people and informal caregivers towards deprescribing in hospital

2.2 Objectives:

1. Estimate patient and informal caregiver rate of consent for completing a questionnaire capturing attitudes towards deprescribing in hospital
2. Estimate how amenable patients and informal caregivers are to deprescribing during a hospital admission
3. Explore any relationships between rPATD factors and willingness to engage with deprescribing of patients and informal caregivers

3.0 Questionnaire

The rPATD was adapted (with the consent of the author) for the UK population by making a small number of changes informed by cognitive interviews with participants representative of the patients and informal caregivers intended for the present study. The adapted questionnaire is designated 'UK-rPATD' and will provide an estimate of the extent to which factors may impact on patients' and informal caregivers' attitudes towards deprescribing.

The UK-rPATD comprises six sections. Sections 1-4 contain between four and five items exploring the four factors associated with attitudes towards deprescribing featured in the original rPATD and described above.

Section 5 comprises two global questions included to capture willingness to engage with deprescribing and satisfaction with current medicines.

The extent to which the participant agrees with each item statement in sections 1 to 5 is captured using a Likert scale ranging from 'strongly disagree' to 'strongly agree'.

Section 6 includes one open question allowing participants to report any further influences on their views of deprescribing not captured previously.

4.0 Methods

Prior to study commencement, ethical approval will be obtained from a National Health Service research ethics committee.

Patients and informal caregivers will be recruited independently (i.e. not paired) and methods are described in sections 4.1 and 4.2 respectively.

4.1 Patients' attitudes towards deprescribing (3 months)

4.1.1 Participant identification and recruitment

Ward staff will identify eligible patients admitted to four Older People's Medicine (OPM) wards at the Norfolk and Norwich University Hospital NHS Foundation Trust (NNUH). Patients will be approached by a senior doctor on the regular morning ward rounds. The senior doctor will provide a very brief account of the study and introduce the researcher. Post ward round, the researcher will approach patients to provide them with a participant information leaflet (appendix 1) and consent form (appendix 2). The researcher will also be available to address any immediate questions. Patients expressing interest will be offered at least 24 hours to consider participation. The initials and bed identification numbers of patients expressing an interest in study participation will be documented by the researcher on the recruitment sheet (patients) (appendix 3). On re-approaching, any further questions will be addressed by the researcher and if continued interest in participation is expressed, the potential participant will asked to sign the study consent form if not already signed (appendix 2).

Inclusion criteria

- Age ≥80 years
- Prescribed ≥5 medicines prior to admission
- Inpatient under the OPM speciality

Exclusion criteria

- Unable to read English
- Deemed by the healthcare team to be unable to provide informed consent
- Deemed by the healthcare team as inappropriate to approach for recruitment for reasons such as being seriously unwell or receiving end of life care
- Unable to make informed decisions about medicines
- Not cared for by the OPM speciality

Initials and bed identification numbers of patients making the research team aware of their desire not to be approached/re-approached for participation in the study will be documented on the recruitment sheet (patients) (appendix 3). The research team will refer to the recruitment sheet throughout the study period to ensure patients who do not wish to be involved are not approached and patients who have already participated are not re-approached.

4.1.2 Consent (5 minutes)

Written, informed consent will be sought from patient participants for the following:

- Administration of the UK-rPATD questionnaire
- Collection of demographic data (section 4.1.4) from the patients' ward-based medical records

4.1.3 Sample size

No participant data are reported for the rPATD in order to inform the sample size estimation. Participant data from the original PATD indicate that the maximum distribution of responses across the response options is 65%:35%[24]. Assuming a similar distribution of responses for the rPATD, a sample size of 75 participants will provide a 95% confidence interval of ±11% for the proportion willing to deprescribe.

Each of the four OPM wards at the NNUH contain approximately 36 beds, thus there are a maximum of 144 occupied OPM beds at any one time. Local data reports the average duration of an admission to hospital for OPM patients is nine days. Therefore, assuming three admission cycles per 28 days, there will be 432 patients occupying OPM beds across the four wards per 28 days.

An estimated 35% of all patients will be ineligible according to the study recruitment criteria. A conservative consent rate of 30% in the remaining 280 participants will provide 84 patients for recruitment per 28 days. It is therefore envisaged that recruitment of patients will be completed within one month. However, the uncertainty introduced by using data from the original PATD questionnaire to calculate the sample size for the rPATD has been accommodated by the recruitment period of patients being extended to three months.

4.1.4 Demographic data collection

The following demographic data will be collected from the patient's medical notes and documented on the demographic data collection sheet (patients) (appendix 4):

- Local hospital number
- Date of birth
- Sex
- Number of pre-admission medicines

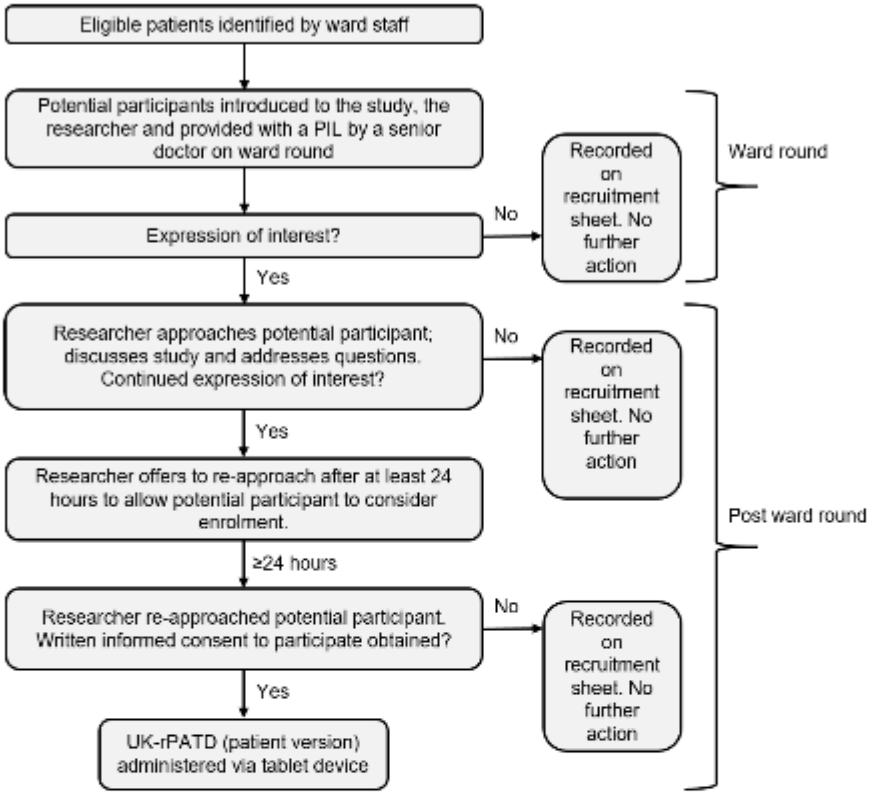
4.1.5 UK-rPATD questionnaire administration (15 minutes)

The UK-rPATD (patient version) (appendix 5) will be administered at the participant's bedside via the Microsoft® Forms platform (University of East Anglia's official recommended forms platform in compliance with the new General Data Protection Regulation (GDPR)) on an

electronic tablet device. In accordance with Trust infection control procedures, only the researcher will handle the tablet device. The researcher will position the device to allow the participant to read questions and vocalise answers. The use of a tablet device will allow the font size of the questions to be adjusted as necessary for the requirements of the participant. The researcher will then select the appropriate answer on the tablet device. The researcher will vocalise questions if requested by the participant.

Figure 1 provides a flowchart for the patient participant pathway.

Figure 1 Patient participant study involvement



4.2 Informal caregivers' attitudes towards (6 months)

4.2.1 Participant identification and recruitment

Recruitment of informal caregivers will occur across four Older People's Medicine wards at two hospital sites: Norfolk and Norwich University Hospital NHS Foundation Trust (NNUH) and The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust (QEH). Members of the Research and Innovation teams (such as a research nurse or other Good Clinical Practice accredited person) employed at the respective sites will identify eligible informal caregivers by reviewing medical notes to identify patients who may receive informal caregiver support. The Research and Innovation team member will be present on wards during designated visiting times to recruit informal caregivers.

Potential participants will be approached by a Research and Innovation team member who will offer a brief account of the study, including the eligibility criteria, and a participant information leaflet (appendix 5). The initials and bed identification number of the patient whom is being visited by the informal caregiver will be documented on the recruitment sheet (informal caregivers) (appendix 6). The Research and Innovation team member will address questions and if an interest in participation is expressed, the potential participant will be invited to complete the UK-rPATD questionnaire (version for informal caregivers) (appendix 7) on paper.

A poster advertisement (appendix 8) will be displayed on the study wards at appropriate locations such as notice boards to inform potential participants of the study and signpost to further information.

Inclusion criteria

- Age ≥18 years
- Informal caregiver (having any self-reported role in the management of health and/or medicines) to a patient who is:
    - Age ≥80 years
    - Prescribed ≥5 medicines prior to admission
    - Inpatient under the OPM speciality at NNUH or QEH

Exclusion criteria

- Unable to speak or read English

Initials and bed identification numbers of patients whom are being visited by informal caregivers making the Research and Innovation team members aware of their desire not to be approached for participation in the study will be documented on the recruitment sheet (informal caregivers) (appendix 6). The Research and Innovation team members will refer to

the recruitment sheet throughout the study period to ensure informal caregivers who do not wish to be involved are not approached and informal caregivers who have already participated are not re-approached.

4.2.2 Consent

Informal caregiver consent will be implied by completion of the questionnaire.

4.2.3 Sample size

Given the patient and caregiver UK-rPATD versions are almost identical and an absence of previously published caregiver rPATD responses, the sample size estimation is based on patient PATD responses[24] and is calculated as described in Section 1.1.2. Based on this, a sample size of 75 participants will provide a 95% confidence interval of 11% for the proportion willing to deprescribe.

The seven wards across the two hospital sites care for 240 patients per admission cycle and thus 720 per 28 days. The proportion of older people who receive informal caregiver support for managing their medicines at home is unknown however, twenty percent of older people have cognitive impairment[25] which is 144 per 28 days. Clinicians estimate that 50% of these 144 patients are likely to receive informal caregiver support, representing 72 informal caregivers across wards at two sites per 28 days. Assuming 50% of informal caregivers present during visiting hours and consent, the study will recruit 36 participants per 28 days. Completion of informal caregiver recruitment is therefore estimated by three months. However, uncertainty introduced by the absence of previously published informal caregiver responses to calculate a sample size and use of clinicians' estimate of informal caregiver prevalence, the recruitment period is extended to six months to account.

4.2.3 Demographic data collection

The following demographic data are requested from informal caregivers while completing the questionnaire (page 2 of UK-rPATD (version for informal caregivers) (appendix 7)):

- Informal caregiver's:
    - Age
    - Gender
    - Relationship with care recipient
- Care recipient's:
    - Age
    - Gender
    - Number of prescribed pre-admission medicines (including 'as required' medicines)

4.2.4 UK-rPATD questionnaire administration (15 minutes)

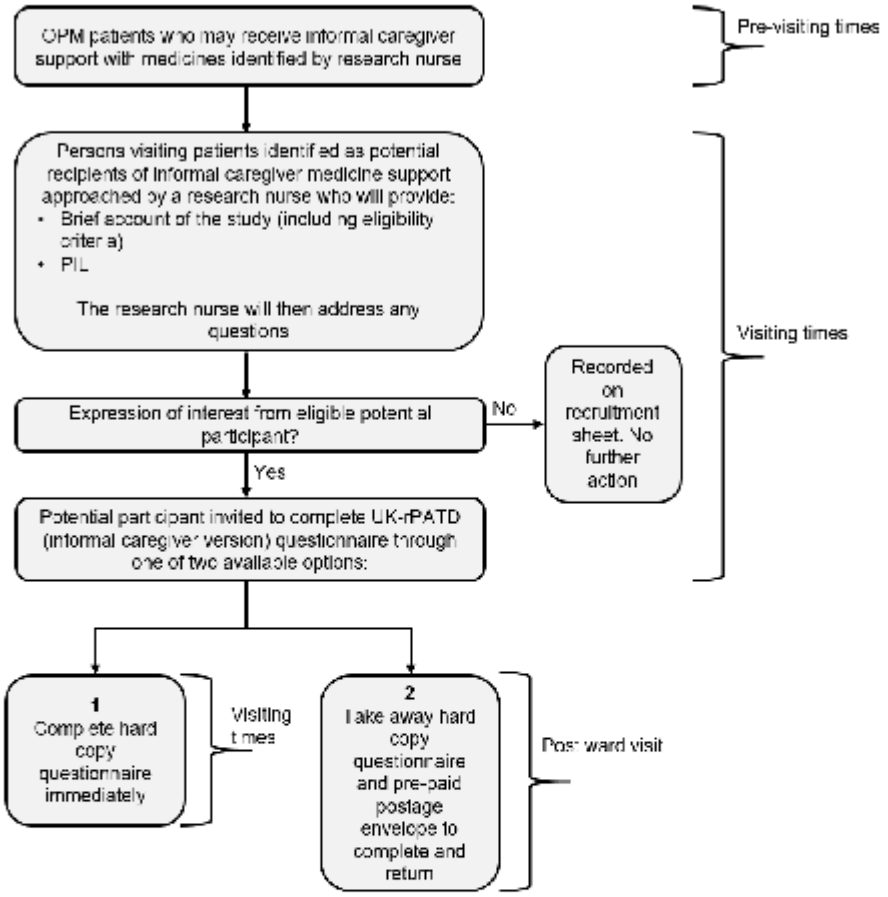
Informal caregivers wishing to participate will choose to complete the UK-rPATD (informal caregiver version) (appendix 7) from two options:

1. Immediate administration on a hard paper copy
2. Receive a hard paper copy and pre-paid enveloped to complete and return

Participants selecting option 2 will have the duration of the project to return their completed questionnaire.

Figure 2 provides a flowchart for the informal caregiver participant pathway.

Figure 2 Informal caregiver participant study involvement



5.0 Analysis (3 months)

Descriptive statistics will be used to describe the participant sample and the questionnaire responses. The relationship between both the patient and informal caregiver and the responses to the questionnaire, and it's four factors, will be investigated using statistical tests and logistic regression. The relationships between the four factors of the questionnaire and the willingness to stop medication will be explored using logistic regression. Thematic analysis will be undertaken for extended participant responses (UK-rPATD section 6).

6.0 Report writing (3 months)

A report presenting the study results and discussing implications for practice and future research will be prepared.

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Appendices

Appendix 1 Participant information leaflet (patient)

A questionnaire study

Your doctor or nurse has invited you to take part in this study. Before deciding to take part, please read this information sheet carefully.

What is the study about?

We don't know what patients in hospital think about doctors stopping medicines they may no longer need. This project is about asking patients what they think by answering a questionnaire.

We will not make any changes to your medicines in this study. **We do not advise or encourage stopping medicines. Decisions about medicines should be discussed with your doctor.** Whether or not you decide to participate will not affect the care that you receive whilst in hospital.

Why have I been invited to take part?

We are working with the ward staff and they think that you may be able to answer a questionnaire. We are interested in people who usually take five or more medicines at home and are over 80 years old.

What happens if I agree to take part?

You will be asked to read and sign a consent form which says that you have read the information in this sheet.

You will then answer a questionnaire asking patients what they think about doctors stopping medicines they may no longer need. You will tell the researcher your answer to each question and they write it on a computer by your bedside.

We will also ask to look at your medicines list and medical records that are kept on the ward. This is so we can see how many medicines the people who have answered the questionnaire are taking.

In total, this will take about 15 minutes.

Is the information I give during this study confidential?
Yes. All study involvement will remain strictly confidential and any information you give us will not be put in your medical records. Your questionnaire answers and the other information we collect about you will only be used for the purpose of the research project. Any information that allows you to be identified will not leave the hospital.

Who is organising and paying for the research?
This research is being organised by the School of Pharmacy, University of East Anglia. The research is paid for by the University of East Anglia and the Norfolk and Norwich University Hospital NHS Foundation Trust. The researchers will not be paid for your participation in this study.

What are the advantages of taking part?
There are not direct advantages to you by taking part. But the information you give will tell us whether we should look at finding a way of safely stopping medicines that may no longer be needed.

What are the disadvantages of taking part?
We do not think that there are any major disadvantages in taking part but you will be giving up some of your time to fill out the questionnaire.

Do you have to take part in the study?
No. Taking part is completely your decision. If you change your mind, you are free to withdraw at any time, without giving a reason. Any information already collected that is anonymised will be kept by the researcher.

Where do I find further information?
For more information, ask a member of the ward staff or a researcher.
For independent advice, please contact the Patient Advice and Liaison Service (PALS) at the Norfolk and Norwich University Hospital on:
☎ 01603 289036 or pals@nnuh.nhs.uk.

What will happen with the results of the research study?
Results from this study will be published in a research journal.

Appendix 2 Consent form

Consent form Version 4
12/10/17

IRAS ID: 233959

Participant number: P_____

CONSENT FORM

Title of Project: STOpping Potentially Problematic mEDicines (STOPPED): Your views (patients and informal caregivers)

A questionnaire study

Name of Researcher: Sion Scott / Alexander Dunne / Ugo Oloto (delete as appropriate)

	Please initial box
1. I confirm that I have read the participant information sheet dated 11/10/17 (Version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had 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, without my medical care or legal rights being affected.	☐
3. (For patients only) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of East Anglia, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4. I understand that the information collected about me will be anonymised and used in journal publications and research presentation.	☐
5. I agree to take part in the above study.	☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

Appendix 3 Recruitment sheet (patients)

STOPPED: Your views (patients and informal caregivers)
A questionnaire study

Recruitment sheet (patients)

Patient initials	Ward	Bed number	Eligibility*	Notes	PIL/consent form given? (Y/N)	Re-approach (date/time)	Recruitment**	Notes	Participant number	Do not approach (tick if yes)
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	
									P	

Researcher: SS / AD / UO (delete as appropriate) **Date:** _____ **Sheet number:** _____
*A=Eligible, E=Unable to read English, C=Unable to provide informed consent, I=Seriously unwell/end of life care, M=Unable to make informed decisions about medicines, S=Not cared for by the OPM speciality, O=Other (add note)
**R=Recruited, L=Return later, H=Discharged, D=Deceased, N=Declined, O=Other (add note)

Appendix 4 Demographic data collection form (patients)

STOPPED: Your views (patients and informal caregivers)
A questionnaire study

Demographic data collection form (patient)

Participant number	Hospital number	Date of birth	Sex (M/F)	Number of pre-admission medicines (including PRN*)
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				
P				

Researcher: SS / AD / UO (delete as appropriate) **Date: _____** **Sheet number: _____**
*PRN='as required'

Appendix 5 UK adapted Revised Patients' Attitudes Towards Deprescribing (UK-rPATD) (patient) questionnaire

University of East Anglia

Norfolk and Norwich University Hospitals NHS Foundation Trust

The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust

A questionnaire asking patients what they think about doctors stopping medicines

Most medicines have benefits and problems and the balance between these can change over time. We want to know what patients think about doctors stopping medicines which might be causing more harm than good. This questionnaire will tell us what your views are about doctors stopping your medicines. **No changes will be made to your medicines as a result of you answering this questionnaire.**

Reference number: P ☐☐

Today's date: ☐☐☐☐☐☐

Please answer the following six sections based on your experiences of your medicines.

	Section 1	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
B1	I feel the National Health Service (NHS) spends a lot of money on my medicines	❒	❒	❒	❒	❒
B2	Taking my medicines every day is very inconvenient	❒	❒	❒	❒	❒
B3	I feel that I am taking a large number of medicines	❒	❒	❒	❒	❒
B4	I feel that my medicines are a burden to me	❒	❒	❒	❒	❒
B5	Sometimes I think I take too many medicines	❒	❒	❒	❒	❒

	Section 2	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
A1	I feel that I may be taking one or more medicines that I no longer need	❒	❒	❒	❒	❒
A2	I would like to try stopping one of my medicines to see how I feel without it	❒	❒	❒	❒	❒
A3	I would like my doctor to reduce the dose of one or more of my medicines	❒	❒	❒	❒	❒
A4	I think one or more of my medicines may not be working	❒	❒	❒	❒	❒
A5	I believe one or more of my medicines may be currently giving me side effects	❒	❒	❒	❒	❒

Section 3		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
C1	I would be reluctant to stop a medicine that I had been taking for a long time	❒	❒	❒	❒	❒
C2	If one of my medicines was stopped, I would be worried about missing out on future benefits	❒	❒	❒	❒	❒
C3	I get stressed whenever changes are made to my medicines	❒	❒	❒	❒	❒
C4	If my doctor recommended stopping a medicine, I would feel that he/she was giving up on me	❒	❒	❒	❒	❒

C5	Have you ever had any of your medicines stopped?	Yes	❒	No	❒

If you answered 'Yes' to C5, please continue to C6.

If you answered 'No' to C5, please continue to Section 4.

C6	I have had a bad experience when stopping a medicine before	❒	❒	❒	❒	❒

Please continue to Section 4

	Section 4	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I1	I have a good understanding of the reasons I was prescribed each of my medicines	❒	❒	❒	❒	❒
I2	I know exactly what medicines I am currently taking, and/or I keep an up-to-date list of my medicines	❒	❒	❒	❒	❒
I3	I like to know as much as possible about my medicines	❒	❒	❒	❒	❒
I4	I like to be involved in making decisions about my medicines with my doctors	❒	❒	❒	❒	❒
I5	I always ask my doctor, pharmacist or other healthcare professional if there is something I don't understand about my medicines	❒	❒	❒	❒	❒

	Section 5	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
G1	If my doctor said it was possible I would be willing to stop one or more of my regular medicines	❒	❒	❒	❒	❒
G2	Overall, I am satisfied with my current medicines	❒	❒	❒	❒	❒

Section 6

Please tell us about anything that we have not asked you that would affect your views about doctors stopping your medicines. Please write your answer in the box below.

Appendix 6 Participant information leaflet (informal caregiver)

A questionnaire study

Before deciding to take part, please read this information sheet carefully.

What is the study about?
Some people have help at home with taking their medicines from an informal caregiver like a family member. We don't know what informal caregivers think about doctors in hospital stopping medicines that may no longer be needed. This project is about asking informal caregivers what they think by answering a questionnaire.
We will not make any changes to the medicines of the person you care for. The person you care for will not be approached for this study.

We do not advise or encourage stopping medicines. Decisions about medicines should be discussed with a doctor. Whether or not you participate will not affect the healthcare given to the person you care for.

Why have I been invited to take part?
We are working with the ward staff and they think that you may help someone with taking their medicines at home. We are interested in people over 18 years old who help people with their medicines at home who are over 80 years old and taking at least 5 medicines.

What happens if I agree to take part?
You will answer some questions about your thoughts on doctors stopping medicines that might not be needed anymore by the person you care for. There are two ways you can answer the questionnaire:

1. Complete the questionnaire now on the ward
2. Take the questionnaire and a pre-paid envelope home and return in the post once you have completed it

In total, filling out the questionnaire takes about 10 minutes.
By completing the questionnaire, you are agreeing to your anonymised data being used for research.

Is the information I give during this study confidential?
Yes. All study involvement will remain strictly confidential and your participation and any information you give us will not be put in the medical records of the person you care for. Your questionnaire answers will only be used for the purpose of the research project. Any information that allows you to be identified will not leave the hospital.

Who is organising and paying for the research?
This research is being organised by the School of Pharmacy, University of East Anglia. The research is paid for by the University of East Anglia and the Norfolk and Norwich University Hospital NHS Foundation Trust. The researchers will not be paid for your participation in this study.

What are the advantages of taking part?
There are not direct advantages to you by taking part. But the information you give will tell us whether we should look at finding a way of safely stopping medicines that may no longer be needed.

What are the disadvantages of taking part?
We do not think that there are any major disadvantages in taking part but you will be giving up some of your time to fill out the questionnaire.

Do you have to take part in the study?
No. Taking part is completely your decision. If you change your mind, you are free to withdraw at any time, without giving a reason, by contacting:

	☎	🖱
Mr Sion Scott Chief Investigator	01603 591973	sion.scott@uea.ac.uk
Dr Debi Bhattacharya Academic Supervisor	01603 593391	d.bhattacharya@uea.ac.uk

Any information already collected that is anonymised will be kept by the researcher.

Where do I find further information?
For more information, ask a member of the ward staff or a researcher.
For independent advice, please contact the Patient Advice and Liaison Service (PALS):

Norfolk and Norwich University Hospital	**The Queen Elizabeth Hospital King's Lynn**
☎ 01603 289036	☎ 01553 613351
🖱 pals@nnuh.nhs.uk	🖱 pals@qehkl.nhs.uk

What will happen with the results of the research study?
Results from this study will be published in a research journal.

Appendix 7 Recruitment sheet (informal caregivers)

1

STOPPED: Your views (patients and informal caregivers)
A questionnaire study

Recruitment sheet (informal caregivers)

Patient initials	Ward	Bed number	*Eligibility (informal caregiver)	Notes	Recruitment**	Notes	Questionnaire administration I = immediately P = post back	Participant number (if recruited)	Do not approach? (tick if yes)
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	
								C	

Site: NNUH/QEH (delete as appropriate) Date: _____ Sheet number: _____
*E=Eligible, R=Unable to read English, M=Not involved in managing medicines, O=Other (add note)
**R=Recruited, L=Return later, H=Declined, O=Other (add note)

Appendix 8 UK adapted Revised Patients' Attitudes Towards Deprescribing (UK-rPATD) (informal caregivers) questionnaire

University of East Anglia

Norfolk and Norwich University Hospitals NHS Foundation Trust

The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust

A questionnaire asking people who help others with their medicines what they think about doctors stopping medicines

Most medicines have benefits and problems and the balance between these can change over time. We want to know what people who help others with their medicines think about doctors stopping medicines which might be causing more harm than good. This questionnaire will tell us what your views are about doctors stopping medicines of the person you care for.

You do not have complete this questionnaire. If you choose to complete the questionnaire, any information that you give will be anonymous and will not affect the healthcare given to the person you care for. **No changes will be made to the medicines of the person you care for as a result of you answering this questionnaire.** The research findings will be reported in a way that prevents individuals from being identified.

Site: NNUH/QEH (delete as appropriate) **Reference number: C** ☐☐

Today's date ☐☐☐☐☐☐

Pre-questionnaire information

Please answer the following questions to help us understand who you help with their medicines.

1. **Which of the following options best describes your relationship with the person you care for?**

   Spouse/partner ❒ Relative ❒ Other ❒

If you answered 'Other' above, please write your relationship with the person you care for below:

_____

2. **Please tell us your age:** ☐ years

3. **Please tell us your gender:**

   Female ❒ Male ❒ Prefer not to say ❒

4. **Please tell us the age of the person you care for:** ☐ years

5. **Please tell us the gender of the person you care for:**

   Female ❒ Male ❒ Prefer not to say ❒

6. **Please tell us the total number of prescribed medicines the person you care for usually takes at home (please include 'as required' medicines):**

   ☐ medicines

Please turn the page to begin the questionnaire.

Please answer the following six sections based on your own experiences of helping the person you care for with their medicines.

	Section 1	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
B1	I feel the National Health Service (NHS) spends a lot of money on my care recipient's medicines	❒	❒	❒	❒	❒
B2	I feel that the person I care for is taking a large number of medicines	❒	❒	❒	❒	❒
B3	I feel that my care recipient's medicines are a burden to them	❒	❒	❒	❒	❒
B4	Sometimes I think the person I care for takes too many medicines	❒	❒	❒	❒	❒

	Section 2	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
A1	I feel that the person that I care for may be taking one or more medicines that they no longer need	❒	❒	❒	❒	❒
A2	I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it	❒	❒	❒	❒	❒
A3	I would like the doctor to reduce the dose of one or more of my care recipient's medicines	❒	❒	❒	❒	❒
A4	I think one or more of my care recipient's medicines may not be working	❒	❒	❒	❒	❒
A5	I believe one or more of my care recipient's medicines may be currently giving them side effects	❒	❒	❒	❒	❒

Section 3		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
C1	I would be reluctant to stop one of my care recipient's medicines that they had been taking for a long time	❒	❒	❒	❒	❒
C2	I get stressed whenever changes are made to my care recipient's medicines	❒	❒	❒	❒	❒
C3	I feel that if I agreed to stopping one of my care recipient's medicines then this is giving up on them	❒	❒	❒	❒	❒

C4	Has your care recipient ever had any of their medicines stopped?	Yes	❒	No	❒

If you answered 'Yes' to C4, please continue to C5.

If you answered 'No' to C4, please continue to Section 4

C5	The person that I care for has had a bad experience when stopping a medicine before	❒	❒	❒	❒	❒

Please continue to Section 4

	Section 4	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I1	I know exactly what medicines the person that I care for is currently taking and/or I have an up-to-date list of their medicines	❒	❒	❒	❒	❒
I2	I like to know as much as possible about my care recipient's medicines	❒	❒	❒	❒	❒
I3	I like to be involved in making decisions about my care recipients medicines with their doctors	❒	❒	❒	❒	❒
I4	I always ask the doctor, pharmacist or other healthcare professional if there is something I don't understand about my care recipient's medicines	❒	❒	❒	❒	❒

	Section 5	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
G1	If their doctor said it was possible I would be willing to stop one or more of my care recipient's medicines	❒	❒	❒	❒	❒
G2	Overall, I am satisfied with my care recipient's current medicines	❒	❒	❒	❒	❒

Section 6

Please tell us about anything that we have not asked you that would affect your views about doctors stopping medicines for the person you care for. Please write your answer in the box below.

Thank you for completing this questionnaire. Please return it to the research nurse or post back in the pre-paid envelope provided.

Appendix 8 Poster

A RESEARCH STUDY LOOKING FOR INFORMAL CAREGIVERS, LIKE A PATIENT'S RELATIVE ,TO COMPLETE A QUESTIONNAIRE

Help us to understand what people think about doctors stopping medicines that are no longer needed.

What will the study involve?

You will need to fill out a questionnaire (about 15 minutes)

There will be NO changes to the medicines of the person you are visiting as a result of you participating in this study.

Requirements

- Over 18 years old
- Informal caregiver (eg relative) involved in helping someone with their medicines

More information and how to take part

Ask a member of the ward staff. They will put you in touch with a researcher who can give you an information leaflet and the questionnaire.

NHS The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust

Norfolk and Norwich NHS University Hospitals NHS Foundation Trust

UEA University of East Anglia

Version 1
31/08/17
IRAS ID:233959

Appendix 6 Ethical and governance approval letters for Chapter 4

NHS
Health Research Authority

North West - Greater Manchester West Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8001

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

11 October 2017

Mr Sion Scott
Research pharmacist/PhD student
University of East Anglia
School of Pharmacy
University of East Anglia
Norwich
NR4 7TJ

Dear Mr Scott

Study title:	**STOpping Potentially Problematic mEDicines (STOPPED): Your views (patients and informal caregivers)**
REC reference:	**17/NW/0582**
Protocol number:	**SS-DB-Rev1**
IRAS project ID:	**233959**

Thank you for the updated informed consent form. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 10 October 2017

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant consent form	2	10 October 2017

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster]	1	31 August 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]		19 September 2017
IRAS Application Form [IRAS_Form_19092017]		19 September 2017
IRAS Application Form XML file [IRAS_Form_19092017]		19 September 2017
IRAS Checklist XML [Checklist_19092017]		19 September 2017
Letter from funder [Pharmacy Research UK contract]		
Letter from sponsor [Letter from sponsor]		19 September 2017
Other [PhD offer letter (including funding information)]		03 June 2016
Participant consent form	2	10 October 2017
Participant information sheet (PIS) [Patient PIL]	1	30 August 2017
Participant information sheet (PIS) [Informal caregiver PIL]	1	30 August 2017
Research protocol or project proposal [Protocol]	1	12 September 2017
Summary CV for Chief Investigator (CI) [Sion Scott CV]		13 September 2017
Summary CV for supervisor (student research) [Debi Bhattacharya CV]		02 May 2017
Summary CV for supervisor (student research) [Allan Clark CV]		02 May 2017
Validated questionnaire [UK-rPATD (patients)]	P4	30 August 2017
Validated questionnaire [UK-rPATD (informal caregivers)]	C5	30 August 2017

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

17/NW/0582 **Please quote this number on all correspondence**

Yours sincerely

Ewan Waters
REC Assistant

E-mail: nrescommittee.northwest-gmwest@nhs.net

Copy to: *Mr Samuel Hills*
Ms Laura Harper, Norfolk And Norwich University Hospital NHS Trust

NHS
Health Research Authority

Mr Sion Scott
Research pharmacist/PhD student
University of East Anglia
School of Pharmacy
University of East Anglia
Norwich
NR4 7TJ
sion.scott@uea.ac.uk

Email: hra.approval@nhs.net

12 October 2017

Dear Mr Scott

Letter of HRA Approval

Study title:	**STOpping Potentially Problematic mEDicines (STOPPED): Your views (patients and informal caregivers)**
IRAS project ID:	**233959**
Protocol number:	**SS-DB-Rev1**
REC reference:	**17/NW/0582**
Sponsor	**University of East Anglia**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

IRAS project ID	233959

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **233959**. Please quote this on all correspondence.

Yours sincerely

Gemma Oakes
Assessor

Email: hra.approval@nhs.net

Copy to: *Mr Samuel Hills, University of East Anglia [Sponsor Contact]*
Samuel.Hills@uea.ac.uk
Ms Laura Harper, Norfolk And Norwich University Hospital NHS Trust [Lead NHS R&D Contact]
LAURA.HARPER@nnuh.nhs.uk

IRAS project ID	233959

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster]	1	31 August 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]		19 September 2017
HRA Schedule of Events [Site Type 1 - NNUH]	1	11 October 2017
HRA Schedule of Events [Site Type 2 - QEHKL]	1	11 October 2017
HRA Statement of Activities [Site Type 2 - QEHKL]	1	11 October 2017
HRA Statement of Activities [Site Type 1 - NNUH]	1	11 October 2017
IRAS Application Form [IRAS_Form_19092017]		19 September 2017
IRAS Application Form XML file [IRAS_Form_19092017]		19 September 2017
IRAS Checklist XML [Checklist_19092017]		19 September 2017
Letter from funder [Pharmacy Research UK contract]		
Letter from sponsor [Letter from sponsor]		19 September 2017
Letter from sponsor [Confirmation changes made for HRA Assessment are Non-Substantial]	1	11 October 2017
Other [PhD offer letter (including funding information)]		03 June 2016
Participant consent form [Consent Form]	4	12 October 2017
Participant information sheet (PIS) [Patient PIL]	2	11 October 2017
Participant information sheet (PIS) [Informal Caregiver PIL]	2	11 October 2017
Research protocol or project proposal [Protocol]	1	12 September 2017
Summary CV for Chief Investigator (CI) [Sion Scott CV]		13 September 2017
Summary CV for supervisor (student research) [Debi Bhattacharya CV]		02 May 2017
Summary CV for supervisor (student research) [Allan Clark CV]		02 May 2017
Validated questionnaire [UK-rPATD (patients)]	P4	30 August 2017
Validated questionnaire [UK-rPATD (informal caregivers)]	C5	30 August 2017

IRAS project ID	233959

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Samuel Hills
Tel: 01603 592 994
Email: samuel.hills@uea.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments.
2.1	Participant information/consent documents and consent process	Yes	Following REC review, the applicant made changes to the participant information sheets and consent form to bring them in line with HRA Standards. The changes were deemed as non-substantial by the sponsor, and as such do not require review by the REC.
3.1	Protocol assessment	Yes	No comments.
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	There are 2 site types involving in this study and the sponsor has provided statement of activities and schedule of events for use with both types of participating NHS sites in the study. The sponsor has confirmed no other form of agreement will be used, or is

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			required.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study.
4.3	Financial arrangements assessed	Yes	The study is funded by Pharmacy Research UK (PRUK) The sponsor has confirmed that funding will not be provided to participating NHS sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	The applicant has confirmed neither hospital number nor NHS number will leave the site; date of birth will be calculated into age which is the information that will leave the site. As per 2.1 above, following REC review, the applicant made changes to the participant information sheets and consent form to bring them in line with Data Protect Act. The changes were deemed as non-substantial by the sponsor, and as such do not require review by the REC.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments.
5.3	Compliance with any applicable laws or regulations	Yes	No comments.
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable Opinion (with additional conditions) was issued on 10 October 2017. The applicant subsequently provided updated documentation and the REC confirmed the conditions had been met on 11

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			October 2017. Following REC review a non-substantial amendment (Non-Substantial Amendment 1 dated 11 October 2017) was submitted and the updated documentation has been listed in Appendix A (above).
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments.
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments.
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments.

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There are two site types participating in this study, the activities being undertaken are as follows: • **Site Type 1 – NNUH** – this NHS site will be required to identify and introduce/invite potential patient participants to the study, and introduce the external researcher. The external researcher will then discuss study and undertake consent procedures. The external researcher will administer the study questionnaire by the participant's bedside and collect patient demographic information from participant medical records post-questionnaire completion to input into Data Collection Form. The local members of staff will also be required to identify and approach informer caregivers about the study and introduce the researcher to the informer caregivers. The external researcher will then, either administer informal caregiver questionnaire face to face/provide self-addressed envelope with option to return when completed. **Site Type 2 – QEHKL** – this NHS site will be required to identify and approach informer caregivers about the study and introduce the researcher to the informer caregivers. The external researcher will then, either administer questionnaire face to face/provide self-addressed envelope with option to return when completed. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local

LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

ALL Participating NHS organisations in England **will be expected to formally confirm their capacity and capability** to host this research.

- The sponsor should ensure that participating NHS organisations are provided with a copy of this letter and all relevant study documentation, and work jointly with NHS organisations to arrange capacity and capability whilst the HRA assessment is ongoing.
- Further detail on how capacity and capability will be confirmed by participating NHS organisations, following issue of the Letter of HRA Approval, is provided in the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this appendix.

The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

The sponsor has confirmed that both site types participating in the study require a Local Collaborator, and they have both already been identified.

Training – Local members of staff will receive training on the protocol and study related procedures.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

In accordance with HR Good Practice Guidelines, HR arrangements at both site types are as follows:

Where arrangements are not already in place, undertaking any research activities that do not impact on the quality of care of the participant (such as questionnaires), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters

of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm standard DBS checks, and occupational health clearance.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.

- The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.
- Please note the final list of documentation does not match with the final list of REC approved documentation. This is due to the submission of a non-substantial amendment (that does not require submission to REC) in order to bring the study in line with HRA Standards.

Appendix 8 Distribution in patient rPATD responses when cross-tabulated with the primary outcome for Chapter 4

B1.d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
B1.d	No	Count	3	2	5
		% within Outcome_A2d	6.8%	6.5%	6.7%
	Yes	Count	41	29	70
		% within Outcome_A2d	93.2%	93.5%	93.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

B2d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
B2d	No	Count	37	22	59
		% within Outcome_A2d	84.1%	71.0%	78.7%
	Yes	Count	7	9	16
		% within Outcome_A2d	15.9%	29.0%	21.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

B3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
B3d	No	Count	24	8	32
		% within Outcome_A2d	54.5%	25.8%	42.7%
	Yes	Count	20	23	43
		% within Outcome_A2d	45.5%	74.2%	57.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

B4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
B4d	No	Count	39	20	59
		% within Outcome_A2d	88.6%	64.5%	78.7%
	Yes	Count	5	11	16
		% within Outcome_A2d	11.4%	35.5%	21.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

B5d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
B5d	No	Count	32	5	37
		% within Outcome_A2d	72.7%	16.1%	49.3%
	Yes	Count	12	26	38
		% within Outcome_A2d	27.3%	83.9%	50.7%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

A1d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
A1d	No	Count	35	7	42
		% within Outcome_A2d	79.5%	22.6%	56.0%
	Yes	Count	9	24	33
		% within Outcome_A2d	20.5%	77.4%	44.0%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

A3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
A3d	No	Count	37	8	45
		% within Outcome_A2d	84.1%	25.8%	60.0%
	Yes	Count	7	23	30
		% within Outcome_A2d	15.9%	74.2%	40.0%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

A4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
A4d	No	Count	30	8	38
		% within Outcome_A2d	68.2%	25.8%	50.7%
	Yes	Count	14	23	37
		% within Outcome_A2d	31.8%	74.2%	49.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

A5d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
A5d	No	Count	33	17	50
		% within Outcome_A2d	75.0%	54.8%	66.7%
	Yes	Count	11	14	25
		% within Outcome_A2d	25.0%	45.2%	33.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

C1d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
C1d	No	Count	25	17	42
		% within Outcome_A2d	56.8%	54.8%	56.0%
	Yes	Count	19	14	33
		% within Outcome_A2d	43.2%	45.2%	44.0%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

C2d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
C2d	No	Count	24	18	42
		% within Outcome_A2d	54.5%	58.1%	56.0%
	Yes	Count	20	13	33
		% within Outcome_A2d	45.5%	41.9%	44.0%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

C3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
C3d	No	Count	35	21	56
		% within Outcome_A2d	79.5%	67.7%	74.7%
	Yes	Count	9	10	19
		% within Outcome_A2d	20.5%	32.3%	25.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

C4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
C4d	No	Count	36	25	61
		% within Outcome_A2d	81.8%	80.6%	81.3%
	Yes	Count	8	6	14
		% within Outcome_A2d	18.2%	19.4%	18.7%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

C5d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
C6d	No	Count	37	27	64
		% within Outcome_A2d	84.1%	87.1%	85.3%
	Yes	Count	7	4	11
		% within Outcome_A2d	15.9%	12.9%	14.7%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

I1d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
I1d	No	Count	1	8	9
		% within Outcome_A2d	2.3%	25.8%	12.0%
	Yes	Count	43	23	66
		% within Outcome_A2d	97.7%	74.2%	88.0%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

I2d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
I2d	No	Count	6	9	15
		% within Outcome_A2d	13.6%	29.0%	20.0%
	Yes	Count	38	22	60
		% within Outcome_A2d	86.4%	71.0%	80.0%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

I3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
I3d	No	Count	8	5	13
		% within Outcome_A2d	18.2%	16.1%	17.3%
	Yes	Count	36	26	62
		% within Outcome_A2d	81.8%	83.9%	82.7%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

I4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
I4d	No	Count	15	10	25
		% within Outcome_A2d	34.1%	32.3%	33.3%
	Yes	Count	29	21	50
		% within Outcome_A2d	65.9%	67.7%	66.7%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

I5d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	No	Total
I5d	No	Count	9	5	14
		% within Outcome_A2d	20.5%	16.1%	18.7%
	Yes	Count	35	26	61
		% within Outcome_A2d	79.5%	83.9%	81.3%
Total		Count	44	31	75
		% within Outcome_A2d	100.0%	100.0%	100.0%

Key

Reference	Corresponding rPATD item
Outcome_A2d	I would like to try stopping one of my medicines to see how I feel without it
B1d	I feel the National Health Service (NHS) spends a lot of money on my medicines
B2d	Taking my medicines every day is very inconvenient
B3d	I feel that I am taking a large number of medicines
B5d	I feel that my medicines are a burden to me
B6d	Sometimes I think I take too many medicines
A1d	I feel that I may be taking one or more medicines that I no longer need
A3d	I would like my doctor to reduce the dose of one or more of my medicines
A4d	I think one or more of my medicines may not be working
A5d	I believe one or more of my medicines may be currently giving me side effects
C1d	I would be reluctant to stop a medicine that I had been taking for a long time
C2d	If one of my medicines was stopped, I would be worried about missing out on future benefits
C3d	I get stressed whenever changes are made to my medicines
C4d	If my doctor recommended stopping a medicine, I would feel that he/she was giving up on me
C5d	I have had a bad experience when stopping a medicine before
I1d	I have a good understanding of the reasons I was prescribed each of my medicines
I2d	I know exactly what medicines I am currently taking, and/or I keep an up-to-date list of my medicines
I3d	I like to know as much as possible about my medicines
I4d	I like to be involved in making decisions about my medicines with my doctors
I5d	I always ask my doctor, pharmacist or other healthcare professional if there is something I don’t understand about my medicines

Appendix 9 Distribution in carer rPATD responses when cross-tabulated with the primary outcome for Chapter 4

B1d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
B1d	.00	Count	4	1	5
		% within Outcome_A2d	13.8%	2.1%	6.6%
	1.00	Count	25	46	71
		% within Outcome_A2d	86.2%	97.9%	93.4%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

B2d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
B2d	.00	Count	9	9	18
		% within Outcome_A2d	31.0%	19.1%	23.7%
	1.00	Count	20	38	58
		% within Outcome_A2d	69.0%	80.9%	76.3%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

B3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
B3d	.00	Count	22	23	45
		% within Outcome_A2d	75.9%	48.9%	59.2%
	1.00	Count	7	24	31
		% within Outcome_A2d	24.1%	51.1%	40.8%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

B4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
B4d	.00	Count	19	10	29
		% within Outcome_A2d	65.5%	21.3%	38.2%
	1.00	Count	10	37	47
		% within Outcome_A2d	34.5%	78.7%	61.8%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

A1d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
A1d	.00	Count	19	7	26
		% within Outcome_A2d	65.5%	14.9%	34.2%
	1.00	Count	10	40	50
		% within Outcome_A2d	34.5%	85.1%	65.8%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

A3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
A3d	.00	Count	24	5	29
		% within Outcome_A2d	82.8%	10.6%	38.2%
	1.00	Count	5	42	47
		% within Outcome_A2d	17.2%	89.4%	61.8%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

A4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
A4d	.00	Count	18	9	27
		% within Outcome_A2d	62.1%	19.1%	35.5%
	1.00	Count	11	38	49
		% within Outcome_A2d	37.9%	80.9%	64.5%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

A5d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
A5d	.00	Count	18	13	31
		% within Outcome_A2d	62.1%	27.7%	40.8%
	1.00	Count	11	34	45
		% within Outcome_A2d	37.9%	72.3%	59.2%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

C1d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
C1d	.00	Count	5	17	22
		% within Outcome_A2d	17.2%	36.2%	28.9%
	1.00	Count	24	30	54
		% within Outcome_A2d	82.8%	63.8%	71.1%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

C2d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
C2d	.00	Count	16	28	44
		% within Outcome_A2d	55.2%	59.6%	57.9%
	1.00	Count	13	19	32
		% within Outcome_A2d	44.8%	40.4%	42.1%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

C3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
C3d	.00	Count	15	29	44
		% within Outcome_A2d	51.7%	61.7%	57.9%
	1.00	Count	14	18	32
		% within Outcome_A2d	48.3%	38.3%	42.1%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

C4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
C5d	.00	Count	27	38	65
		% within Outcome_A2d	93.1%	80.9%	85.5%
	1.00	Count	2	9	11
		% within Outcome_A2d	6.9%	19.1%	14.5%
Total		Count	29	47	76
		% within Outcome_A2d	100.0%	100.0%	100.0%

I1d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
I1d	.00	Count	3	9	12
		% within Outcome_A2d	10.7%	20.5%	16.7%
	1.00	Count	25	35	60
		% within Outcome_A2d	89.3%	79.5%	83.3%
Total		Count	28	44	72
		% within Outcome_A2d	100.0%	100.0%	100.0%

I2d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
I2d	.00	Count	1	2	3
		% within Outcome_A2d	3.6%	4.5%	4.2%
	1.00	Count	27	42	69
		% within Outcome_A2d	96.4%	95.5%	95.8%
Total		Count	28	44	72
		% within Outcome_A2d	100.0%	100.0%	100.0%

I3d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
I3d	.00	Count	4	8	12
		% within Outcome_A2d	14.3%	18.2%	16.7%
	1.00	Count	24	36	60
		% within Outcome_A2d	85.7%	81.8%	83.3%
Total		Count	28	44	72
		% within Outcome_A2d	100.0%	100.0%	100.0%

I4d * Outcome_A2d Crosstabulation

			Outcome_A2d		
			.00	1.00	Total
I4d	.00	Count	2	9	11
		% within Outcome_A2d	7.1%	20.5%	15.3%
	1.00	Count	26	35	61
		% within Outcome_A2d	92.9%	79.5%	84.7%
Total		Count	28	44	72
		% within Outcome_A2d	100.0%	100.0%	100.0%

Key

Reference	Corresponding rPATD item
Outcome_A2d	I would like the doctor to try stopping one of my care recipient's medicines to see how they feel without it
B1d	I feel the National Health Service (NHS) spends a lot of money on my care recipient's medicines
B2d	I feel that the person I care for is taking a large number of medicines
B3d	I feel that my care recipient's medicines are a burden to them
B4d	Sometimes I think the person I care for takes too many medicines
A1d	I feel that the person that I care for may be taking one or more medicines that they no longer need
A3d	I would like the doctor to reduce the dose of one or more of my care recipient's medicines
A4d	I think one or more of my care recipient's medicines may not be working
A5d	I believe one or more of my care recipient's medicines may be currently giving them side effects
C1d	I would be reluctant to stop one of my care recipient's medicines that they had been taking for a long time
C2d	I get stressed whenever changes are made to my care recipient's medicines
C3d	I feel that if I agreed to stopping one of my care recipient's medicines then this is giving up on them
C4d	The person that I care for has had a bad experience when stopping a medicine before
I1d	I know exactly what medicines the person that I care for is currently taking and/or I have an up-to-date list of their medicines
I2d	I like to know as much as possible about my care recipient's medicines
I3d	I like to be involved in making decisions about my care recipients medicines with their doctors
I4d	I always ask the doctor, pharmacist or other healthcare professional if there is something I don't understand about my care recipient's medicines

Appendix 10 Study protocol for Chapter 5

University of East Anglia

Norfolk and Norwich University Hospitals NHS Foundation Trust

STOPPED

STOpping **P**otentially **P**roblematic m**ED**icines

Your views

Hospital doctors and pharmacists
A focus group study

Protocol
Version 1

Study start date: 05/02/2018
Study end date: 05/02/2019

Chief investigator	Sion Scott (PhD student, University of East Anglia)
Supervisors	Dr Debi Bhattacharya (Senior Lecturer, University of East Anglia) Dr Allan Clark (Senior Lecturer, University of East Anglia) Dr Michael Twigg (Lecturer, University of East Anglia) Professor David Wright (Professor, University of East Anglia) Dr Helen May (Consultant, NNUH NHS Foundation Trust) Dr Martyn Patel (Consultant, NNUH NHS Foundation Trust) Professor Carol Farrow (Director of Pharmacy, NNUH NHS Foundation Trust)

1.0 Background

Prescribing multiple medicines, referred to as polypharmacy, to manage patients' long term conditions is increasingly common. The average number of medicines dispensed per person in England increased by over 60% between 2002 and 2012[1]. A large Scottish study reported an increase in the proportion of people prescribed between five and nine medicines from 9.7% in 1995 to 16.3% in 2010[2]. In the same study, the proportion of people prescribed between 10 and 14 medicines increased over the same period from 1.5% and 4.7%. Older people, often living with multiple long term conditions (co-morbidity), represent the majority of polypharmacy recipients, with one fifth of people aged ≥80 years prescribed are prescribed 10 or more medicines [3].

The terms 'appropriate' and 'inappropriate' polypharmacy have emerged[4,5]. Distinguishing between these two extremes is important in order to acknowledge the value of safe and effective polypharmacy and develop strategies to identify and minimise unsafe use of multiple medicines. Appropriate polypharmacy refers to clinically indicated medicines that provide benefits to patients which outweigh potential harms[4,6]. Conversely, inappropriate polypharmacy describes medication regimes containing potentially inappropriate medicines (PIMs)[5] and/or the medicines that are not clinically necessary[3], leading an unfavourable risk-benefit balance[7]. Inappropriate polypharmacy is associated with adverse drug reactions (ADRs), hospitalisation and impaired quality of life[8].

Data from two cross-sectional studies investigating predictors of inappropriate polypharmacy have suggested the number of medicines prescribed is the largest independent risk-factor[8,9]. It is therefore unsurprising that older people are most exposed to inappropriate polypharmacy, with studies reporting between 51% and 65% prevalence in this population[9,10].

Despite the emergence of initiatives such as medicines optimisation; which aims to improve medication safety through strategies such as avoiding the use of unnecessary medicines[11], practice has remained focused on prescribing new medicines with little attention paid to addressing inappropriate polypharmacy. Akin to prescribing, the process of stopping inappropriate medicines is complex. Factors to consider include adverse drug withdrawal events, return of the condition for which the medicine was indicated and the prescriber:patient relationship. The term 'deprescribing' emerged in the literature in 2003[12] to describe the rational withdrawal of inappropriate medicines if existing or potential harms outweigh the intended benefits[13]. Given there are two distinct circumstances, deprescribing may be described as 'proactive' or 'reactive', dependent on the trigger[14]. These terms are referred to

in a qualitative study exploring views towards deprescribing in primary care[14], however they are not defined in the literature. The aforementioned study found deprescribing approached at present were dominated by reactive behaviours, with clinicians reporting little proactive deprescribing in their practice[14]. There may therefore exist discrete challenges to proactive and reactive deprescribing. Given this, the research team have proposed to following definitions for use in this research study:

- Proactive deprescribing: discontinuing a medicine in response to present observed harm
- Reactive deprescribing: discontinuing a medicine if future gains are unlikely or prevent future harm

Crucial to the deprescribing process is establishing an accurate account of a patient's prescribed medicines and provision of adequate physiological monitoring to observe response to medication withdrawal[15]. Given these requirements, an admission to hospital where a medicines reconciliation is routinely undertaken and physiological and biochemical parameters are monitored, may provide an appropriate opportunity for a deprescribing intervention.

Medical Research Council guidance for the development and evaluation of complex interventions and process evaluations emphasise the importance of the development phase which should comprise[15]:

1. Identifying the evidence base
2. Identifying/developing theory
3. Modelling process and outcomes

Identifying the evidence base includes reviewing the current literature and supplementing with new primary research if necessary. Theory development is informed by the evidence base and an understanding of the likely processes of change is established. The Behaviour Change Wheel[17] is an integrative framework developed to assist researchers with undertaking a theoretically informed behavioural diagnosis (understanding what needs to change) and selecting evidence based behaviour change techniques[18] to form an intervention. The aforementioned framework has been successfully applied to the development of interventions targeting healthcare practitioner behaviour, including promoting active medication reviews in primary care[19]. The intervention then enters the modelling phase, where important information about design and evaluation are synthesised.

An intervention to promote deprescribing in hospital will focus on encouraging clinicians to change their practice. Understanding clinicians' views, including the barriers and facilitators to routine deprescribing during a hospital admission, is therefore crucial to identifying the evidence base.

A 2014 systematic review by Scott et al sought to synthesise the literature exploring prescribers' barriers and facilitators to deprescribing inappropriate medicines in adults[20]. A total of 21 articles were included, all of which concerned medical prescribers. Eighteen studies were undertaken in a primary care context, two in care homes and only one study explored the views of hospital doctors. The latter study reported on the processes leading to inappropriate use of medicines in hospital, such as prescribing errors on admission to hospital. Some themes emerged which may apply to a deprescribing context such as emphasis on managing the acute healthcare problems and short term treatments. However, a study focused on deprescribing in hospital should yield a more comprehensive account of clinician's views on deprescribing.

Scott et al identified four barrier and facilitator themes to deprescribing; awareness (insight into the appropriateness of one's prescribing), inertia (failure to act despite awareness of inappropriate prescribing), self-efficacy (factors influencing a prescriber's belief and confidence in their ability to undertake medication discontinuation) and feasibility (factors external to the prescriber which determine the ease of change)[20]. Examples of barriers include disparity between beliefs about inappropriate medicines at a population and individual patient level (awareness), fear of unknown or negative consequences (inertia), difficulty balancing the benefits and harms of medicines (self-efficacy) and discomfort with questioning the prescribing of a peer such as a specialist (feasibility). Facilitators to deprescribing included interventions to raise awareness of inappropriate prescribing (awareness), belief that discontinuing inappropriate medicines can bring benefits (inertia), training in prescribing for older people (self-efficacy) and access to specialist and allied healthcare professionals such those located in hospitals (feasibility)[20].

Compared to their primary care counterparts, hospital practitioners' views towards deprescribing are under researched[20]. Several barriers and facilitators are likely generalisable across healthcare settings, such as limited time available to review and discontinue medicines[20]. However, dissimilarities between hospital and primacy care may also lead to divergence. For example, new challenges to deprescribing may present in hospital such as limited pre-existing clinician:patient relationship and pressure to concentrate resources on discharging. Conversely, advantages to deprescribing in hospital may include access to

specialist and allied healthcare professionals and routine physiological monitoring. Moreover, the views of non-medical healthcare practitioners involved in prescribing decisions are also underrepresented in the literature[20]. Pharmacists are involved in all stages of medicines management in hospital from undertaking medicines reconciliation on admission through to counselling patients on changes to their regimes at discharge[21]. Accordingly, pharmacists will likely play an important role in many aspects of deprescribing in hospital. It is therefore important to capture pharmacists' views to inform development of a deprescribing intervention.

The absence of hospital practitioner's views represented in the deprescribing literature[20] requires new primary research to address the knowledge gap. Capturing the views of doctors representing the Older People's Medicine in the present study will ensure a future intervention is informed by clinicians who are most likely to encounter patients requiring deprescribing. Pharmacists' proximity to medicines management decisions and processes, including deprescribing, warrants their representation in the development of an intervention through participation in the present study.

2.0 Aim and Objectives

2.1 Aim

- Explore the views of doctors and pharmacists towards deprescribing in hospital

2.2 Objective

1. Check agreement with the research team's proposed definitions for proactive and reactive deprescribing
2. Describe and explore the barriers and facilitators to deprescribing from the doctor and pharmacist perspectives
3. Define the potential contribution of other healthcare professionals to deprescribing

3.0 Method

3.1 Phenomenological approach

Phenomenological inquiry is a qualitative research approach adopted for this focus group. The individual's lived experiences of a single concept or idea (the phenomenon) are explored and reduced to a description of the universal essence[22]. Phenomenology therefore provides a composite description of the experiences of all individuals in the study. The description includes 'what' they have experienced and 'how' they experienced it[22]. This approach is appropriate to the present study as the aim is to explore the broad views of two groups of healthcare professionals (doctors and pharmacists) towards deprescribing in hospital through their experiences of practice. In phenomenological studies, the researcher often sets their own experiences of the phenomenon aside, referred to as 'bracketing', to minimise the influence of their own experiences on the data collection process[22]. This allows the research to focus on the experiences of participants. Bracketing is important in the present study as the researchers are healthcare professionals with experience of deprescribing research and related evidence and may therefore have preconceptions regarding deprescribing in hospital.

3.2 Focus group rationale

This study is a component of a programme of work which aims to develop an intervention to facilitate hospital practitioner deprescribing. Outputs from this study will inform the development of the intervention, which will be tailored based on the views expressed by hospital clinicians. The data should reflect the broad views of hospital doctors and pharmacists

representing two large UK teaching hospitals (Norfolk and Norwich University Hospitals NHS Foundation Trust and Cambridge University Hospitals NHS Foundation Trust) and two district general hospitals (The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust and The Ipswich Hospital NHS Trust).

Given the absence of published literature to derive a survey to capture the views of hospital doctors and pharmacists[20], qualitative focus groups will be undertaken. Conducting focus groups is an ideal method for answering the research question as data are generated by the interactions between participants. Views are presented and reflected on, leading to generation of additional material not otherwise captured through other qualitative methods such as in-depth interviews[23]. This interaction is important as group 'brainstorming' and 'problem solving' are allowed to occur, presenting a more natural environment analogous to clinical decision making in practice[24]. Participants assume some responsibility for directing the discussion and the researcher's role is less pronounced and thus less influential than in individual interviews.

3.3 Recruitment

This study will recruit doctors and pharmacists in up to eight uni-professional focus groups from the Norfolk and Norwich University Hospital NHS Foundation Trust, Cambridge University Hospitals NHS Foundation Trust, The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust and The Ipswich Hospital NHS Trust (up to 1x doctor focus group and 1x pharmacist focus group per site).

Prior to study commencement, ethical approval will be secured from the Faculty of Medicine and Health Sciences Research Ethics committee at the University of East Anglia and governance approval from the Health Research Authority.

3.3.1 Hospital doctors

Senior doctors (registrars and consultants) representative of the Older People's Medicine speciality will be recruited. The inclusion and exclusion criteria for doctor participants are:

Inclusion criteria

- Senior hospital doctor (registrar or consultant) working in Older People's Medicine

Exclusion criteria

- Member of the research team

Clinical leads from the Older People's Medicine speciality across all research sites have expressed interest in their respective specialities being represented in this research. The clinical leads have also been involved in developing the recruitment strategy. Focus groups will be convened during periods of availability for senior doctors to attend as advised by the clinical leads.

3.3.2 Hospital pharmacists

Senior pharmacists (Agenda for Change Band 7 or higher) will be recruited. The inclusion and exclusion criteria for pharmacist participants are:

Inclusion criteria

- Pharmacist (Agenda for Change Band 7 or higher +/- prescribing credentials) with a ward-based role

Exclusion criteria

- Member of the research team
- Undertaking <2 days per week of ward based clinical pharmacy activities

Clinical leads from Pharmacy across all sites have expressed interest in their respective specialities being represented in this research and acting as gatekeepers. The clinical leads have also been involved in developing the recruitment strategy. Focus groups will be convened during periods of availability for pharmacists to attend as advised by the local clinical leads.

3.3.3 Incentives and remuneration

Refreshments will be provided to participants during the focus group sessions. Each speciality department within the hospital research sites will be paid a reimbursement fee of £75 per doctor participant and £50 per pharmacist participant for their time (based on Clinical Research Network costings). This reimbursement is offered to the hospital departments because the focus groups will be convened during clinicians' working day.

3.4 Focus groups (6 months)

3.4.1 Participant invitation

3.4.1.2 Hospital doctors

Clinical leads from the specialities will act as gatekeepers and invite eligible doctors to participate. Gatekeeper consent will be formally requested once ethical approval has been granted. The email text requesting gatekeeper consent is provided in appendix 1. The following post-holders at each hospital site will be requested to act as gatekeepers for doctor participants:

- Norfolk and Norwich University Hospital – Consultant Geriatrician and Service Director for Older Peoples Medicine Department
- Addenbrooke's Hospital - Consultant Geriatrician
- The Queen Elizabeth Hospital King's Lynn - Consultant Geriatrician
- Ipswich Hospital - Consultant Geriatrician

An invitation email (appendix 2) containing a brief account of the study, attached participant information leaflet (appendix 3) and a link to complete an online recruitment survey (sample available in appendix 4) (hosted by Microsoft® Forms – University of East Anglia's official recommended forms platform in compliance with the new GDPR) will be will be sent to the gatekeepers' Trust email address. Gatekeepers will then forward the invite email plus attachments to eligible doctors within their respective specialities via trust internal email. Any potential participants who do not complete the availability survey will not be contacted further.

The doctor branch of the online recruitment survey will request the following information:

1. Name
2. Hospital
3. Trust email address
4. Speciality
5. Grade e.g. consultant
6. Relevant 1 hour slot date availability over four months from January 2018 to July 2018*
7. Dietary requirements (free text box)

*Available answers will correspond to the selected speciality's pre-determined available focus group time slots as advised by the clinical leads post ethical/governance approval.

3.4.1.2 Hospital pharmacists

The clinical leads will act as a gatekeeper and invite eligible pharmacists to participate. An invitation email (appendix 5) containing a brief account of the study, attached participant

information leaflet (appendix 6) and a link to complete the online recruitment survey (appendix 4) will be will be sent to the gatekeepers' Trust email address. The gatekeeper will then forward the invite email plus attachments to eligible pharmacists via Trust internal email. Any potential participants who do not complete the availability survey will not be contacted further.

The following post-holders at each hospital site will be requested to act as gatekeepers for pharmacist participants:

- Norfolk and Norwich University Hospital – Clinical Director of Pharmacy Services
- Addenbrooke's Hospital – Lead Pharmacist (Medicine)
- The Queen Elizabeth Hospital King's Lynn – Chief Pharmacist
- Ipswich Hospital – Chief Pharmacist

The pharmacists' branch of the online recruitment survey will request the following information from potential participants:

1. Name
2. Hospital
3. Trust email address
4. Grade e.g. Band 7
5. Non-medical prescriber status
6. Relevant 1 hour slot date availability over four months from January 2018 to July 2018*
7. Dietary requirements (free text box)

*Available answers will correspond to the selected speciality's pre-determined available focus group time slots as advised by the clinical leads post ethical/governance approval.

3.4.2 Scheduling

The chief investigator, with support from the supervisory team, will determine the most appropriate date and time to convene the focus groups by reviewing the online recruitment survey responses and considering research site room booking availability. Of the survey responses, potential participants will be selected for invitation by purposive sampling to facilitate an even mix demographic and seniority characteristics.

Once appropriate scheduling is complete, the chief investigator will book an appropriate meeting room at the research site with support from relevant gatekeepers. The meeting room booking will fulfil the following criterial:

- Located at the research site
- Minimum capacity 10 people

- 120 minute booking (30 minutes for room preparation, 60 minutes for focus group conduction and 30 minutes for tidying up/returning meeting room to original arrangement).

3.4.2 Participant notification of selection/non-selection

After receiving confirmation of all room bookings, the chief investigator will send selected participants a corresponding scheduling email to inform them of the focus group details (date/time, location) (appendix 7). The email will also request selected participants to confirm their intention to participate in their allocated focus group by responding to the scheduling email within 7 days. Selected participants not responding will be sent the scheduling email again at least 5 days after the initial email is sent. Any potential participants not responding after the second scheduling email will not be contact further and will be excluded. A reminder email (appendix 8) will be sent to all confirmed participants at least 48 hours prior to their scheduled focus group.

Respondents who are not selected for invitation will be sent a non-selection email informing them of this outcome and thanking them for their interest (appendix 9).

In the event of potential participants informing the chief investigator that they are no longer able their allocated focus group, any remaining appropriate non-selected potential participants will be for invited for selection as above. Participants will be made aware of this eventuality in the non-selection email (appendix 9) and are informed they can opt-out by responding accordingly.

3.4.2 Focus group design

Up to eight uni-speciality focus groups will comprise of 6-8 participants, each with a moderator (SS) and assistant moderator (member of the research team). During the focus groups, a semi-structured topic guide informed by the Behaviour Change Wheel[17] will be used to facilitate discussion (appendix 10). The discussion will commence by presenting the research team's suggested definitions for 'reactive' and 'proactive' deprescribing, as defined in the introduction and on page 3 of the topic guide (appendix 10) (either by providing a hand out of appendix 10, page 3 or via computer projector if available). Suggestions for revisions accepted by the research team will be retained and presented at future focus groups (i.e. definitions may be refined iteratively throughout the study). The group discussion will then proceed through the topics outlined in appendix 10.

The moderator will manage the group and encourage free discussion to generate a wide range of views around the individual topics suggested in the guide. The focus group will last up to 60 minutes and refreshments will be provided.

The assistant moderator will be responsible for ensuring recording equipment is functioning correctly and they may also make notes during the session. Additionally, they will be responsible for ensuring participants are comfortable and will be available to provide assistance if necessary during the session.

The moderator and assistant moderator will available for 30 minutes to address participants' questions after the scheduled focus group termination time.

3.4.3 Consent

Written, informed consent will be sought when participants arrive at the focus group session. The focus group and audio-recording will not commence until all participants have signed the consent form (appendix 11 (doctor version) and appendix 12 (pharmacist version)) indicating their agreement to participate and have the session audio-recorded.

3.4.4 Participant withdrawal and their data

Participants will be free to withdraw from the study at any time, without providing a reason, by informing the Chief Investigator. If participants chose to withdraw during or after a focus group session, it will not be possible to withdraw their individual anonymised data. Potential participants are fully informed of this eventuality in the participant information leaflets (appendix 3 (doctors) and 6 (pharmacists)).

3.4.5 Data collection

All recruitment data collected through the Microsoft® Forms platform will be securely stored on a password protected computer at the University of East Anglia. All focus group discussions will be recorded using two identical audio-recording devices. Recordings will be transferred to a password protected university computer and subsequently deleted from the recording device. Recordings will be anonymously transcribed verbatim, with each participant assigned an anonymous identifier indicating their profession only, by the chief investigator and checked for accuracy by a member of the research team.

3.5 Data analysis (3 months)

A concurrent thematic analysis approach supported by qualitative data analysis software (NVivo 11) will be used after each focus group[25]. This will involve coding and comparing emerging themes within transcripts and finally across the entire dataset, identifying shared and disparate views. Analysis will be checked by a member of the supervisory team. The resultant themes will be mapped to the behaviour change wheel[17] and a behavioural diagnosis performed.

Suggestions for revised definitions of 'reactive' and 'proactive' deprescribing will be reviewed by the research team and amended accordingly. Any revised definitions will be retained and presented at the next available focus group.

3.6 Report writing (3 months)

A report presenting the study results and discussing implications for practice and future research will be prepared.

4.0 Future study

The results this focus group study will be used to develop a theory-informed deprescribing intervention for implementation in hospital. The outputs of the behavioural diagnosis performed in the analysis of this study will allow selection of evidence based behaviour change techniques[18] to promote deprescribing in hospital. The intervention will subsequently progress to a modelling phase.

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Appendices

Appendix 1 Email requesting gatekeeper consent

Gatekeeper consent email Version 1 08.09.17 IRAS ID: 231262

Email to potential gatekeepers:
Dear NAME,

I am emailing you regarding the 'STOpping Potentially Problematic mEDicines (STOPPED): Your views (hospital doctors and pharmacists)' focus groups study. Thank you for reviewing the study protocol and confirming your department's intention to participate in the study.
As you are aware, in order for the project to take place, participants need to be recruited to take part in focus groups.

Your involvement with the research and the connections you have with potential participants means that you are well placed to become a 'Gatekeeper' for recruitment of participants to the research project.

Your role as a Gatekeeper would involve liaising with potential participants (please see inclusion and exclusion criteria) within your Trust department on behalf of the research team. You may be asked to email potential participants with information from the research team and assist the research team in organising focus groups and recruiting participants.
If you are happy to act as a 'Gatekeeper' for the purpose of recruiting participants for this research, please could you respond to this email with the following statement:
"I, NAME, provide my consent to act as a Gatekeeper for the recruitment of participants as part of the 'STOpping Potentially Problematic mEDicines (STOPPED): Your views (hospital doctors and pharmacists)' focus groups study"

If you have any further questions, please do not hesitate to contact me.

Warmest Regards,

Sion Scott
Research Pharmacist
School of Pharmacy
University of East Anglia, Norwich Research Park
Norwich, Norfolk
NR4 7TJ

Office: CAP 01.109
Tel: 01603 591973
Web: www.uea.ac.uk

Appendix 2 Invitation email (doctors)

Invitation email (doctors) Version 1 08.09.17 IRAS ID: 231262

Subject heading: Invitation to participate in a 1 hour focus group study asking your views on deprescribing

Body of text

Dear Clinician,

Researchers from the School of Pharmacy, University of East Anglia invite you to take part in a 1 hour focus group study at your hospital site. The aim of the study is to capture your views towards deprescribing (identifying and discontinuing potentially problematic medicines) for the older people population.

The senior clinician in your speciality has forward you this email because they believe you may be interested in expressing your views on this subject. Further details are provided in the attached participant information leaflet.

After reading the leaflet, if you would like to participate, please complete an online availability survey: https://goo.gl/9CyPw4 to allow us to arrange a convenient focus group session. If you require any further information, please contact me via the details below.

Thanks and kind regards,

Sion Scott
Research Pharmacist and Chief Investigator
School of Pharmacy
University of East Anglia, Norwich Research Park
Norwich, Norfolk
NR4 7TJ

Office: CAP 01.109
Tel: 01603 591973
Email: sion.scott@uea.ac.uk
Web: www.uea.ac.uk

Attachment: Participant information leaflet (appendix 3)

Appendix 3 Participant information leaflet (doctors)

Norfolk and Norwich University Hospitals NHS

STOPPED

STOpping Potentially Problematic mEDicines Your views

A focus group study

A senior clinician within your speciality has invited you to take part in this study. Before decided to take part, please read this information sheet carefully.

What is the study about?

Approximately 50% of older people are prescribed medicines with more risks than benefits (potentially problematic medicines). These medicines are associated with adverse drug events, impaired quality of life and unnecessary hospital admissions. The term deprescribing described the identification and discontinuation of potentially problematic medicines as a partnership between patients and healthcare practitioners. The views of general practitioners towards deprescribing are well described in the literature. Conversely, the views of hospital practitioners are underrepresented.

The aim of this focus group study is to capture the views of hospital doctors and pharmacists towards deprescribing.

This research in being conducted by the School of Pharmacy, University of East Anglia. The research is funded by the Norfolk and Norwich University Hospital NHS Foundation Trust, University of East Anglia and Pharmacy Research UK.

Why have I been chosen?

Your speciality has been identified as performing a role in managing the medicines of older people during a hospital admission. You may therefore be involved with deprescribing for older people currently or in the future. We would therefore like to capture your views towards deprescribing.

Do I have to take part?

No. Whether or not you decide to participate is completely your decision. Your organisation will not be notified of your decision.

What if I agree to take part?

The research team and a senior clinician in your speciality have identified opportunities to undertake the 1 hour focus group. You will need to fill out a short online survey indicating your availability at the proposed focus group session dates and times plus tell us a bit about yourself like your grade. We will schedule a convenient time and let you know by email whether or not you have been selected to attend and provide details (date, time, location). The focus group will be held in a meeting room at your hospital site.

The focus group will consist of 6-8 members of your speciality plus two researchers. The lead researcher, Sion Scott, will lead the discussion and guide the group through topics to explore. There are no right or wrong answers in this discussion; we are interested in all opinions. A second researcher will be present to support the group and take notes. All group discussion will be audio-recorded so that we can listen back and transcribe them.

At the beginning of the focus group, you will be asked to sign a consent form indicating you are happy

to take part. Anything discussed in the focus group relating to bad practice, such as leading to patient harm, will be considered by the researchers in private and referral action taken as appropriate.

Free refreshments provided and your department will be reimbursed for your time.

What about confidentiality?
All data will be treated in accordance with the Data Protection Act 1998. Only the researchers running the focus group will be able to identify you. We will ask participants not to discuss what is said outside the focus group. The audio recordings will be transcribed, anonymised and analysed by the researchers and all data will be kept in a secure location at the University of East Anglia. Nobody at your organisation will have access to this data. Any personal data collected such as your name will be destroyed after 3 years. Research data such as the anonymised audio transcript from the focus groups will be kept for 10 years.

Are there benefits to taking part?
There are no direct benefits of taking in this study. However, as the overall aim of the STOPPED project is to develop an intervention to support hospital practitioners to deprescribe, your views will therefore help an intervention designed to support you.

Are there costs to taking part?
We do not foresee any costs other than your time spent at the focus group.

What if I want to withdraw from the study?
You are free to withdraw from the study at any time, without giving a reason, by informing the lead researcher Sion Scott:
sion.scott@uea.ac.uk ☎ 01603 591973 or in person.

If you chose to withdraw during or after the focus group, it will not be possible to withdraw your anonymised data.

What will happen to the results?
The results will be published in a research journal. You will not be identifiable.

For more information and to fill out the availability survey
Please contact the lead researcher for more information:
sion.scott@uea.ac.uk ☎ 01603 591973

To fill out the availability survey, follow: https://goo.gl/9CyPw4

For complaints, please contact Professor Mark Searcey, Head of the School of Pharmacy:
m.searcey@uea.ac.uk ☎ 01603 592026

Appendix 4 Online recruitment survey text

<table>
<tr><td colspan="2">What is your full name? (free text)</td></tr>
<tr><td colspan="2">Which hospital Trust do you work at?
• Norfolk and Norwich University Hospital NHS Foundation Trust
• Cambridge University Hospitals NHS Foundation Trust
• The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
• The Ipswich Hospital NHS Trust</td></tr>
<tr><td colspan="2">What is your Trust email address? (free text)</td></tr>
<tr><td colspan="2">To which of the following professions do you belong?
• Older People's Medicine (doctor)
• Pharmacy</td></tr>
<tr><td>Doctor branch</td><td>Pharmacist branch</td></tr>
<tr><td>What is your grade?
• Consultant
• Registrar</td><td>What is your grade? (MCQ)
• Band 7
• Band 8</td></tr>
<tr><td rowspan="2">The focus group will be convened during an existing protected education/research session. Which of the following dates are you available to attend? (please tick all that apply)*
• DATE/TIME
• DATE/TIME
• DATE/TIME
• DATE/TIME</td><td>Are you an independent prescriber?
• Yes
• No</td></tr>
<tr><td>The focus group will be convened during an existing protected education/research session. Which of the following dates are you available to attend? (please tick all that apply)*
• DATE/TIME
• DATE/TIME
• DATE/TIME
• DATE/TIME</td></tr>
<tr><td colspan="2">You will be provided with lunch during the focus group. Please detail any dietary requirements in the box below. (free text)</td></tr>
</table>

*Options depend on individual speciality and site, informed by gatekeepers and clinical leads post ethical/governance approval

Appendix 5 Invitation email (pharmacists)

Invitation email (pharmacists) Version 1 12/09/17 IRAS ID: 231262

Subject heading: Invitation to participate in a 1 hour focus group study asking your views on deprescribing

Body of text

Dear Clinician,

Researchers from the Pharmacy, University of East Anglia invite you to take part in a 1 hour focus group study at the Norfolk and Norwich University Hospital site. The aim of the study is to capture your views towards deprescribing (identifying and discontinuing potentially problematic medicines) for the older people population.

The senior clinician in your speciality has forward you this email because they believe you may be interested in expressing your views on this subject. Further details are provided in the attached participant information leaflet.

Please note, you will not be eligible to take part in this study if your role involves less than two days per week of ward based clinical pharmacy activities.

After reading the leaflet, if you would like to participate, please complete an online recruitment survey: https://goo.gl/9CyPw4. to allow us to arrange a convenient focus group session. If you require any further information, please contact me via the details below.

Thanks and kind regards,

Sion Scott
Research Pharmacist and Chief Investigator
School of Pharmacy
University of East Anglia, Norwich Research Park
Norwich, Norfolk
NR4 7TJ

Office: CAP 01.109
Tel: 01603 591973
Email: sion.scott@uea.ac.uk
Web: www.uea.ac.uk

Attachment: Participant information leaflet (appendix 6)

Appendix 6 Participant information leaflet (pharmacists)

A focus group study

A senior clinician within your speciality has invited you to take part in this study. Before decided to take part, please read this information sheet carefully.

What is the study about?

Approximately 50% of older people are prescribed medicines with more risks than benefits (potentially problematic medicines). These medicines are associated with adverse drug events, impaired quality of life and unnecessary hospital admissions. The term deprescribing described the identification and discontinuation of potentially problematic medicines as a partnership between patients and healthcare practitioners. The views of general practitioners towards deprescribing are well described in the literature. Conversely, the views of hospital practitioners are underrepresented.

The aim of this focus group study is to capture the views of hospital doctors and pharmacists towards deprescribing.

This research in being conducted by the School of Pharmacy, University of East Anglia. The research is funded by the Norfolk and Norwich University Hospital NHS Foundation Trust, University of East Anglia and Pharmacy Research UK.

Why have I been chosen?

Your speciality has been identified as performing a role in managing the medicines of older people during a hospital admission. You may therefore be involved with deprescribing for older people currently or in the future. We would therefore like to capture your views towards deprescribing.

Please note, you will not be eligible to take part in this study if your role involves less than two days per week of ward based clinical pharmacy activities

Do I have to take part?

No. Whether or not you decide to participate is completely your decision. Your organisation will not be notified of your decision.

What if I agree to take part?

The research team and a senior clinician in your speciality have identified opportunities to undertake the 1 hour focus group. You will need to fill out a short online survey indicating your availability at the proposed focus group session dates and times plus tell us a bit about yourself like your grade. We will schedule a convenient time and let you know by email whether or not you have been selected to attend and provide details (date, time, location). The focus group will be held in a meeting room at your hospital site.

The focus group will consist of 6-8 members of your speciality plus two researchers. The lead researcher, Sion Scott, will lead the discussion and guide the group through topics to explore. There are no right or wrong answers in this discussion; we are interested in all opinions. A second researcher will be present to support the group and take notes. All group discussion will be audio-recorded so

that we can listen back and transcribe them.

At the beginning of the focus group, you will be asked to sign a consent form indicating you are happy to take part. Anything discussed in the focus group relating to bad practice, such as leading to patient harm, will be considered by the researchers in private and referral action taken as appropriate.

Free refreshments provided and your department will be reimbursed for your time.

What about confidentiality?
All data will be treated in accordance with the Data Protection Act 1998. Only the researchers running the focus group will be able to identify you. We will ask participants not to discuss what is said outside the focus group. The audio recordings will be transcribed, anonymised and analysed by the researchers and all data will be kept in a secure location at the University of East Anglia. Nobody at your organisation will have access to this data. Any personal data collected such as your name will be destroyed after 3 years. Research data such as the anonymised audio transcripts from the focus groups will be kept for 10 years.

Are there benefits to taking part?
There are no direct benefits of taking in this study. However, as the overall aim of the STOPPED project is to develop an intervention to support hospital practitioners to deprescribe, your views will therefore help an intervention designed to support you.

Are there costs to taking part?
We do not foresee any costs other than your time spent at the focus group.

What if I want to withdraw from the study?
You are free to withdraw from the study at any time, without giving a reason, by informing the lead researcher Sion Scott:
sion.scott@uea.ac.uk ☎ 01603 591973 or in person.

If you chose to withdraw during or after the focus group, it will not be possible to withdraw your anonymised data.

What will happen to the results?
The results will be published in a research journal. You will not be identifiable.

For more information and to fill out the availability survey
Please contact the lead researcher for more information:
sion.scott@uea.ac.uk ☎ 01603 591973

To fill out the availability survey, follow: https://goo.gl/9CyPw4

For complaints, please contact Professor Mark Searcey, Head of the School of Pharmacy:
m.searcey@uea.ac.uk ☎ 01603 592026

Appendix 7 Scheduling email

Scheduling email Version 1 08/09/17 IRAS ID: 231262

Subject heading: STOPPED focus group confirmation and details

Body of text:

Dear NAME,

Thank you for completing the online availability survey for the STOPPED focus group study. Please see the below the details of your scheduled focus group:

Date: DD/MM/YYYY
Time: HH:MM-HH:MM
Location: ROOM, BUILDING +/-ANY RELEVANT DIRECTIONS

The focus group will comprise of 6-8 members of your speciality plus two researchers. You will also be provided with light refreshments.

Please reply to this email confirming your attendance at the above focus group within 7 days. If you are no longer able to attend, please also reply and let me know.

If you require any further information, please contact me using the details below.

I look forward to meeting with you at your focus group session.

Thanks and kind regards,

Sion Scott
Research Pharmacist and Chief Investigator
School of Pharmacy
University of East Anglia, Norwich Research Park
Norwich, Norfolk
NR4 7TJ

Office: CAP 01.109
Tel: 01603 591973
Email: sion.scott@uea.ac.uk
Web: www.uea.ac.uk

Appendix 8 Reminder email

Reminder email Version 1 23/11/17 IRAS ID: 231262

Subject heading: STOPPED focus group reminder

Body of text:

Dear NAME,

Thank you for agreeing to participate in the STOPPED focus group study. This is a curtesy reminder email detailing your focus group details. Please see the below the details of your scheduled focus group:

Date: DD/MM/YYYY
Time: HH:MM-HH:MM
Location: ROOM, BUILDING +/-ANY RELEVANT DIRECTIONS

The focus group will comprise of 6-8 members of your speciality plus two researchers. You will also be provided with light refreshments.

If you are no longer able to attend, please reply to this email to inform me at your earliest convenience.

If you require any further information, please contact me using the details below.

I look forward to meeting with you at your focus group session.

Thanks and kind regards,

Sion Scott
Research Pharmacist and Chief Investigator
School of Pharmacy
University of East Anglia, Norwich Research Park
Norwich, Norfolk
NR4 7TJ

Office: CAP 01.109
Tel: 01603 591973
Email: sion.scott@uea.ac.uk
Web: www.uea.ac.uk

Appendix 9 Non-selection email

Non-selection email Version 1 08/09/17 IRAS ID: 231262

Subject heading: STOPPED focus group

Body of text:

Dear NAME,

Thank you for completing the online availability survey for the STOPPED focus group study. There has been substantial interest from clinicians wishing to participate in the research and there are only a limited number of places available. Unfortunately, you have not been selected to attend the focus group on this occasion.

If space does become available, I may email you to invite you to participate at a scheduled focus group. If you do not wish to be contacted, please let me know by replying to this email.

If you have any questions regarding the study, please contact me via the details below.

Thanks and kind regards,

Sion Scott
Research Pharmacist and Chief Investigator
School of Pharmacy
University of East Anglia, Norwich Research Park
Norwich, Norfolk
NR4 7TJ

Office: CAP 01.109
Tel: 01603 591973
Email: sion.scott@uea.ac.uk
Web: www.uea.ac.uk

Appendix 10 Topic guide

Focus group topic guide

Pre-discussion tasks

1. Invite participants to sit down and help themselves to light refreshments
2. Introduce the research team and their roles (Sion Scott (discussion moderator) and the assistant moderator.
3. Invite participants to read and sign the consent form (available on their table)
4. Begin group discussion, following the topic guide (Table 1)
5. End group discussion
6. Thank participants for their contribution
7. Remind participants to maintain confidentiality of discussed materials beyond the focus group
8. Excuse participants

Table 1 Focus group topic guide

Question	Probes (TDF domain number)
1. (Present proactive and reactive deprescribing definitions/provide handouts – see last page of topic guide) What are your thoughts about the proposed definitions for proactive and reactive deprescribing?	
2. What are your thoughts on proactive deprescribing during the hospital admission?	• What is the first thing that pops into your head? Is this something that you do? (3) • What are the benefits? (9) • What are the disadvantages? (risks, harms, missed opportunities for alternative activities) (9)
3. What point or points during a hospital admission is it best to undertake proactive deprescribing	• At what point would you like it to happen? (11) • Who do you think is best placed to do this? (6)
4. (Approximately a ¼ of medication histories on admission contain an inappropriate medicine. Audit data suggested deprescribing prevalence is <1% and dominated by reactive activity) What are the reasons for low rates of proactive deprescribing? (Barriers)	
5. What can we do to increase proactive deprescribing activity? (Facilitators)	• What additional resources do you require? (access to computers, time etc.) (4) • What additional skills/training do you require? (1, 2) • What is the role of other healthcare professionals in proactive deprescribing? (6)

6. We talked about a number of factors that might help or hinder you in deprescribing. What we haven't talked about is x. Is that something that you think may be relevant to facilitating proactive deprescribing?

COM-B/TDF domain	Example probe	Covered
Psychological capability		
Knowledge (1) *An awareness of the existence of something*	What do you know about deprescribing?	☐
Skills (2) *An ability or proficiency acquired through practice*	Do you know how to deprescribe? (Identify and stop potentially problematic medicines)	☐
Memory, attention and decision processes (3) *The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives*	Is deprescribing something you usually do?	☐
Behavioural regulation (4) *Anything aimed at managing or changing objectively observed or measured actions*	How could you monitor whether you are proactively deprescribing all inappropriate medicines?	☐
Social opportunity		
Environmental context and recourses (5) *Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour*	To what extent do physical or recourse factors facilitate or hinder deprescribing? (e.g. time or information sources)	☐
Social opportunity		
Social influences (6) *Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours*	To what extent does what other people think influence your decision to deprescribe? (Patients, relatives, colleagues)	☐
Reflective motivation		
Social/professional role and identity (7) *A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting*	Should deprescribing be part of your job?	☐
Beliefs about capabilities (8) *Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use*	How difficult or easy is it for you deprescribe?	☐
Optimism (9) *The confidence that things will happen for the best or that desired goals will be attained*	What do you think about the feasibility of deprescribe in hospital?	☐
Beliefs about consequences (10) *Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation*	Do you think deprescribing will confer benefits? Or Harms?	☐
Intentions (11) *A conscious decision to perform a behaviour or a resolve to act in a certain way*	How likely are you to deprescribe?	☐
Goals (12) *Mental representations of outcomes or end states that an individual wants to achieve*	Where would you like to start with deprescribing (e.g. specific patient groups)?	☐
Automatic motivation		
Reinforcement (13) *Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus*	What would incentivise you to deprescribe?	☐
Emotion (14) *A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event*	What emotions or feelings do you have about deprescribing?	☐

7. If we wanted to increase deprescribing activity, what advice would you give us?		

Proactive deprescribing: discontinuing a medicine in response to an adverse clinical trigger

Reactive deprescribing: discontinuing a medicine if future gains are unlikely or prevent future harm

Appendix 11 Consent form (doctors)

Consent form (doctors) Version 2 15/01/18
IRAS ID: 231262

Participant Identification Number for this study:

CONSENT FORM

Title of Project: STopping Potentially Ptoblematic mEDicined: Your views (Hospital doctors and pharmacists)

Name of Researcher: Mr Sion Scott

Please initial box

1. I confirm that I have read the information sheet for doctors dated 15/01/18 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had 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, without my legal rights being affected. ☐
3. I understand that the session in which I participate will be audio recorded and the researchers will make notes of what I say ☐
4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 12 **Consent form (pharmacists)**

1

Consent form (pharmacists) Version 2 15/01/18
IRAS ID: 231262

Participant Identification Number for this study:

CONSENT FORM

Title of Project: STopping Potentially Ptoblematic mEDicined: Your views (Hospital doctors and pharmacists)

Name of Researcher: Mr Sion Scott

Please initial box

1. I confirm that I have read the information sheet for pharmacists dated 15/01/18 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had 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, without my legal rights being affected. ☐
3. I understand that the session in which I participate will be audio recorded and the researchers will make notes of what I say ☐
4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 11 Ethical and governance approval letters for Chapter 5

Faculty of Medicine and Health Sciences Research Ethics Committee

Sion Scott
PHA

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

18.1.18

Dear Sion,

Project Title: STOpping Potentially Probelmatic mEDicines (STOPPED): Your views (hospital doctors and pharmacists)
Reference: 2017/2018 - 59

The submission of your above proposal has been considered by the Faculty Research Ethics Committee 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.

Yours sincerely,

Professor M J Wilkinson
Chair
FMH Research Ethics Committee

CC David Wright

NHS
Health Research Authority

Mr Sion Scott
School of Pharmacy
University of East Anglia
Norwich
NR4 7TJ

Email: hra.approval@nhs.net

18 January 2018

Dear Mr Scott

Letter of HRA Approval

Study title:	**Stopping Potentially Problematic mEDicines: Your views (hospital doctors and pharmacists)**
IRAS project ID:	**231262**
Protocol number:	**R205180**
Sponsor	**University of East Anglia**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

and further information about working with the research management function for each organisation can be accessed from the HRA website.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The attached document ***"After HRA Approval** – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found through IRAS.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details on the HRA website.

Your IRAS project ID is **231262**. Please quote this on all correspondence.

Yours sincerely

Kelly Rowe
Assessor

Email: hra.approval@nhs.net

Copy to: *Mr Samuel Hills, University of East Anglia, Sponsor contact*
Ms Laura Harper, Norfolk And Norwich University Hospital, Lead NHS R&D contact

IRAS project ID	231262

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor insurance]		
HRA Schedule of Events [Validated SOE]	1.0	18 January 2018
HRA Statement of Activities [Validated SOA]	1.0	18 January 2018
Interview schedules or topic guides for participants [Topic guide]	3	31 October 2017
IRAS Application Form [IRAS_Form_15012018]		15 January 2018
Letter from funder [Pharmacy Research UK funding contract]		
Letter from sponsor [:etter from sponsor]		
Other [Gatekeeper consent email (request)]	1	08 September 2017
Other [Gatekeeper responses]	1	15 January 2018
Other [Invitation email (doctors)]	1	08 September 2017
Other [PIL (doctors)]	2	15 January 2018
Other [Online recruitment survey text]	1	28 November 2017
Other [Invitation email (pharmacists)]	1	12 September 2017
Other [PIL (pharmacists)]	2	15 January 2018
Other [Scheduling email]	1	08 September 2017
Other [Reminder email]	1	23 November 2017
Other [Non-selection email]	1	08 September 2017
Other [Consent form (doctors)]	2	15 January 2018
Other [Consent form (pharmacists)]	2	15 January 2018
Other [PhD offer letter (including funding information)]		
Research protocol or project proposal [Protocol]	2	15 December 2018
Summary CV for Chief Investigator (CI) [CI CV]	1	27 November 2017
Summary CV for student [Sion Scott CV]		
Summary CV for supervisor (student research) [Michael Twigg CV]		
Summary CV for supervisor (student research) [David Wright CV]		
Summary CV for supervisor (student research) [Debi Bhattacharya CV]		

IRAS project ID	231262

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Mr Samuel Hills
Tel: 01603592994
Email: samuel.hills@uea.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The statement of activities will act as agreement of an NHS organisation to participate. No further agreements expected.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			research study
4.3	Financial arrangements assessed	Yes	Funding has been secured from Pharmacy Research UK, as part of a personal research award. The statement of activities confirms the funding available to sites from the sponsor.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	The applicant has confirmed that a member of the central research team will transcribe the audio recordings.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Not Applicable	Staff only study
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
Participating NHS organisations will conduct all study activities as per the protocol. Participants will be identified by gatekeepers, with responses directly to the external research team. The focus groups will take place at site. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A local collaborator is expected at participating sites in order to identify eligible participants and arrange rooms/access for the external researchers. GCP training is not a generic training expectation, in line with the HRA/MHRA statement on training expectations.

IRAS project ID	231262

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
A Letter of Access (or equivalent) would be expected for any external NHS/research staff undertaking the focus groups at the participating sites where the research team will access areas where patient care is delivered.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 12 Consolidated criteria for reporting qualitative research (COREQ) checklist for Chapter 5

Item No.	Topic	Guide Questions/Description	Response / reported on Page No.
Domains 1: Research team and reflexivity			
Personal characteristics			
1	Interviewer/facilitator	Which author/s conducted the interview or focus group?	SS and DB / Page 4
2	Credentials	What were the researcher's credentials? E.g. PhD, MD	SS's credentials were 'MPharm' and DB's credentials were 'BPharm, PhD' / Not reported in manuscript
3	Occupation	What was their occupation at the time of the study?	SS was a UK registered pharmacist who was undertaking a PhD in pharmacy practice and DB was a UK registered pharmacist and Senior Lecturer in Health Services Research / Page 4
4	Gender	Was the researcher male or female?	SS (male) and DB (female) / Not reported in manuscript
5	Experience and training	What experience or training did the researcher have?	SS completed training in qualitative research methodology and the principles and practice of behaviour change research / Not reported in manuscript
Relationship with participants			
6	Relationship established	Was a relationship established prior to study commencement?	There were no established relationships between the researchers and the focus group participants. A relationship was established between the researchers and gatekeepers for each group of participants for the purposes of recruitment / Page 3
7	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Participants were informed that the researchers (SS/DB) were pharmacists and they were informed of the research aims / Pages 3&4
8	Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias,	Participants were informed that the researchers (SS/DB) were pharmacists, of the research aims

		assumptions, reasons and interests in the research topic	and that the research was being undertaken as part of SS's PhD / Not reported in manuscript
Domain 2: Study design			
Theoretical framework			
9	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Thematic analysis as described by Braun and Clark underpinned by the Theoretical Domains Framework / Pages 4&5
Participant selection			
10	Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Participants were purposively sampled across four UK hospitals to maximise variation in demographic and practitioner seniority grade / Page 3
11	Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	All potentially eligible participants at the hospital sites were invited by email from a nominated gatekeeper of their respective specialities / Page 3
12	Sample size	How many participants were in the study?	54 participants (28 geriatricians and 26 pharmacists) / Page 5
13	Non-participation	How many people refused to participate or dropped out? Reasons?	All geriatricians and pharmacists who were purposively sampled agreed to participate in the focus groups. No participants dropped out. / Page 5
Setting			
14	Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	All focus groups were convened in meeting rooms and the respective hospital sites / Page 4
15	Presence of non- participants	Was anyone else present besides the participants and researchers?	No / Not explicitly reported in manuscript
16	Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Refer to table 1 for demographic data and data were collected between February and May 2018 / Pages 4&5

Data collection			
17	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	A semi-structured topic guide was designed to illicit participants' views regarding the following: Perception of existing deprescribing practice Barriers to increasing deprescribing practice Enablers for increasing deprescribing practice Probes to explore the 14 TDF domains were also included and used where necessary. See supplementary file 2 for the full topic guide / Pages 3&4
18	Repeat interviews	Were repeat inter views carried out? If yes, how many?	No / Not explicitly reported in manuscript
19	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Focus groups discussions were audio recorded / Page 4
20	Field notes	Were field notes made during and/or after the interview or focus group?	Field notes were made during the focus groups and referred to during analysis / Page 4
21	Duration	What was the duration of the interviews or focus group?	The mean (SD) focus group duration was 55 (5) minutes / Page 5
22	Data saturation	Was data saturation discussed?	To determine whether data saturation had been achieved, the principles for deciding saturation in theory-based qualitative studies outlined by Francis et al. were followed. Themes were recurring after the third focus group and no new themes emerged after the sixth focus group. / Pages 3&6
23	Transcripts returned	Were transcripts returned to participants for comment and/or correction	No / Not explicitly reported in manuscript
Domain 3: Analysis and findings			
Data analysis			

24	Number of data coders	How many data coders coded the data?	SS inductively coded for the thematic analysis which was checked by MJT (qualitative research expert). SS and DB mapped codes to the TDF which was checked by JT (health psychologist). / Pages 4&5
25	Description of the coding tree	Did authors provide a description of the coding tree?	The TDF was used as a basis for the coding tree (refer to table 2) / Pages 11-15
26	Derivation of themes	Were themes identified in advance or derived from the data?	Inductive and deductive approaches were utilised to identify the key themes relating to deprescribing for older people in hospital. The phase 1 thematic analysis involved inductive coding of data and thus no pre-determined themes were applied. For the phase 2 mapping to the TDF, the pre-defined domains were deductively applied to the phase 1 data. / Pages 4&5
27	Software	What software, if applicable, was used to manage the data?	Data were managed using NVivo 11 (QSR International, Melbourne, Australia) / Page 4
28	Participant checking	Did participants provide feedback on the findings?	No / Not explicitly reported in manuscript
Reporting			
29	Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Quotations are provided to contextualise novel concepts and participant/hospital numbers are provided. / Pages 6-9
30	Data and findings consistent	Was there consistency between the data presented and the findings?	Data including quotations are provided in a manner consistent with the findings / Refer to results and discussion
31	Clarity of major themes	Were major themes clearly presented in the findings?	The four major themes are presented and explained in the results section / Pages 6-9
32	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Divergence between geriatricians and pharmacists are reported and explained in the

			results and discussed in the discussion. The TDF domains which were mapped onto the four major themes and the constituent inductive codes (and the relationships between the three) are presented in table 2. / Refer to results and dicsussion

Appendix 13 Study protocol for Chapter 6

University of East Anglia

Norfolk and Norwich University Hospitals NHS Foundation Trust

Developing a theory and evidence based deprescribing model for older people in hospital; selecting intervention components and modes of delivery

A consensus study

Protocol
Version 1

Study start date: 01/12/2018
Study end date: 31/05/2019

Chief investigator	Sion Scott (PhD student/Clinical Pharmacist, UEA/NNUH NHS Foundation Trust)
Supervisors	Dr Debi Bhattacharya (Senior Lecturer, UEA) Dr Allan Clark (Senior Lecturer, UEA) Professor Carol Farrow (Director of Pharmacy, NNUH NHS Foundation Trust) Dr Alexandra Dima (Behavioural Psychologist, University of Lyon) Dr Helen May (Consultant Geriatrician, NNUH NHS Foundation Trust) Dr Martyn Patel (Consultant Geriatrician, NNUH NHS Foundation Trust) Dr Jo Taylor (Health Psychologist, University of York) Dr Michael Twigg (Lecturer, UEA) Professor David Wright (Professor, UEA)

1.0 Background

Potentially inappropriate medicines (PIMs) are those which may offer more risks than benefits and are associated with adverse outcomes including morbidity, hospitalisation and mortality[1]. A prospective study across six European hospitals reported between 34.7% and 77.3% of inpatients ≥65 years were prescribed a PIM on admission[2]. There is therefore a need for practitioners to review PIMs to determine suitability for discontinuation, a process termed 'deprescribing'[3]. Given that deprescribing requires an accurate medication history and monitoring to observe response to medication withdrawal[4], an admission to hospital where these two activities are routine, provides an opportunity to develop and implement a deprescribing intervention for older people.

A systematic review of the effect of interventions to deprescribe PIMs for older people in hospitals reported variation in intervention performance[5]. Of the nine included randomised controlled trials (RCTs), seven favoured the deprescribing intervention and the remainder found no significant difference between the intervention and usual care. Of the seven studies favouring the intervention, six reported an average reduction in the intervention arm of ≤1 PIM between admission and discharge. Given that over half of older patients admitted to hospital are prescribed at least one PIM and over a quarter are prescribed multiple PIMs[2,6], this small effect size is unlikely to be of clinical significance[5]. The remaining study was a six-month randomised controlled trial reported a promising median reduction of 2.5 PIMs in intervention arm between admission and discharge[7]. There is therefore some evidence to suggest deprescribing in hospital may be feasible, however implementation and sustainability beyond the short-term trial environment has not been demonstrated.

A recent evaluation of admission medication at a large UK teaching hospital revealed deprescribing practice was very limited, with only 0.6% of all admission medication deprescribed[8]. This suggests that deprescribing is not routine practice in hospital. There remains a need to develop a deprescribing intervention for the hospital setting that is implementable within existing personnel, resource and environmental contexts.

The Medical Research Council's guidance on developing complex interventions emphasises the importance of applying theory to understand the processes of change required adopting a new behaviour, such as deprescribing[9]. This methodological approach has demonstrated superiority in terms of interventions that are successfully implemented and sustained versus a pragmatic design approach[10,11].

The Theoretical Domains Framework (TDF) is an integrative framework of behaviour change theories organised into 14 theoretical domains, for the purpose of developing and implementing Behaviour Change Interventions (BCIs)[12]. Each theoretical domain is linked to a taxonomy of 93 Behaviour Change Techniques (BCTs)[13], which are the 'active ingredients' included in a BCI that bring about the desired change. The present research team have undertaken a multi-centre qualitative study exploring geriatricians' and hospital pharmacists' barriers and facilitators to deprescribing in hospital. Analysis of the aforementioned study was underpinned by the TDF. Five 'key' TDF domains important to geriatricians' and pharmacists' deprescribing behaviour in hospital and 37 corresponding potentially effective BCTs have been identified and are listed in appendix 1.

There remains a need to select from the list of 37 potentially effective BCTs, those which are acceptable and feasible for inclusion in a deprescribing intervention for older people in hospital, through engagement with the target audience of geriatricians and hospital pharmacists. A consensus-based and structured approached to BCT selection by the target audience, informed by explicit criteria, is necessary. Once desired BCTs are selected, there is then a need to characterise how the intervention is operationalised, termed the mode of delivery. For each BCT, the modes of delivery should be characterised, for example educational materials may be delivered face-to-face or through distance learning and individually or in a group setting[14].

The APEASE criteria for designing and evaluating interventions are provided in table 1 and offer a systematic approach to selecting the BCTs most appropriate for the context of interest by considering six factors which are all equally relevant to intervention success[14]. APEASE has been utilised in the development of numerous BCIs by the target audience, such as healthcare professionals using consensus methods[15].

Table 1 The APEASE criteria for designing and evaluating interventions (reproduced from Michie, Atkins and West[14])

Criterion	Description
Affordability	Interventions often have an implicit or explicit budget. It does not matter how effective, or even cost effective it may be if it cannot be afforded. An intervention is affordable if within an acceptable budget it can be delivered to, or accessed by, all for whom it could be relevant or of benefit.
Practicability	An intervention is practicable to the extent that it can be delivered as designed through the means intended to the target population. For example, an intervention may be effective when delivered by highly trained staff with extensive resources but in routine practice this may not be achievable.
Effectiveness and cost-effectiveness	Effectiveness refers to the effect size of the intervention in relation to the desired objectives in a real world context. It is distinct from efficacy which refers to the effect size of the intervention when delivered under optimal conditions in comparative evaluations. Cost-effectiveness refers to the ratio of effect to cost. If two interventions are equally effective then clearly the most cost-effective should be chosen. If one is more effective but less cost-effective than another, other issues such as affordability come to the forefront of the decision-making process.
Acceptability	Acceptability refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders (public, professional, and political). Acceptability may be different for different stakeholders.
Side effects/safety	An intervention may be effective and practicable but have unwanted side-effects or unintended consequences. These need to be considered when deciding whether or not to proceed.
Equity	An important consideration is the extent to which an intervention may reduce or increase the disparities in standard of living, wellbeing, or health between different sectors of society.

Consensus methods are used in research to problem solve, generate ideas or determine priorities. Nominal Group Technique (NGT) is a consensus method employed to generate potential solutions to research questions through idea generation, problem solving, prioritisation and agreement. NGT is a highly structured and facilitated face-to-face group interaction of between two and 14 participants designed to enable presentation, listening and discussion of thoughts and ideas. Participants are usually provided with questions to consider in advance of the session. The NGT session then comprises of four stages introduced in figure 1 and described below.

Figure 1 Nominal Group Technique stages

Silent generation (~30 minutes)
Participants are given approximately 30 minutes to silently reflect and record their individual thoughts and ideas about the questions provided beforehand

Round robin (~30 minutes)
One participant at a time is then asked to propose a single idea to the group during the 'Round robin' stage and record this verbatim for example, on a flipchart. Participants are encouraged to think of new ideas during this process, however they must wait their turn before sharing with the group and no discussion of ideas occurs. The round robin stage continues until no new ideas are generated.

Clarification (~30 minutes)
Clarification follows where participants are encouraged to discussed ideas and ensure understanding to enable informed decision-making. Participants are encouraged to group similar ideas together and modify or exclude ideas as necessary.

Voting (ranking or rating)
Participants are asked to select their top ideas from the previous stages and rank these in order of preference by assigning a number to each item, with a larger number indicating greater importance. The facilitator asserts the number of ideas to be ranked, with five ideas being commonly specified in the literature. Finally, the scores for each idea are summed and presented to the group for discussion.

Various modified NGT methods have been applied across a range of disciplines, including selecting and prioritising BCTs[16]. Modified NGT frequently borrows elements of the Delphi method for reaching consensus, whereby geographically diverse participants respond to a consensus survey[16]. In this form of modified NGT, participants complete a pre-session consensus survey and the results of which inform the latter face-to-face NGT session. An advantage of this adaptation to NGT is that an early indication of participants' views towards the research problem and the magnitude of consensus is obtained prior to the face-to-face meeting. This allows the NGT facilitator to guide the face-to-face discussion to focus on areas of non-consensus amongst participants, as informed by the survey.

2.0 Aim and Objectives

2.1 Aim

- Refine a theory and evidence based deprescribing intervention for older people in hospital through engagement with the target audience of senior hospital pharmacists and geriatricians.

2.2 Objectives

1. Develop a consensus survey to facilitate target audience assessment of Behaviour Change Techniques for inclusion in a deprescribing intervention for older people in hospital.
2. Select Behaviour Change Techniques for inclusion in a hospital deprescribing intervention that are acceptable and feasible and feasible to the target audience.
3. Characterise the target audiences' preferred modes of delivery for selected Behaviour Change Techniques.

3.0 Methods

Prior to study commencement, ethical approval will be secured from the Faculty of Medicine and Health Sciences Research Ethics committee at the University of East Anglia.

This project will comprise of two phases:

Phase 1

Development of an online consensus survey to facilitate target audience assessment and selection of Behaviour Change Techniques for inclusion in a deprescribing intervention for older people in hospital.

Phase 2

Target audience selection of Behaviour Change Techniques for inclusion in a hospital deprescribing intervention for older people in hospital and characterisation of preferred modes of delivery for selected Behaviour Change Techniques.

3.1 Phase 1: Development of an online consensus survey

3.1.1 Online consensus survey development

An online survey will be developed by four members of the research team with experience in the field of behaviour change research (SS, DB, AD AND JT) for the Microsoft® Forms platform (University of East Anglia's official recommended forms platform in compliance with the new General Data Protection Regulation (GDPR). The survey will facilitate target audience assessment of BCTs for inclusion in a deprescribing intervention for older people in hospital using the APEASE criteria. To enable full participation by the target audience, for each of the 37 potentially effective BCTs (appendix 1), a detailed and contextualised plain English description will be prepared. For example, for the BCT 'Information about others' approval', the following definition will be provided:

> *Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do.*

Additionally, for each of the six APEASE criteria (table 1), a brief plain English statement will be prepared. The survey will therefore comprise of 37 sections (each representing one of the BCTs), each containing six statements requiring a response (representing the six APEASE criteria). Participants will be asked to rate their level of agreement with each of the APEASE criteria in relation to the BCTs on a four-point Likert scale from strongly disagree to strongly agree. An optional free-text box will be provided at the end of each BCT section to allow respondents to support their decisions.

An example illustration of a BCT section for 'Information about others' approval' is provided in table 2.

The consensus survey will be piloted and refined with the wider research group, which includes senior clinical pharmacists and consultant geriatricians representative of the target audience. As the wider research group do not have experience in behaviour change research, this piloting/refinement will objectively identify any difficulties with interpreting the survey statements and formulating informed responses. The consensus survey will be refined iteratively based on the wider research team's feedback until no further adaptations are deemed necessary.

Table 1 Example illustration of the online consensus survey section for the BCT 'Information about others' approval'

Please rate the intervention component defined below according to the following six criteria

The intervention component: 'Information about others' approval'

Definition: *Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do.*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable *An intervention is affordable if within an acceptable budget it can be delivered to, or accessed by, all for whom it could be relevant or of benefit.*	☐	☐	☐	☐
Practicable *An intervention is practicable to the extent that it can be delivered as designed through the means intended to the target population. For example, an intervention may be effective when delivered by highly trained staff with extensive resources but in routine practice this may not be achievable.*	☐	☐	☐	☐
Effective/cost effective *Effectiveness refers to the effect size of the intervention in relation to the desired objectives in a real world context. Cost-effectiveness refers to the ratio of effect to cost.*	☐	☐	☐	☐
Acceptable *Acceptability refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders (public, professional, and political). Acceptability may be different for different stakeholders.*	☐	☐	☐	☐

Safe/have no side-effects *An intervention may be effective and practicable but have unwanted side-effects or unintended consequences.*	☐	☐	☐	☐
Provides equity *An important consideration is the extent to which an intervention may reduce or increase the disparities in standard of living, wellbeing, or health between different sectors of society.*	☐	☐	☐	☐

Please provide any comments regarding your responses to the statements in the box below:

3.2 Phase 2 Modified NGT

A modified NGT will be employed to engage senior hospital pharmacists and geriatricians with reaching a consensus on which BCTs to select for inclusion in a deprescribing intervention for older people in hospital, and to characterise desired modes of delivery. The method is a modification of NGT because participants will be required to vote using an online consensus survey in advance of a face-to-face session. The modified NGT will comprise of two stages:

- Stage 1: Pre-NGT session completion of the online consensus survey developed in phase 1
- Stage 2: Face-to-face Nominal Group Technique session

A schematic of phase 2 is provided at the end of the methods section in figure 2.

3.3.1 Recruitment

The University of East Anglia has recently established a Medicines Optimisation Group (MOG) comprising of senior hospital pharmacists and geriatricians representing six hospitals from across the East of England. The group convenes monthly for three hours at the University of East Anglia to initiate, implement and advise on medicines optimisation research. The MOG's chair has agreed to one of the MOG meetings hosting the face-to-face modified NGT.

The chief investigator has previously attended a MOG meeting and presented this project concept to the group as part of the 'next steps' of a previous research project presentation. All 12 members of the group have indicated a desire to participate in the study and confirmed that the time commitments and remuneration offer described later in this protocol are acceptable. This study aims to recruit all 12 members of the MOG to represent pharmacists and geriatricians from the six aforementioned hospitals.

Post-ethical approval, all members of the MOG will be emailed an invitation to participate (appendix 2) and Participant Information Sheet (PIS) (appendix 3) by the MOG secretary. The chief investigator will attend the next available MOG meeting and occupy a 30 minute slot to answer any questions regarding participation in the study and take written, informed consent from all group members wishing to participate via the consent form (appendix 4). A demographic information collection form (appendix 5) will be presented to consenting participants to complete, which will request the following information:

- Age
- Gender
- Profession (pharmacist or geriatrician)
- Email address*
- Job title
- Hospital Trust place of work**

*To enable emailing of the individualised link to the online consensus survey
**Information collected to allow reporting of the number and nature of hospital organisations represented in the study. Details of individual hospital Trusts will not feature in the analysis nor will they appear in any subsequent reports/publications.

Inclusion criteria

- Geriatrician (registrar or consultant) or hospital pharmacist (Agenda for Change Band 8 or above) members of the UEA MOG

There are no exclusion criteria for this study.

3.3.2 Consent

Written, informed consent will be obtained by asking participants to complete the consent form (appendix 4) as described above in section 3.3.1. No participant-related research activity, including the collection of any participant information, will occur until written, informed consent has been provided.

3.3.3 Scheduling

After members of the MOG have consented to participate as described above, the chief investigator will agree with the group chair, the next available suitable MOG meeting slot to occupy the three hour face-to-face NGT session (stage 2 below). Once the session has been agreed, the chief investigator will email each participate an individualised link to complete the online consensus survey approximately two weeks prior. Participants will be notified of the agreed meeting slot and agenda for the face-to-face NGT session by the MOG secretary, as is usual practice for the MOG meetings.

3.3.4 Remuneration

Refreshments will be provided to participants during the stage 2 face-to-face NGT session. Each participant will also receive £300.00 remuneration (based on discussions between the

MOG group, research team and approved by the project funder, Pharmacy Research UK (National Institute for Health Research non-commercial partner) to cover time commitment costs (total approximately up to 4.5 hours for the entire study per participant).

3.3.4 Stage 1 Pre-NGT session online consensus survey completion (1 hour-1.5 hours)

The aim of stage 1 is to identify BCTs where there is consensus and/or non-consensus to accept or reject for inclusion in a deprescribing intervention for older people in hospital.

Participants who have consented to participate (as described in section 3.3.1 and 3.3.2 above) will be emailed an individualised link to complete the online consensus survey on the Microsoft® Forms platform approximately two weeks prior to the pre-arranged face-to-face NGT session. The survey estimated completion time is up to 1.5 hours, however an informed estimate will be derived from the phase 1 (section 3.1.1) piloting. The participant information sheet (appendix 3) will be amended accordingly to reflect the informed estimated time to complete the online consensus survey. This time will not exceed 1.5 hours.

3.3.4.1 Consensus survey analysis

Descriptive statistics will be used to identify consensus amongst participants regarding their agreement/disagreement that BCTs meet each of the six APEASE criteria.

A consensus criterion of 80% amongst participants has been set for the present study. A systematic review of methodological criteria for consensus studies reported a median threshold of 75% definition for consensus, ranging from 50-97%. A stringent criterion has been adopted for the present study owing to the relatively small number of participants and the large number of items requiring a response; 6 APEASE criteria for 37 BCTs[16].

Based on the consensus analysis, all 37 BCTs will be categorised into one of the following groups:

a) **Accepted:** BCTs where all six APEASE criteria reach ≥80% agreement
b) **Rejected:** BCTs where one or more APEASE criteria reach ≥80% disagreement
c) **Requires consensus discussion:** BCTs where some or all APEASE criteria fail to reach ≥80% agreement

BCTs categorised as 'requires consensus discussion' and 'accepted' will proceed to the stage 2 face-to-face NGT for further discussion. BCTs categorised as rejected will be excluded from further consideration.

Stage 2 Face-to-face NGT session (3 hours)

The aims of stage 2 are to reach a consensus regarding whether to accept or reject the BCTs categorised as 'requires consensus discussion' and to characterise the desired modes of delivery for all accepted BCTs.

Reaching a consensus on BCTs categorised as 'requires consensus discussion' (2 hours)

The session will commence with participants being presented descriptions of the BCTs categorised as 'requires consensus discussion' and the APEASE criteria/criterion where the group did not reach consensus via the consensus survey. Participants will not have access to their individualised consensus survey responses during the NGT, as the aim is for the group to work collaboratively to reach a consensus.

The session will commence with a traditional NGT as described in the introduction to reach a consensus regarding whether to accept or reject the BCTs. Participants will be provided with ample paper and stationary to document ideas, thoughts and views. The final 'voting' NGT stage will comprise of participants repeating the online consensus survey at the meeting for the APEASE criteria/criterion relevant to BCTs categorised as 'requires consensus discussion'. Electronic tablet devises owned and maintained by the School of Pharmacy, University of East Anglia will be provided for participants to respond to the survey. The consensus criterion of 80% will again be applied at this stage.

Responses to the repeated online consensus survey will be analysed in real-time at the meeting by the chief investigator described in section 3.3.4.1. Any BCTs whereby participants are unable to reach a consensus as to 'accept' or 'reject' according to the criteria at this stage will be automatically rejected and excluded from further consideration. The rationale for this decision is after discussion there is non-consensus regarding whether these BCTs should be included in a deprescribing intervention for older people in hospital.

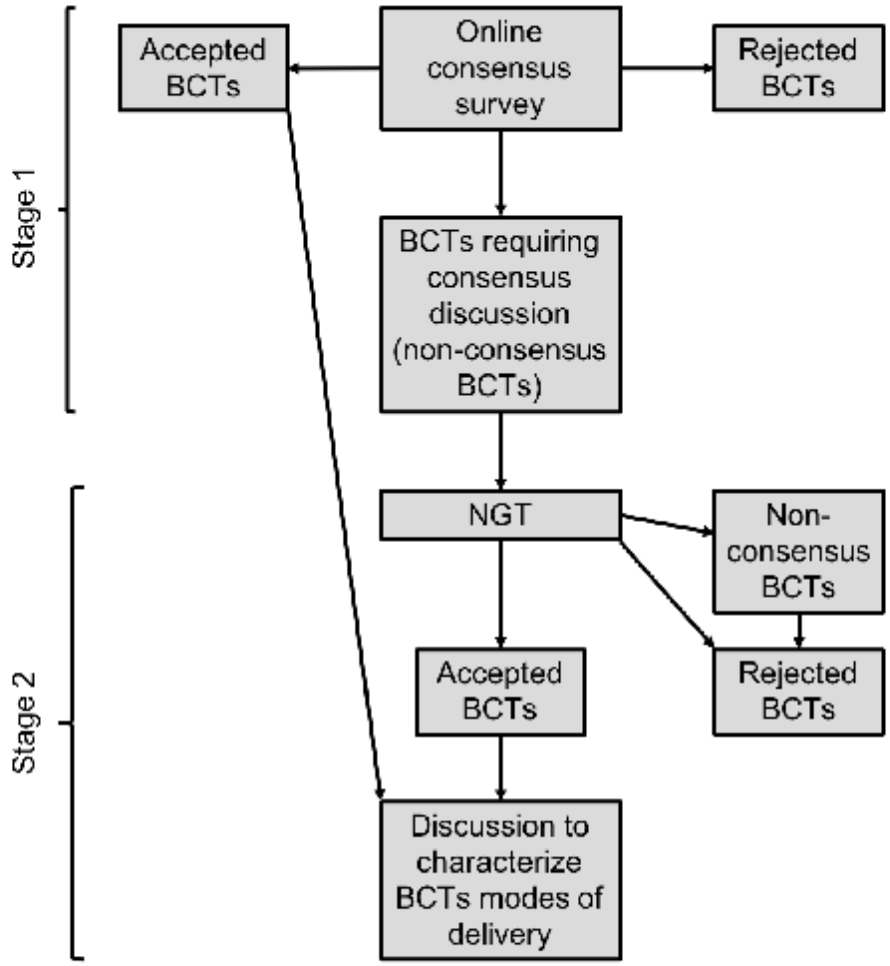
Characterising desired modes of delivery for accepted BCTs (1 hour)

Those BCTs categorised as 'accepted' from the consensus activities in stage 1 and stage 2 will be re-presented to the group for a discussion regarding the desired modes of delivery.

The discussion will represent an informal brainstorming exercise, guided by the chief investigator. Each 'accepted' BCT will be presented to the group and the ideas generated documented on flipcharts for further discussion and refinement.

3.3.4.2 Face-to-face NGT session analysis

Analysis of the NGT 'voting' stage will occur in real-time at the face-to-face NGT session as described above. Analysis of the desired modes of delivery will comprise of the chief investigator, with support from the research team, drafting comprehensive specification of the desired modes of delivery, informed by the notes taken during the brainstorming exercise.



BCTs: Behavior Change Techniques
NGT: Nominal Group Technique

Figure 2 Phase 2 schematic

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Appendices

Appendix 1 Potentially effective Behaviour Change Techniques for inclusion in a deprescribing intervention for older people in hospital

Potentially effective Behaviour Change Techniques for inclusion in a deprescribing intervention for older people in hospital

Version 1 28.09.18

Emotional consequences
Salience of consequences
Covert sensitization
Anticipated regret
Social and environmental consequences
Comparative imagining of future outcomes
Vicarious reinforcement
Threat
Pros and cons
Covert conditioning
Social comparison
Social support or encouragement (general)
Information about others' approval
Social support (emotional)
Social support (practical)
Restructuring the social environment
Modelling or demonstrating the behaviour
Identification of self as role model
Social reward
Restructuring the physical environment
Discriminative (learned)
Prompts/cues
Avoidance/changing exposure to cues for the behaviour
Self-reward
Differential reinforcement
Incentive
Thinning
Negative reinforcement
Shaping
Counter conditioning
Discrimination training
Material reward
Non-specific reward
Response cost
Anticipation of future rewards or removal of punishment
Extinction
Classical conditioning

Appendix 2 Invitation email to potential participants

Invitation email to potential participants
Version 1 28.09.18

Invitation email to potential participants

Dear Medicines Optimisation Group member,

I am emailing regarding my recent presentation to you at the Medicines Optimisation Group (26/07/2018) regarding our programme of work to develop a deprescribing intervention for older people in hospital. You may recall the next steps in our research is to select intervention components for inclusion in the intervention and, we would like this to be done by a senior clinician such as yourself.

I invite you to participate in our upcoming consensus study, the details of which are included in the attached Participant Information Sheet.

I will be attending the Medicines Optimisation Group meeting on XX/XX/XXXX (date to be decided post ethical approval) to answer any questions.

If you have any questions in the meantime, please do not hesitate to contact me.

Warmest Regards,

Sion Scott
Lead Researcher

Attachment: Participant information sheet (appendix 3)

Appendix 3 Participant information sheet

Developing a theory and evidence based deprescribing intervention for older people in hospital; selecting intervention components and modes of delivery

A consensus study

You are being invited to take part in this consensus study. Before decided to take part, please read this information sheet carefully.

What is the study about?

One in two older people in hospital are prescribed a potentially inappropriate medicine (medicines with more risks than benefits), which are associated with several adverse outcomes. The term 'deprescribing' describes the process of identifying and discontinuation potentially inappropriate medicines in partnership between patients and healthcare practitioners.

Researchers are developing an intervention to support healthcare practitioners like you to deprescribe in hospital. Several intervention components (the building blocks of interventions) have been identified as potential candidates for inclusion in the deprescribing intervention.

The aim of this consensus study is for healthcare practitioners to select the intervention components that they would like to be included in the deprescribing intervention.

This research in being conducted by the School of Pharmacy, University of East Anglia. The research is funded by the Norfolk and Norwich University Hospital NHS Foundation Trust, University of East Anglia and Pharmacy Research UK.

Why have I been chosen?

You are a senior pharmacist or geriatrician and attend the University of East Anglia's Medicine Optimisation Group (MOG) meetings, performing a role in managing the medicines of older people during a hospital admission. You may therefore be involved with deprescribing for older people currently or in the future. We would therefore like you to help shape the deprescribing intervention.

Do I have to take part?

No. Whether or not you decide to participate is completely your decision.

What happens if I agree to take part?

The study comprises of two parts:

Part 1

A survey to be completed in your own time where we will ask your views regarding the potential intervention component candidates. The survey will be emailed to you and you can compete this online. The survey should take a maximum of 1.5 hours to complete.

Part 2

A face-to-face session at the University of East Anglia which will occupy one of the MOG meetings which you already attend to discuss two things:

1. Potential intervention component candidates where it is unclear from the survey responses (part 1) whether these should be include or excluded in the deprescribing intervention. A researcher will help to guide the group through a discussion to reach a consensus.
2. For the intervention component candidates which have been accepted by the group for inclusion in the deprescribing intervention; an informal discussion regarding how the group would like the intervention components to work practically in the hospital setting.

The part 2 session will comprise of all members of the MOG who want to take part in this study plus the researcher, Sion Scott (University of East Anglia PhD Student)

Please note, anything discussed during the course of this research relating to bad practice will be considered by the researchers in private and referral action taken as appropriate.

What happens next?

The lead researcher will attend the next MOG meeting briefly and will answer any questions you may have. If you decide to take part, will you will be asked to sign a consent form indicating you are happy to take part. You will also be asked to provide some basic information about yourself such as gender and age, by completing a short form.

The researcher will then agree with the MOG chair when to host the face-to-face session (part 2 above), which will occupy an existing scheduled MOG meeting. Approximately two weeks prior to the chosen MOG meeting, the researcher will email you a link to complete the online survey (part 1 above). We will ask you to complete the survey within one week.

What about confidentiality?

All data will be treated in accordance with the Data Protection Act 1998. Only the researcher running the study will be able to identify you. We will ask participants not to discuss what is said outside the study. Any personal data collected such as your name will be destroyed after 3 years. Research data such as the survey responses will be anonymous and kept for 10 years.

Are there benefits to taking part?

As the aim of this study is to develop a deprescribing intervention to support hospital practitioners to deprescribe, your participation will help develop an intervention designed to support you. We will pay you £300.00 for your time and participation in the study. We will also provide a light lunch and refreshments throughout the face-to-face session (part 2 above).

Are there costs to taking part?

We do not foresee any costs other than your time spent on the study.

What if I want to withdraw from the study?

You are free to withdraw from the study at any time, without giving a reason, by informing the lead researcher on the detail at the bottom of this page. If you chose to withdraw during or after the study, it will not be possible to withdraw your anonymised data.

What will happen to the results?

The results will be published in a research journal. You will not be identifiable.

Contact information

For complains	For more information
Professor Mark Searcey	**Mr Sion Scott**
Head of the School of Pharmacy	Lead Researcher
m.searcey@uea.ac.uk	sion.scott@uea.ac.uk
☎ 01603 592026	01603 591973

Appendix 4 Consent form

Consent form
Version 1 28/09/18

Pharmacy Research UK

Participant Identification Number for this study: ☐

Consent Form

Study title:

Developing a theory and evidence based deprescribing model for older people in hospital; selecting intervention components and modes of delivery: A consensus study

Name of Lead Researcher:

Mr Sion Scott

Please initial box

1. I confirm that I have read the participant information sheet dated 28/09/18 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had 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, without my legal rights being affected. ☐
3. I agree to take part in the above study. ☐

Name of Participant	Date	Signature

Name of Person taking consent	Date	Signature
Mr Sion Scott		

Appendix 5 Demographic information collection form

Demographic information collection form
Version 1 01/10/18

Pharmacy Research UK

Participant Identification Number for this study: ☐

Demographic Information Collection Form

Study title:

Developing a theory and evidence based deprescribing model for older people in hospital; selecting intervention components and modes of delivery: A consensus study

Please provide the following details about yourself:

Age: ☐

Gender: Female ☐ Male ☐ Prefer not to say ☐

Profession: Hospital pharmacist ☐ Geriatrician ☐

Please write your job title: _____

Please write your email address*: _____

Hospital Trust place of work:** _____

*To enable us to email you a link to the part 1 online survey

**Information collected to allow reporting of the number and nature of hospital organisations represented in the study. Details of individual hospital Trusts will not feature in the analysis nor will they appear in any subsequent reports/publications. We will not inform your hospital Trust regarding whether did/did not participate in this study.

Appendix 14 Ethical approval letter for Chapter 6

Faculty of Medicine and Health Sciences Research Ethics Committee

Sion Scott
PHA

Research & Innovation Services
Floor 1, The Registry
University of East Anglia
Norwich Research Park
Norwich, NR4 7TJ

Email: fmh.ethics@uea.ac.uk

Web: www.uea.ac.uk/researchandenterprise

06 November 2018

Dear Sion

Project title: Developing a theory and evidence based deprescribing model for older people in hospital; selecting intervention components and modes of delivery

Reference: 2018/19 - 009

Your submission (above) was considered by the Faculty Research Ethics Committee at their meeting on (date), and I 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.

Approval by the FMH Research Committee should not be taken as evidence that your study is compliant with GDPR and the Data Protection Act 2018. If you need guidance on how to make your study GDPR compliant, please contact your institution's Data Protection Officer.

Yours sincerely,

Professor M J Wilkinson
Chair
FMH Research Ethics Committee

CC Debi Bhattacharya

Appendix 15 Initial voting round survey for Chapter 6

Selecting components for a hospital deprescribing intervention for older people

Page 1: Instructions

Thank you for participating in this study

Over the next 5 pages, you will be presented with 4 barriers and 1 enabler to deprescribing. We will tell you:

- Which healthcare practitioner the barrier or enabler relates (geriatrician, pharmacist or both)
- What the target deprescribing behaviour(s) we are trying to encourage is

For each of the barriers/enabler, we have provided several potential intervention components for you to consider. Please rate each of the intervention components according to whether you think it is:

1. **Affordable** for your hospital
2. **Practical** to deliver as intended
3. Likely to be **effective** and **cost-effective** in addressing the barrier or enabler
4. **Acceptable** to patients, carers and practitioners in your hospital
5. Likely to be **safe** and free of undesirable consequences
6. **Equitable** in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender

Space is provided after each intervention component for any comments to support your decision or any ideas for how you'd like components to look in practice (optional).

1. **Please enter your token number and click next to begin the survey**

Page 2: Barrier 1: Geriatricians and pharmacists perceive patients and carers are likely to resist deprescribing proposals due to attachment to medication

Target behaviour: Geriatricians and pharmacists to engage with patients and caregivers in deprescribing discussions

2. **Intervention 1**: Social comparison - Draw attention to other practitioners who are successfully deprescribing by navigating the challenges of patients and carers being attached to medication

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

2.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

3 / 31

3. **Intervention 2:** Information about others' approval - Tell geriatricians and pharmacists that the vast majority of patients and carers are willing to have one or more of their medications deprescribed if this is proposed by a practitioner

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

3.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

4. **Intervention 3:** Social support emotional - Arrange for geriatricians and pharmacists to receive emotional support from a colleague when engaging with patients and carers in deprescribing discussions

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐

Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

4.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

5. **Intervention 4:** Social support practical - Arrange for geriatricians and pharmacists to receive practical help from a colleague when engaging with patients and carers in deprescribing discussions

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐

Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

5.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

6. **Intervention 5:** Vicarious reinforcement - Draw geriatricians' and pharmacists' attention to the positive consequences for colleagues who engage with patients and carers in deprescribing discussions to encourage them to do the same

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

6.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

7. **Intervention 6:** Restructuring the social environment - Arrange for geriatricians and pharmacists to spend time with colleagues who are successfully engaging with patients and carers in deprescribing discussions

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

7.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

8. **Intervention 7:** Modelling or demonstrating the behaviour - Arrange for geriatricians and pharmacists to observe colleagues who are successfully engaging with patients and carers in deprescribing discussions

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

8.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

9. **Intervention 8:** Identification of self as role model - Inform geriatricians and pharmacists that if they engage with patients and carers in deprescribing discussions then others are likely to follow

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐

Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

9.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

10. **Intervention 9:** Social reward **-** Arrange for verbal or non-verbal congratulations for geriatricians and pharmacists who are successfully engaging with patients and carers in deprescribing discussions

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐

Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

10.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

Page 3: Barrier 2: Pharmacists perceive that deprescribing is generally always more risky than continuing to prescribe a medication, even if the future harms from that medication are suspected to outweigh future gains

Target behaviour: Pharmacists to identify inappropriate medications and advise geriatricians/patients to deprescribe these medications (actively supporting deprescribing)

11. **Intervention 1:** Emotional consequences - Explain to pharmacists that deprescribing inappropriate medication can generate positive feelings for both practitioners and patients/carers

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

11.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

12. **Intervention 2:** Salience of consequences - Emphasise the benefits of deprescribing and harmful consequences of failing to deprescribe in terms which will resonate with pharmacists

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

12.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

13. **Intervention 3:** Covert sensitisation - Advise pharmacists to imagine failing to

deprescribe in a real life situation followed by imagining the adverse outcomes resulting from continuing an inappropriate medication for patients/carers, their hospital and themselves

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

13.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

14. **Intervention 4:** Social and environmental consequences - Provide information to pharmacists about the positive health and financial consequences of deprescribing inappropriate medication and/or the negative health and financial consequences of failing to deprescribe

	Strongly disagree	Disagree	Agree	Strongly agree

Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

14.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

15. **Intervention 5:** Vicarious reinforcement - Draw attention to the positive consequences for pharmacist colleagues who are actively supporting deprescribing of inappropriate medication

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐

Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

15.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

16. **Intervention 6:** Pros and cons - Advise pharmacists to list and compare the advantages and disadvantages of actively supporting deprescribing of inappropriate medication

Please don't select more than 1 answer(s) per row.

Please select at least 6 answer(s).

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐

Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

16.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

Page 4: Barrier 3: Pharmacists' current working patterns limit the time available to actively support deprescribing

Target behaviour: Pharmacists to identify inappropriate medications and advise geriatricians/patients to deprescribe these medications (actively supporting deprescribing)

17. **Intervention 1:** Restructure the physical environment - Change or advise change to pharmacists' working patterns to enable them to actively support deprescribing *e.g. pharmacists to attend ward rounds with geriatricians*

Please don't select more than 1 answer(s) per row.

Please select at least 6 answer(s).

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

17.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

Page 5: Barrier 4: Geriatricians and pharmacists perceive that deprescribing of inappropriate medication is not a priority in hospital

Target behaviours:

Geriatricians – for identified inappropriate medicines, engage with patients and caregivers about deprescribing discussions and implement any agreed deprescribing

Pharmacists - Identify inappropriate medications and advise geriatricians and/or patients to deprescribe these medications (actively supporting deprescribing)

18. **Intervention 1:** Goal setting (behaviour) - Geriatricians and pharmacists set a target for the frequency with which they initiate activities that may lead to deprescribing *e.g. assigning a target for the proportion of patients with a confirmed appropriate indication for all prescribed medicatio*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

18.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

19. **Intervention 2:** Review behaviour goals - Geriatricians and pharmacists to review their performance against the previous deprescribing target(s) set and consider either modifying goals and/or the strategies for achieving the goal

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

19.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

20. **Intervention 3:** Action planning (implementation intention) - Prompt detailed

planning by individual geriatricians and pharmacists of how they will be deprescribing/supporting deprescribing of inappropriate medication

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

20.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

Page 6: Enabler: Geriatricians and pharmacists want to be incentivised to deprescribe

Target behaviours:

Geriatricians – for identified inappropriate medicines, engage with patients and caregivers about deprescribing discussions and implement any agreed deprescribing

Pharmacists - Identify inappropriate medications and advise geriatricians and/or patients to deprescribe these medications (actively supporting deprescribing)

21. **Intervention 1:** Self-reward - Encourage geriatricians and pharmacists to reward themselves for initiating activities that may lead to deprescribing of inappropriate medication *e.g. self-awarding professional development points*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

21.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

22. **Intervention 2:** Material incentive - Inform that a material reward will be delivered if geriatricians and pharmacists initiate activities that may lead to deprescribing *e.g. confirming appropriate indication for all prescribed medication*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

22.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

23. **Intervention 3:** Thinning - Gradually increase the threshold for rewards to be made

to geriatricians and pharmacists based on frequency of activities that may lead to deprescribing of inappropriate medication *e.g. reward for 40% of patients with confirmed appropriate indication for all prescribed medication in month 1, reward for 60% in month 2 etc.*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

23.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

24. **Intervention 4:** Negative reinforcement - Arrange for an unpleasant consequence if geriatricians and pharmacists do not initiate activities that may lead to deprescribing of inappropriate medication *e.g. announcement to the practitioner regarding failure to initiate activities that may lead to deprescribing of inappropriate medication when a patient is discharged*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

24.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

25. **Intervention 5:** Shaping - Arrange a reward for any approximation of deprescribing activities by geriatricians and pharmacists, gradually rewarding only performance closer to the full process of deprescribing inappropriate medication *e.g. a practitioner is initially rewarded for being a champion of deprescribing. Subsequently, in order to receive a reward, a practitioner will need to demonstrate additional commitments to deprescribing*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐

Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

25.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

26. **Intervention 6:** Counter conditioning - Arrange a reward for geriatricians and pharmacists responding differently to a stimulus to deprescribe relative to previous practice *e.g. practitioners who investigate prompts of potentially inappropriate medication receive a reward*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐

Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

26.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

27. **Intervention 7:** Material reward - Provide a material reward when geriatricians and pharmacists initiate activities that may lead to deprescribing

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

27.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

28. **Intervention 8:** Extinction - Arrange for permanent discontinuation of promised rewards if geriatricians and pharmacists fail to initiate activities that may lead to deprescribing of inappropriate medication *e.g. if practitioners fail to meet one of a set of targets regarding initiating activities that may lead to deprescribing, then no rewards will be provided for meeting any remaining targets*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
Likely to be safe and free of undesirable consequences	☐	☐	☐	☐
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

28.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

29. **Intervention 9:** Classical conditioning - Arrange for a stimulus to be combined with another stimulus that already elicits the initiation of activities that may lead to deprescribing for geriatricians and pharmacists *e.g. combine an electronically generated prompt for initiating deprescribing activities with a more resource intensive prompt such as a deprescribing champion. The latter element will be removed after a specified period of time, leaving only the electronically generated prompt*

	Strongly disagree	Disagree	Agree	Strongly agree
Affordable for my hospital	☐	☐	☐	☐
Practical to deliver as intended	☐	☐	☐	☐
Likely to be effective and cost-effective in addressing the barrier	☐	☐	☐	☐
Acceptable to patients, carers and practitioners in my hospital	☐	☐	☐	☐
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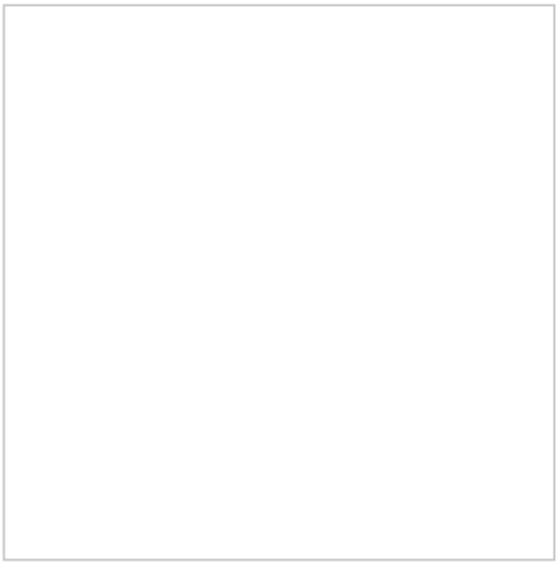
Equitable in that it is unlikely to increase disparities between different sectors of society e.g. different ethnicities and gender	☐	☐	☐	☐

29.a. Please add any comments to support your decision or any ideas for how you'd like this component to look in practice

29 / 31

Page 7: You're all finished!



What happens next?

We will analyse the results and identify the intervention components that respondents agree should form part of the hospital deprescribing intervention. We will also identify the intervention components that respondents did not agree on whether they should or should not be included in the intervention.

At the face-to-face session, as a group we will do the following:

- Discuss the intervetnion components that respondents did not agree on, with a view of coming to a group consensus
- For all components that there was agreement these should be included in the intervention, we will discuss how we would like these to look in practice

Reminder

The face-to-face session is scheduled for **Thursday 28th March 2019 15:00-17:00** at **Thomas Paine Study Centre, Room 2.05a (The Hub), University of East Anglia**.

Please arrive from 13:30 if you would like a complementary light lunch.

30 / 31