Assessing health literacy in a routine healthcare environment

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Submitted for the degree of Doctor of Philosophy

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Submitted in March 2018

Abstract

Keywords

Health literacy, patient assessment, health knowledge, patient engagement, healthcare environments, heuristics, pharmacist decision making, health literacy indicators.

Background

Individuals with limited health literacy ability have poorer health outcomes compared with individuals with adequate health literacy. Health literacy ability is not assessed in routine healthcare environments in the UK. The objective of the thesis is to assess how healthcare professionals could identify an individual's health literacy ability in daily practice.

Methods

A systematic review of existing health literacy assessment instruments was undertaken to identify the optimal health literacy instrument for use in a clinical setting. The selected health literacy instrument was evaluated in a community pharmacy setting to provide an early indication of the feasibility for regular use. A theory based heuristic assessment instrument was developed and piloted as an alternative instrument for use in routine practice.

Results

The systematic review identified the NVS instrument to be the most practical health literacy instrument to use. However, the early findings when used in practice indicated that there were barriers that could limit use. The preliminary findings of a heuristic assessment instrument indicate that recall of written potentially could be used.

Conclusions

At present, there is no accepted practice to identify an individual's health literacy ability in UK healthcare. Further research, with a larger sample size, into the use of heuristic indicators could identify a simple process to accurately assess health literacy ability that can be used in routine healthcare environments. Further work is also required to formulate more structured

guidance on how to use the heuristic in consistent way so that the predictive ability demonstrated by the experienced pharmacists can be replicated by all.

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List of abbreviations

ANQ	Asthma Numeracy Questionnaire
AUC	Area Under Curve
AUROC	Area under Receiver Operator Curve
CCG	Clinical Commissioning Group
CEST	Cognitive Experiential Self Theory
CI	Confidence Interval
CFA	Confirmatory Factor Analysis
DNT	Diabetes Numeracy Test
EFA	Exploratory Factor Analysis
FTE	Full Time Equivalent
GHNT	General Health Numeracy Test
GP	General Practitioner
HDPI	Heart Disease Predictive Instrument
IPA	Interpretative Phenomenological Analysis
IQR	Inter Quartile Range
LR	Likelihood Ratio
MART	Medical Achievement Reading Test
METER	Medical Term Recognition Test
MUR	Medicine Use Review
NMS	New Medicine Service
NPV	Negative Predictive Value
NUMi	Numerical Understanding in Medicine Instrument
NVS	Newest Vital Sign
OR	Odds Ratio
OTC	Over the Counter
PMM	Probabilistic Mental Models
PPV	Positive Predictive Value
PSA	Prostrate Specific Antigen
REALM	Rapid Estimate of Adult Literacy in Medicine

REALM-S	Rapid Estimate of Adult Literacy in Medicine-Short
REALM-R	Rapid Estimate of Adult Literacy in Medicine-Revised
ROC	Reciever Operator Curve
RR	Relative Risk
SILS	Single Item Literacy Screener
S-TOFHLA	Short Test of Functional Health Literacy in Adults
TOFHLA	Test of Functional Health Literacy in Adults
UK	United Kingdom
US	United States of America
USA	United States of America
WRAT	Wide Range Achievement Test

Initials

AR	Andre Renzaho
DB	Debi Bhattacharya
PD	Paul Duell
QB	Quang Bui

Acknowledgements

Dedication

This thesis is dedicated to the loving memory of my parents

Gordon Sidney Duell

and

Phyllis Ruth Duell

Thank you for all your love, support and belief in me. I am so thankful for all that you taught me in word and deed. I am proud to be your son. You will always be in my heart.

Chapter 1 Health literacy

1 Health Literacy

1.0 Thesis overview

The objective of this thesis is to identify a mechanism to assess health literacy in a healthcare environment such as a community pharmacy setting. Figure 1.1 shows a flow diagram of the order of the studies within the thesis. Chapters 2, 4 and 5 provide the details on each of the studies. Chapter 3 introduces the major theories regarding decision making and Hueristics which underpin the third study. This chapter reports explains the impact of health literacy on health care provision and introduces the more established health literacy instruments used in research.

First study
- Systematic review of health literacy instruments

Second study
- Assessment of the NVS in community pharmacies

Third study
- Heuristic assessment of health literacy using the NVS as a comparator indicator
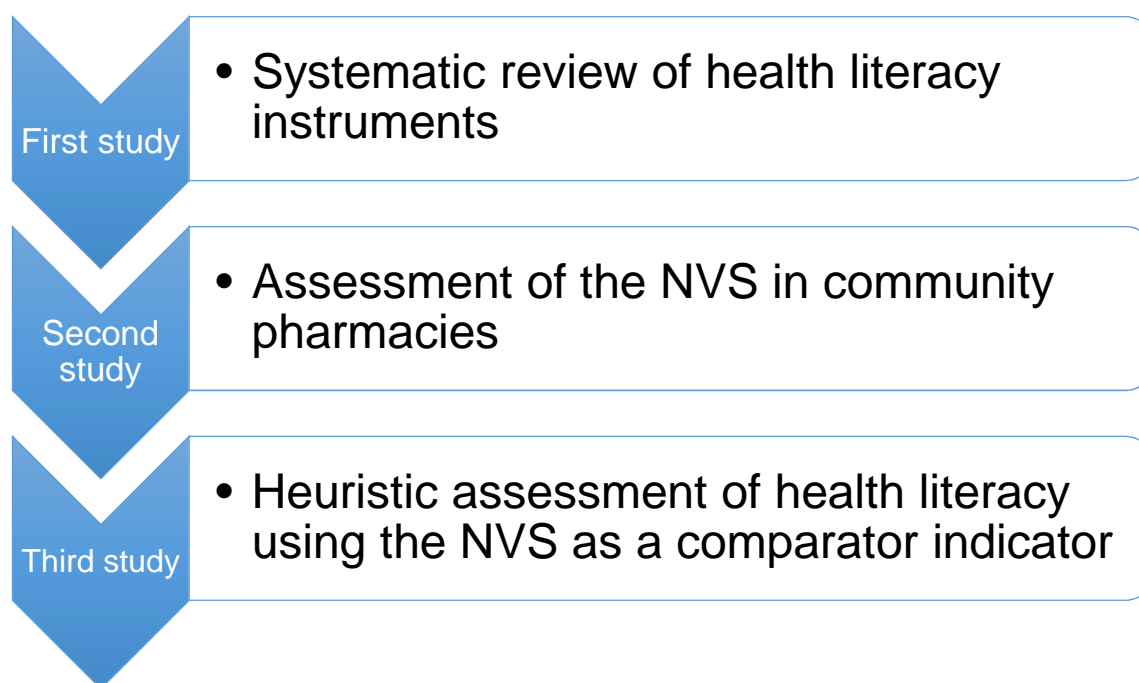
FIGURE 1.1 STUDIES FLOW DIAGRAM

1.1 Introduction

Health literacy is recognised as an important determinant of population health (1) and addressing limited health literacy is a government aim (2-4). However, UK government policy does not indicate how individuals with limited health literacy can be identified or quantify the number of people that may be affected by having limited health literacy. The national educational literacy data is used instead as a proxy measure for health literacy ability.

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National educational literacy data obtained from the English National Qualifications Framework (5) indicates that the percentage of people of working age that cannot understand and use text documents of a readability level of a 14 year old is 43% (15 million people). The data also indicates that 57% (20 million) cannot understand or use numbers to a level expected by a 14-year-old. This data excludes those retired from work and therefore does not reflect the whole population. Evidence from health literacy studies in the US indicates that older adults are more likely to have limited health literacy than younger adults (6, 7). Consequently, the national framework data is likely to underestimate the impact of low literacy on the adult population.

Current UK health literacy policy and implementation is limited. Where health literacy is taken into consideration a common approach used is to simplify written and verbal communication for everyone. This approach is sometimes referred to as taking 'universal precautions'. Practising universal precautions has been described as 'structuring healthcare services to minimise risk for everyone when it is unclear which patients will benefit' (8). The rationale for this approach stems from a discussion paper written in 2008 by Paasche-Orlow and Wolf (9) who were sceptical of using research health literacy instruments in practice for universal screening. Concerns focused on 'whether patients would respond differently when tested by clinical staff with whom they have a relationship, and during times when they may be ill, anxious, and expecting medical care'. There were also concerns that assessing health literacy in practice might cause harm through shame and alienation so they recommended not screening in practice. This view has gained momentum with others recommending using universal precautions (8, 10). This is the approach advocated by Public Health England (11). A universal precaution toolkit has been developed (8) for use in practice however difficulties in its use have been identified (12, 13).

Universal precautions are not used in community pharmacies to address variations in health literacy nor are patients screened for health literacy. Pharmacy awareness of the problems associated with limited health literacy is not as advanced as that observed in the USA where staff are trained to consider the impact of limited health literacy on the care they provide.

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Whilst universal precautions provides a generic solution, and is very pragmatic, the creation of a one size fits all policy contradicts the existing health agenda of providing patient centred care designed around the individual's health needs (14-18). Health care professionals, including pharmacists, are encouraged to provide tailored care rather than using a standardised approach that is applied to everyone regardless of their personal needs. Paasche-Orlow and Wolf's concerns regarding the acceptability and utility of measuring health literacy in the routine healthcare setting indicate a need for further research to identify or develop potentially suitable methods for measuring in the healthcare setting and to investigate its impact on patient participants.

The aim of this thesis is to identify how an individual's health literacy may be assessed in a routine healthcare environment so that the principles of patient centred care are fulfilled.

This chapter provides a review of the existing literature on the problems associated with limited health literacy and the impact it has on medicine taking. It also introduces some of the most frequently reported health literacy instruments that are used to assess health literacy.

1.1.2 Definition of Health Literacy

Since health literacy was first described in 1974 there have been numerous definitions. Berkman et al. (19) recognise that the difficulty in agreeing a definition comes from the complexity and breadth of elements involved. A much-cited definition of health literacy is 'the degree to which individuals can obtain, process, and understand the basic health information and services needed to make appropriate health decisions' (20).

The World Health Organisation's definition of health literacy is more expansive than Ratzan's and Parker's definition and identifies the key components involved. It defines health literacy as 'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health' (21). This definition identifies three distinct areas or domains:

1. Gaining access to information

2. Understanding information

3. Using information

The identification of three areas of importance within health literacy highlights a flaw within the universal precaution approach. Whilst it is possible to simplify information for all individuals this only addresses the understanding construct not variations in ability to obtain and apply health information or motivation to access.

The definition of health literacy used within this thesis is the Ratzan and Parker definition 'the degree to which individuals can obtain, process, and understand the basic health information and services needed to make appropriate health decisions'. This definition, keeps to the principle of explaining in everyday language and not overcomplicating a complex topic. It succinctly describes health literacy in terms that are easily understood whilst showing the range of skills required to be health literate and identifies distinct stages that must be completed to make health decisions.

Literature reviews carried out for this chapter identified that health literacy research predominated in either in English speaking countries or countries where it was the second language.

1.2 Impact of limited health literacy

1.2.1 Increased hospitalisation

Analysis of a prospective cohort study, by Baker et al., of USA emergency department patients identified the association between limited health literacy and hospitalisation (21-23). The first research paper found that study participants with limited literacy were more likely to report a recent hospital admission than those with adequate health literacy (23). The second report (21) found that of the 979 patients recruited those with limited literacy were twice as likely as patients with adequate health literacy to be hospitalised during the two year period (31.5% versus 14.9% p<0.001). The third report (22) involved a cohort of 3260 participants. The relative risk of hospitalisation was greater for those with limited and marginal health literacy compared to those with adequate health literacy (limited n=800 RR=1.43; 95 % CI=1.24-1.65; marginal n=366 RR=1.33; 95%CI=1.09-1.61; adequate n=2094).

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Cimasi et al., in 2013, provided a statistical analysis of hospital data (24) that evaluated the financial implications of limited health literacy on hospital admissions in Missouri. It found that health literacy was inversely associated with preventable hospital admissions and accounted for 21% of the variation in preventable hospital admission rates. This study demonstrated the significant financial cost of limited health literacy as well as the significant impact on health.

1.2.2 Use of emergency care

Patients with limited health literacy, in a USA observational cross-sectional study carried out in 2013 by Schumacher et al. (25), were found to have more preventable hospital admissions. The odds of them having more than one emergency department attendance in a six month period was 1.57 (95%CI 1.02-2.43) compared to patients with adequate health literacy. They also expressed, during structured interviews, a preference for treatment at emergency departments rather than with their personal physician due to a belief that the quality of care was better in the emergency department.

1.2.3 Lower uptake of preventive services

Taking proactive steps to prevent the likelihood of becoming ill is an important element of public health work and the impact of limited health literacy on accessing preventive services is described in the following section.

1.2.3.1 Reduced use of mammography services

Davis et al. in 1996, reported a study of 445 female American citizens aged 40 and over who had not had a mammogram in the last 12 months (26) found that limited literacy was significantly correlated (r= 0.71 p<0.0001) with limited mammography knowledge. Furthermore, women with limited literacy were less likely to identify correctly what a mammogram was and did not know the reason for having one.

Other cross-sectional studies of mammography uptake (27-31) reported that individuals with limited health literacy are less likely to access mammography screening. A postal survey (28), by Pagan et al. in 2012 of 772 Mexican women living in the USA reported that women with adequate health literacy were more likely to have had a mammogram in the past (OR = 2.92; 95% confidence interval = 1.62-5.28) or in the last two years (OR = 1.70; 95% confidence interval (CI) =

1.14-2.53) compared with women with marginal or limited health literacy. A 2015 prospective cohort study (29) by Komenaka et al. assessed 1664 consecutive patients aged over 40 years old, found that of the eight-sociodemographic variables studied, limited health literacy was the strongest predictor of the uptake of screening mammography.

1.2.3.2 Influenza vaccination

Two large cross-sectional studies (31, 32) both reported the association between limited health literacy and influenza vaccination uptake. The USA study, by Bennett et al. in 2009, of 2668 adults aged over 65 years (32) found that adults with adequate health literacy were more likely than those with limited health literacy to self-report having an influenza vaccination in the previous twelve months. Similarly the study by Scott et al. in 2002 of 2722 Medicare managed care enrolees (31) found that participants with limited health literacy were more likely to report never having an influenza vaccination compared with those with adequate health literacy.

1.2.3.3 Cancer screening

Limited health literacy affects cancer-screening uptake. Research studies (33-35) concluded that individuals with limited health literacy had less knowledge of screening and reported more barriers to completing fecal occult blood tests. A UK based study of 3087 patients in 2014 by Kobayashi et al. (36) found that adequate health literacy was associated with greater odds of screening OR = 1.20 95% CI 1.00-1.44 than limited health literacy. Other colorectal screening studies (35, 37) produced similar findings.

Limited health literacy has also been associated with other forms of cancer screening. A study of cervical screening uptake in the USA by Lindau et al. in 2002 (38) found that individuals with limited health literacy had a poorer understanding of the purpose of the test. A 1998 study by Bennett et al. of men with prostate cancer (39) in the USA found that those with limited health literacy were more likely to be diagnosed much later and have a more advanced form of the cancer on the first presentation of symptoms.

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1.2.4 Poorer health outcomes

A 2015 longitudinal cohort study, by Smith et al., of 529 American adults (40) reported that limited health literacy is a predictor of faster physical decline over time for older adults. After a follow up period of three years, those with limited health literacy were two and a half times more likely to have clinically decreased physical function compared to those with adequate health literacy.

As described earlier in this chapter, when discussing the impact of limited health literacy on accessing preventative treatments, limited health literacy is often associated with a lack of knowledge about a disease (41). This knowledge gap results in a poorer self-management process.

1.2.4.1 Asthma

The lack of knowledge of asthma by those with limited health literacy and a diagnosis of asthma has been investigated to assess its impact on inhaler technique (42) (43). In 2015 structured interviews were conducted by O'Connor et al. of 425 patients aged over 60 years of age (43) in the USA. They compared inhaler technique and adherence to health literacy ability and found that poorer adherence to controller metered dose inhalers was associated with limited health literacy as was an inadequate technique of use of dry powdered inhalers. A cross-sectional survey, by Williams et al. in 1998, of patients presenting at an emergency department in the USA and an asthma clinic for routine care (42) assessed reading ability and found that limited health literacy was strongly associated with asthma knowledge and incorrect metered dosage inhaler technique.

Reduced asthma knowledge was not just limited to inhaler technique. A 2013 cross-sectional study, by Federman et al., of 420 American asthmatics older than 60 years of age identified that twenty percent believed they could be cured of asthma and 54% believed they only had asthma when they had symptoms (44).

1.2.4.2 Diabetes

Limited health literacy is associated with limited knowledge of diabetes (45). The 1998 cross-sectional study, by Williams et al., reported that only 50% (n=189) of American diabetic patients with limited health knew the symptoms of

hypoglycaemia compared with 94% (n=155) of those with adequate health literacy (p<0.001). Another cross-sectional study, conducted in 2002 by Schillinger et al. (46), found, in a study of type 2 diabetic patients in primary care in the USA, that limited health literacy was associated with worse glycaemic control than individuals with adequate health literacy. They were also found to have higher rates of retinopathy (OR= 2.33 95% CI 1.19-4.57 p= 0.01).

1.2.4.3 Hypertension

Hypertension knowledge is also associated with limited health literacy; patients with limited health literacy were less likely to know the normal range for blood pressure and be unaware that exercise reduces blood pressure (p<0.001) (45). Two other USA studies of hypertensive patients (47, 48), by Veghari et al. in 2013 and by Shibuya et al. in 2011, reveal that limited health literacy is associated with poorer blood pressure control compared with those with adequate health literacy.

1.2.5 Higher risk of mortality

A 2012 UK longitudinal cohort study of 7857 patients (49) by Bostock et al. followed up individuals for a mean period of 5.3 years. Individuals with limited health literacy had a hazard ratio for all-cause mortality of 1.26 (1-02-1.22) after an adjustment for cognitive ability compared to those with adequate health literacy. The findings of this study support previous studies (50, 51). A cohort study of American heart failure patients (51), by McNaughton et al. in 2015 indicated that limited health literacy was associated with greater risk of death after hospitalisation for acute heart failure.

1.2.6 Health literacy and medicine taking

The previous section demonstrated the impact of limited health literacy on health outcomes and identified some of the problems of individuals not fully understanding their condition and its management. The next section focuses on the impact of limited health literacy on the process of taking medication, which is an intrinsic part of successfully managing their condition.

1.2.6.1 Poor recall of medication name, purpose, dosage and frequency.

A 2012 cross-sectional study of 79 patients at three USA outpatient pharmacies (52) found that 27 had inadequate health literacy. The study by Backes and Kuo

found that patients with inadequate health literacy could not recall as frequently the names of their medication as compared to patients in the study with adequate health literacy (60% versus 84% p < 0.001). They were also less able to report the correct dosage (71% compared with 83% p=0.03) and administration frequency (62% compared with 85% p < 0.001). Another study carried out interviews of 119 participants prescribed blood pressure medication (53) at three primary care clinics in Michigan. The 2007 study by Persell et al. found that those with limited health literacy they were less able to recall any of the names of their medicines compared to those with adequate health literacy (40.5% [n=37] versus 68% [n=82], p=0.005). These studies support the 1995 prospective observational study (54) of 1556 patients attending two urban trauma centres in the USA. The study by Williams et al. identified that patients with limited health literacy were less likely to recall their discharge medication name or directions for use than those with adequate health literacy (p<0.001). They were also less likely to know the purpose of each medicine. A 2006 cross-sectional study (55), by Kriplani et al., further quantified this where it found that individuals with limited health literacy were 10 to 18 times more likely to not be able to correctly identify all their medications compared with those with adequate health literacy (p<0.05).

1.2.6.2 Poor recall of verbal instructions

A 2013 cross-sectional study (56) by McCarthy et al. assessed 755 patients recall of verbal information in two hypothetical medical video scenarios. In both scenarios, the overall recall of key information, such as when to take their medication, was poor; individuals with adequate health literacy performed better in both tests compared to those with marginal and limited health literacy (p<0.001). It has been suggested, by Schillinger et al. in 2003 (57), that recall is poor in most USA outpatient consultations. Recall of what a doctor says is less than 50% after the event and comprehension is rarely checked. The study also reported that individuals with limited health literacy were more likely to have problems with verbal instruction recall.

1.2.6.3 Written medicine information

The writing of health information is at a higher school reading age than the average reading age and this affects the reader's ability to utilise the information

effectively and safely (58-63). A 2009 cross-sectional survey (64), by Lokker et al., reported that USA caregivers were willing to give children under a year old medication that stated only for use in children older than 2 years of age. Kumar et al. carried out in 2010 a cross-sectional study at three paediatric clinics in the USA (65). The study indicated that of 182 caregivers of infants under 13 months 47% were unable to correctly explain how to make up an infant formula milk from a concentrate.

Medicine prescription labels can also be difficult to understand. Two studies demonstrate this in different ways. The first study by Mayeaux et al. in 1996 (63) provides a case study of the impact of limited literacy on an elderly American gentleman prescribed an alternating daily dose of digoxin, to treat cardiac failure, who misunderstood and took both dosages daily. On questioning, it became clear that the man could not read very well but hid the fact, as he did not want to appear stupid. The hiding of limited skills has been reported as a common problem (66) with individuals going to great lengths to hide their limited abilities even from the partner or spouse; nineteen percent told no one of their problem and 67% kept the information from their spouse.

The second study, by Davis et al. in 2006 (67), evaluated 395 structured interviews, held at three primary care clinics in the USA, to ascertain the patients' ability to understand information on five medicine labels. Whilst 70.7% of those with limited literacy could state the label instructions, only 34% could correctly state the number of tablets intended each day. There was an association between the number of medications taken each day and the level of misunderstanding.

The language used in every day labelling of prescriptions can be too difficult for many to comprehend. A 1995 cross-sectional study by Williams et al. (68) found that out of a sample of 2659 patients attending two American public hospitals that 42% did not understand the label directions for taking the medicine on an empty stomach.

1.2.6.4 Use of medical terminology

The concept that understanding medical terminology was intrinsic to comprehending health information underpins the design of several health literacy instruments described later in the chapter. Instruments such as the Rapid Estimate

of Adult Literacy in Medicine test an individual's ability to read medical terminology. Consequently, it is not surprising that research studies demonstrate the relationship between limited health literacy and the use of medical terminology.

A study of over the counter medicine usage (69) by Calamusa et al. in 2012 reported that 42% of a convenience sample of 1206 Italian adults were confused by the difference between 'contraindications' and 'side effects'. The literature indicates that not only do patients with limited health literacy have a poorer understanding of terminology they are less likely to use it in conversations (70).

1.2.6.5 Information seeking

Information seeking is an essential component for individuals to manage their health: and to the three domains within the health literacy definition. It can take different forms such as clarification, resolving queries or requesting new information and can be through self-research or through question asking.

1.2.6.5.1 New information

A mixed-methods study (70) by Katz et al. in 2007 found that individuals with limited health literacy asked fewer questions during a consultation than those with adequate health literacy (median 7 v 10 p=0.070) and were less likely to seek new information. A larger Taiwanese study (71) of 752 adults carried out in 2013 by Wei found similar results identifying that individuals with limited health literacy were less likely to ask health professionals questions and were less likely to use the Internet or books to seek new information. This is consistent with a systematic review in 2015 to determine individual's health literacy and ability to evaluate online health information (72). Diviani et al. found those with limited health literacy were less likely to use the Internet for information and had greater difficulty understanding Internet information and were less likely to trust the information.

1.2.6.5.2 Asking questions

The mixed-methods study by Katz et al. in 2007 (70) ,described in the new information section, also identified that individuals with limited health literacy who asked fewer questions were more likely to ask for previous statements to be repeated in order to aid understanding. Whereas the earlier study by Katz et al. in

2006 identified individuals with adequate health literacy ask more questions about risks and benefits (62).

A 2012 qualitative study (73) by Dahm that consisted of 28 semi-structured interviews of Australian patients and physicians highlighted that consultations that had a higher medical terminology content from the practitioner resulted in less information seeking behaviour from the consultees. A second study (74) by the same author in the same year explored this further by discussing the impact of terminology use with patients and doctors. The patients explained that they did not ask questions to clarify unfamiliar medical terminology for one of two reasons. Either feeling they were wasting the doctor's time or due to not wanting to disclose feelings of insecurity, inferiority and anxiety.

Studies have found that those with limited health literacy have problems interpreting dosage instructions. A survey of Italian shoppers (69) by Calamusa et al. found that 42% of 182 caregivers could not calculate simple dosages. Similarly a 2010 mixed-methods study of 289 caregivers (75) by Yin et al. found that 41% made a dosing error. Having the confidence to ask questions of health care professionals could have prevented these errors.

1.2.6.5.3 Prescription signing

Health literacy researchers have realised that patients with limited health literacy have difficulty in completing medical paperwork. A Chicago based prospective study (76) by Sharp et al. in 2013 investigated if the time taken to sign the patient's name on the back of a prescription was associated with health literacy ability. The study identified a positive association between the time taken to sign their name and limited health literacy. It found that the length of the patient's name was not important and if someone signed their name in less than six seconds, they were more likely to have adequate health literacy. Observation of participants signing indicated that those who signed quickly abbreviated their signature whereas those with limited health literacy were more likely to spell out every letter in their name.

1.3 Incidence of low health literacy

It is estimated (77) that 80 million adults in the USA have low health literacy. Work in Australia in 2006 reported that 59% of Australians between the ages of 15 and

74 had poor health literacy (78). UK data regarding the prevalence of low health literary is limited. The Skills for life survey (79) captured the literacy and numeracy skills of 8730 people and reported that 46% had a literacy level that prevented them from achieving their full potential. The situation was worse for numeracy skills as 75% had numeracy skill levels that prevented them achieving their full potential. In total five percent were functionally innumerate. A longitudinal cohort study (80) found that 'one-third of older adults in England have difficulties reading and understanding basic health related information'.

1.4 Measurement of health literacy

This section describes some of the more widely used and recognised health literacy instruments as an introduction to health literacy measurement. The reported instruments show the chronological development of health literacy instruments from assessment of literacy and numeracy to health literacy assessment. The following chapter will go into an evidence-based assessment of all the instruments that are available for assessment purposes and assess to what extent they measure the three domains identified within the health literacy definition.

1.4.1 Wide Range Achievement Test (WRAT)

One of the first published instruments, in 1946, was the Wide Range Achievement Test. Whilst this instrument was created before the construct of health literacy was developed it is still used by researchers as an assessment of an individuals literacy and numeracy ability. The test (81) measures word reading; spelling abilities and mathematical computation. The time allocated to the test is variable depending on the age of the participant. The time range is between 15 and 45 minutes.

This makes this instrument very different to other tests, which have a fixed time length and expect all respondents, regardless of age, to complete it within the set timescale.

It is a norm-referenced test and was standardised using a representative USA national sample that ranged in age from 5 to 94 years old.

Since publication alternative versions have been created and the latest WRAT4 was created in 2006 (82) using 3,000 USA citizens to create the standardisation. This version now includes a comprehension assessment as well as the existing assessments. It is a modified cloze procedure (see below).

1.4.2 Cloze procedure

The Cloze procedure was first validated in 1953 (83) and is a comprehension test. The procedure requires the removal of words from a piece of text at regular intervals (nth Word) for example every sixth or seventh word. The participants must choose the correct word to fill in the gaps from a given a list of words or must try to fill the gaps from their own vocabulary. These two methods vary in difficulty. Consequently, it is important to know which version is used. The later version does not provide a list of words and is a much more difficult form making the test harder to complete successfully. A score can be calculated which is the percentage of correct answers. The difficulty of the test would depend on the reading level of the material and the frequency of the blanked-out words. The greater the frequency of missing words the greater is the difficulty of the test. The early work using the cloze procedure did not use health related text and used passages using everyday vocabulary.

1.4.3 REALM

In 1991, the REALM – the Rapid Estimate of Adult Literacy in Medicine was created by Davis et al. (84). This is a reading assessment instrument. It differs from previous tests reported in this chapter in that it was the first test that used words that had a medical context. Participants receive a list containing 125 words that increase in difficulty. The assessment is how well they pronounce the words. The assessor identifies the point at which they can no longer correctly pronounce the words. Each score relates to USA school reading grades.

Two years later in 1993 the same researchers (85) created a shortened version of the REALM (REALM-S). This version is identical to the original version apart from the number of words in the test is reduced to 66 words making it easier to administer. In 2003 an even shorter version was created called the REALM-R (86). In this version, the number of words is reduced to 8. The rationale for creating the

REALM-R was to shorten the time required to complete the assessment which was perceived as being too burdensome.

1.4.4 TOFHLA

In 1995 the TOFHLA was developed (87). The Test of Functional Health Literacy in Adults assesses both comprehension and numeracy skills. The comprehension section adapts the Cloze procedure by using health related text. It removes the fifth to seventh word and gives the participant a choice of four words for every missing word. There are fifty removed words in three health-related passages. The three passages each have a different level of complexity as measured by the Gunning FOG readability scale. The Gunning FOG scale is a universally used assessment method to measure the reading level of written text. The first passage has a level of 4.3, the second 10.4 and the final passage 19.5 (reading US grades 4, 10 and 20).

The numeracy section is a 17-item test. It tests patients' ability to understand directions given in a health care setting such as taking medicines, keeping appointments and monitoring blood glucose. Each correct numeracy answer is multiplied by 2.941 to give a possible score out of 50. The numeracy score is then added to the obtained comprehension score to give a score out of 100. TOFHLA was the first health literacy assessment that categorised the results in terms of health literacy ability and created the categories of inadequate, marginal and adequate health literacy.

The WRAT is a measure of educational attainment and assesses a wide range of skills in a broad context. Whereas, the TOFHLA was also the first health literacy instrument that identified the importance of numeracy within health literacy and in doing so started to move the measurement away from purely reading assessments. It is worth noting that the TOFHLA puts equal emphasis on the numerical and reading comprehension elements, indicating that they are equally important components of health literacy. The TOFHLA instrument consequently expands the measurement of the ability of the individual described within the WHO definition of health literacy.

1.4.5 MART

The MART, the Medical Achievement Reading Test was developed in 1997 (88). This alternative reading test uses 42 words taken from prescription labels and from a medical dictionary. Like the REALM, the reading assessment uses US school reading grades.

1.4.6 S-TOFHLA

In 1999 two new versions of the TOFHLA were developed (89). The S-TOFHLA shortens the time taken to carry out a health literacy assessment in a clinical setting. The established TOFHLA took approximately 22 minutes a patient to complete which is an unrealistic proposition in a busy health care environment. The shortened version had a good internal consistency to the full assessment (89) and reduced the time required. There are two versions. One version, called the brief version, took twelve minutes to complete and the other, the short version, three minutes. The number of prose passages reduced to two and the items from 50 to 36. The passage removed was the one set at the higher-grade reading level (level 20). The numeracy section reduced from 17 items to four items for the brief version and was absent for the short version.

The brief version S-TOFHLA, as the original TOFHLA, has a maximum score of a 100. There are two marks allocated for each correct prose answer and seven points for each correct numeracy answer. In comparison, the short S-TOFHLA has a maximum score of 72, as it allocates two marks per prose question.

The S-TOFHLA is a very popular instrument but having the same name for two different versions can cause confusion when reviewing the literature. The two instruments are very different assessments with one being a purely reading based assessment and one a reading and numeracy assessment.

1.4.7 NVS

In 2005 another instrument, the New Vital Sign (NVS), was developed (90). This involves patients reading a nutritional label and answering six questions based on the content of the nutritional label. It is reported to only take three minutes to administer and was the first significant instrument that focused on problem solving rather than literal comprehension. The NVS, like the WRAT and TOFHLA involves

the measurement of numerical skills, which are very relevant when considering health literacy.

1.5 Existing health literacy interventions

Early studies focused in simplifying the English used so that a lower school reading level was required to understand the information and using pictorial information instead of written materials. Examples are described below.

1.5.1 Health literacy and medication use

As this thesis is from a pharmacy perspective the interventions reported relate to medication usage.

1.5.1.2 Pictograms

The use of pictograms to support health literacy (91-94) has produced mixed results. A literature review by Hanson-Divers in 1997 (88) indicated that studies vary on the benefits of pictograms in pharmacy. The author argued that this overall lack of benefit may be due to the poor design and testing of the pictograms. The review also indicated that pictograms work best in conjunction with text or verbal explanations rather than a stand-alone intervention. A USA randomised trial by Davis et al. in 1991 (84) found that using pictograms with counselling reduced the error rate of dosing accuracy compared with counselling alone.

1.5.1.3 Improving prescription label instructions

There have been studies to alter drug labelling to improve understanding for individuals with low health literacy (67, 95, 96). Patients were significantly more likely to understand instructions that had explicit times e.g. at night or precise times of day compared to instructions stating hourly intervals or number of times a day e.g. twice.

1.5.1.4 Medication adherence

There are mixed results from studies on health literacy interventions to improve medication adherence. Some studies indicate that interventions to support lower levels of health literacy are beneficial (97-100), whilst others could not find an effect (101-103). Many studies (104-106) use prescription collection refills as a proxy for adherence. This does not differentiate between intentional

non-adherence and non-intentional non-adherence. A survey of 254 older American adults at an urban hospital (107), by Lindquist et al. in 2012, suggested that this is a significant explanation for the variation in the outcomes produced. It found that participants with inadequate and marginal health literacy were significantly more likely to have intentional non-adherence whereas those with adequate health literacy were significantly more likely to have non-intentional non-adherence.

1.6 Gap analysis within a pharmacy context

There has been little research into health literacy in the UK and within pharmacy setting. Many of the studies that relate to health literacy and medication adherence have used doctors and nurses in primary and secondary care environments to complete the studies. Studies in a pharmacy setting that focused on using a health literacy intervention to improve medication adherence are limited (101, 103, 107, 108).

To start health literacy research within a community pharmacy environment in the UK it is important to establish first what the most appropriate health literacy instrument to use is. The next chapter will describe a systematic review to find the most appropriate instrument.

Chapter Two

Identifying the optimal measurement instrument for assessing health literacy in a clinical setting: A systematic review

2 Identifying the optimal measurement instrument for assessing health literacy in a clinical setting: A systematic review

2.1 Chapter introduction

The previous chapter reported that health literacy is an important determinant of population health and is a growing priority to address poor health outcomes. The complexity and breadth of elements constituting health literacy and the rapidly developing nature of this research area have contributed to the wide range of health literacy instruments available.

Health literacy measurement has been used for research purposes but it is not routinely undertaken in healthcare environments and there is no widely accepted instrument for use in practice. Therefore, there is a need to identify which of the available health literacy instruments would be appropriate to accurately measure limited health literacy in a clinical setting. Not only would the instrument have to be reliable and accurate, it would also have to be acceptable to patients and clinicians and be feasible to fit into daily practice.

The aim of this chapter is to systematically review existing health literacy instruments in order to assess their psychometric properties and to assess the acceptability and feasibility of use in a community pharmacy setting.

2.2 Systematic review methodology

The systematic review was conducted according to the PRISMA guidelines and the Cochrane collaboration's instrument for assessing risk of bias in randomised trials (109, 110). The study protocol was registered with PROSPERO (register reference CRD42013003874). The systematic review was led by Paul Duell (PD) and Quang Bui (QB) who worked as the second reviewer; both were supervised by Debi Bhattacharya (DB). Additional supervisory guidance was provided by David Wright (DW) and Andre Renzaho (AR).

Chapter 2 Identifying the optimal measurement instrument for assessing health literacy in a clinical setting: A systematic review

2.2.1 Aims and objectives

2.2.1.1 Aims

To identify the optimal health literacy instrument in terms of breadth and accuracy of skills assessed plus the acceptability and validity of use within the clinical environment.

2.2.1.2 Objectives

To describe existing health literacy measures in terms of:

- The domains of health literacy assessed
- Validity and sensitivity for identifying low health literacy
- Comparison against other health literacy assessment instruments used for research purposes
- Suitability of use within routine clinical practice from the participant and healthcare professional perspective

2.2.2 Literature search strategy

Scoping searches of research papers were carried out to identify commonly used terms and phrases to describe health literacy assessment instruments. The identified words were then used to identify research papers for inclusion in the systematic review.

The following databases were used to conduct the literature search for papers in English:

1. MEDLINE
2. EMBASE
3. PsychINFO
4. CINAHL
5. PHARMLINE (provided initially through National electronic Library for Medicines (NeLM) and then via the NICE evidence search site)
6. Cochrane Database of Systematic Reviews (CDSR)

The bibliography of included studies were reviewed to further identify additional references. In addition, the reference section of the health literacy group website:

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http://www.healthliteracy.org.uk was searched for relevant papers, as was the reference sections of any review papers identified by the search.

2.2.3 Search terms

Studies were identified through electronic and manual searches to identify published studies. Search strategies used appropriate subject headings plus text words; truncations (*), wild cards ($), hyphens and other relevant Boolean operators where permitted by the databases. Further scoping searches were conducted to inform the inclusion and exclusion criteria and finalise the search strategy.

The following search terms were used.

1. Measur* or Instrument* or assess*
2. Health literacy or health competen*
3. Critical or functional or communicat* or motivation or cognitive or social skill or numeracy
4. Acceptab* or feasibl* or valid* or perform* or psychometric* or scor* or sensitive* or specific* or reliabl* (see appendix 2.1)

2.2.4.1 Inclusion criteria

The study inclusion criteria were developed using the PICOS model (111) as this provides a structured approach to the assessment. When considering inclusion criteria the aim was not to be too restrictive in order to prevent useful instruments being excluded at an early stage. Study populations and sites in any healthcare setting were included if the studies involved adolescents or adults.

All studies that measured at least one of the three domains of health literacy: accessing information, understanding information and using health information were included. Studies considering numeracy from a health literacy perspective were also included. The health literacy measure could have been administered by any individual or group in any setting.

Studies reporting descriptive and / or psychometric data on new health literacy instruments or screening questions. Or studies that assess health literacy in a population by comparing existing health literacy instruments or questions with new

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measures or questions. Both qualitative and quantitative studies were considered for inclusion.

2.2.4.2 Exclusion criteria

Studies were excluded if solely validating a translation of an existing health literacy assessment instrument developed in English, conference abstracts or reporting a quantitative study sample size less than 50 participants.

The early scoping exercises indicated that there were many health literacy assessment instruments in existence and that a systematic review was likely to generate many research papers that met the inclusion criteria. Literature reviews carried out for chapter one identified that health literacy research predominated in either in English speaking countries or countries where it was the second language. Therefore, as the objective of the systematic review was to identify an instrument acceptable for use in a community pharmacy in the UK, the decision was taken to exclude research papers not written in English.

In clinical practice the emphasis is on treating the patient as an individual and on tailoring care to the patient's individual requirements. Therefore, the use of health literacy assessment to inform how care should be provided would be required at an individual level. Consequently, health literacy instruments that are designed to measure population health literacy were excluded from the systematic review.

2.2.5 Screening and selection

The systematic review considered any studies that reported the measurement of health literacy by testing patients and assessing the measurement instrument by either comparison with an existing validated measure or by reporting validity, acceptability or feasibility of the measurement instrument.

An abstract screening instrument was developed based on the study inclusion and exclusion criteria to identify the articles to be included in the systematic review. All the abstracts were screened by title and abstract by two independent reviewers using the screening instrument developed (PD and QB). QB was a fourth-year pharmacy undergraduate student and completed this work as part of his final year project.

The screening instrument asked three questions.

- Is it a study that uses a defined method or question(s) or instrument to assess or measure health literacy?
- Does the abstract indicate individual health literacy patient data was collected in the study?
- Does the abstract indicate the study uses psychometric assessment, or validation techniques of the health literacy measurement?

To pilot the abstraction process, six randomly selected abstracts were reviewed by each reviewer and the results compared to ensure that a consistent approach was taken to evaluating the selection criteria. Each abstract was then assessed individually.

After reviewing each of the abstracts four groups were formed; papers that clearly meet all of the screening questions; papers that needed reading to confirm if all the criteria were met; papers that did not meet the criteria but were worthy of background reading and papers that did not meet the criteria and were irrelevant to the research. In cases of discrepancy, consensus was agreed through discussion and where necessary, referral to a third independent reviewer (DB).

Full texts of papers identified were reviewed independently by both reviewers.

2.2.6 Data extraction

A data extraction instrument was developed to collect information from each of the full papers that met the screening criteria. The following information was collected:

- Paper's publication details – title; authors; journal; publication date; country of origin
- Population – geographical location; disease; population demographics – gender; age; language spoken; income; educational attainment; race
- Intervention details – study objective; number of questions within the instrument; health literacy instrument scoring categories
- Comparison – health literacy definition; health literacy instrument used as a comparator; domain area of health literacy measured; time required to test
- Outcome – variation in health literacy within the studied population;

> drop-out rate; sample size; details of psychometric assessment if assessed – content validity; face validity; criterion validity; construct validity and reliability

- Study characteristics – design; method of development; self-reported measurement or direct measurement; exclusion criteria

2.2.7 Quality assessment

A quality assessment of all included studies was undertaken (110). The quality assessment instrument was modified as it is designed for randomised control trials whereas most of the studies in the systematic review were cross sectional studies. Hence risk of bias was evaluated for the five domains deemed relevant to the included studies: selection; performance; detection; attrition and reporting.

For each study, the risk of bias in each of the five domains, was classified as low, uncertain or high, as recommended in the guidelines. These classifications were depicted in a table format by using the use of colours green for low; yellow for uncertain and red for high. Each type of bias had a number of potential sources of bias and using the described traffic light system a single rating was identified by considering all the individual ratings that made up the assessment.

The quality assessment process was undertaken independently by the two reviewers PD and QB, with consensus on the final risk classifications reached through discussion. No paper was excluded on the basis of being identified as a poor quality study.

2.2.8 Psychometric analysis

Health literacy assessment instruments measure an individual's strengths and weaknesses associated with health information. Each instrument is assessing psychological skills and consequently there is a similarity with the design of health literacy instruments to the design of psychological tests. The American Educational Research Association has since 1977 produced standards for educational and psychological testing regarding test construction and evaluation. The key factors are described below.

2.2.8.1 Validity

The 1985 version (112) of the standards argues that validity is the most important aspect of instrument development and defines validity as 'the appropriateness, meaningfulness, and usefulness of the specific inferences made from the test scores'. Sireci and Faulkner-Bond (113) quotes the 1999 version of the Standards for Educational and Psychological testing definition of validity as 'the degree to which evidence and theory support the interpretations of test scores entailed by proposed uses of tests'. This later, broader, definition builds in the importance of linking the instrument to the underpinning theory that the test was set up to measure.

Different researchers over the last century have categorised validity into different subcategories in order to focus on specific aspects. There is significant overlap between these subcategories but they are still useful in clarifying the underpinning concepts and teasing out the constructs involved in the tests design.

2.2.8.1.2 Criterion validity

Criterion Validity is sometimes referred to as empirical or statistical validity. It can be described as the extent that a proposed instrument 'corresponds to some other observation that measures accurately the phenomenon of interest' (114). Two types of criterion validity exist; one where the new measure corresponds to a criterion measured simultaneously which is known as concurrent validity and the other where the measure is used to forecast a future criterion which is known as predictive validity.

2.2.8.1.3 Content Validity

The content validity 'demonstrates the degree to which the sample of items, tasks or questions on a test are representative of some defined universe or domain of content' (112). Sireci (115) took this definition further to identify four elements of content validity - domain definition, domain representation, domain relevance and appropriateness of test construction procedures. Domain based assessments often involve the use of expert panels to assess the content validity or are by empirical methods. Content validity is sometimes referred to as face validity which

is described as 'the simple appearance that the items are related to the construct of interest' (112).

2.2.8.1.4 Construct validity

Cronbach and Meehl (116) described a construct as 'some postulated attribute of people, assumed to be reflected in test performance'. The definition of construct validity proposed by Heppner et al. (117) considered how well the variables chosen by the researcher to represent a construct really 'capture the essence' of that construct. Consequently, construct validity should answer the question does the instrument measure what it says it measures? (118).

2.2.8.2 Factor Analysis

For many researchers factor analysis is the mechanism to demonstrate construct validity as factors and constructs are believed to be synonymous terms (119). Factor analysis is not a new conceptual model as it is credited to Pearson (1901) and Spearman (1904). Both were interested in summarising the relationships among measured variables and trying to determine whether these relationships can be summarised in a smaller number of latent constructs. Factor analysis is separated into two types known as Exploratory Factor Analysis (EFA) and Confirmatory Factor Analysis (CFA).

2.2.8.2.1 Exploratory Factor Analysis

Exploratory Factor Analysis (EFA) is used as an exploratory theory generating process by identifying the factor model for a set of variables: identifying the number of factors and the factor loadings. EFA is based on the common factor model created by Thurston (120) that postulates 'each measured variable in a battery of measured variables is a linear function of one or more common factors and one unique factor. Common factors are unobservable latent variables that influence more than one measured variable in a battery and are presumed to account for the correlations (covariances) among the measured variables'. The aim of EFA is therefore to demonstrate the intercorrelations between variables and to find the factors that most strongly influence the construct under review.

2.2.8.2.2 Confirmatory Factor Analysis

Confirmatory Factor Analysis differs from EFA in that it requires the researcher to already understand the variables linked to the factors under consideration and have a knowledge of the number of factors and their interrelationship. It is consequently a process to test an existing theory or conceptual model.

2.2.8.3 Reliability

Reliability has been described as 'the degree to which test scores are consistent, dependable or repeatable, that is, the degree to which they are free of errors of measurement' (112). The assessment of reliability can occur in a number of ways and the systematic review would anticipate that any new instrument development would use some of these to demonstrate the reliability of their health literacy instrument.

Internal analysis of reliability describes a group of methods to assess reliability each of which uses a single test, examples of these include coefficient alpha and Kuder-Richardson formulas.

The reliability coefficient is a coefficient of correlation between two administrations of a test. (112). Depending on the method of administration different coefficients may be assessed. Administration could assess the impact of time (test retest reliability) or the impact of different administrators or scorers (rater reliability).

2.2.8.4 Psychometric analysis within the systematic review

Section 2.2.8 has, so far, described the properties of psychometric assessments that can be used for test construction and validation. The next paragraph describes the psychometric analysis adopted for the systematic review.

The methodological quality of the psychometric scales and their measurement properties were assessed using an established research framework (121). The framework assesses criterion; content; construct validity as well as reliability of the instrument, hence meeting all the required elements for psychometric analysis. Scales were assessed to establish whether items were developed based on literature review, pilot studies or panel of experts. The assessment of reliability was by either an internal consistency measurement or test-retest reliability. The

three aspects of scale validity assessed were: content validity by establishing whether the scale had all facets of health literacy, construct validity by establishing whether the scale were established through both exploratory and confirmatory factor analyses; and criterion validity by establishing the extent to which health literacy scales were correlated with other health outcome measures (122). The framework does not differentiate between different forms of validity and places an equal importance on each. Consequently, each item could obtain a score of zero or one. A score of zero indicated the item was absent and a score of one indicated the item was included. Therefore, scores ranged from zero to six, with a score ≤ 2 representing poor quality; a score between three and four representing medium quality; and a score ≥ 5 representing high quality.

2.2.9 Suitability

Research designed health literacy instruments may not be readily transferable for adoption in clinical practice. This lack of transferability can be for several reasons. In terms of this thesis, a key factor was to identify health literacy instruments that were ready to test in UK practice rather than to identify health literacy instruments that had the potential for use in the future after development and / or adaptation. It was therefore important that the systematic review addressed the issue of suitability of transference into UK practice.

Six criteria were used to determine health literacy instrument suitability for use within routine clinical practice from the participant, healthcare professional and researcher's perspective. These were identified by an initial literature search and by discussion amongst the practitioners within the research team.

Population – suitable for all
Intervention - involve text and numerical elements
Comparison – Length of time set to complete the assessment
Outcome – written in English
Study design – assess more than domain of health literacy as defined by Nutbeam and not solely rely on self-assessment

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2.2.9.1 Population

The primary aim of the systematic review was to identify a health literacy assessment instrument that can be used in clinical practice and particularly in a community pharmacy environment. The time pressures faced by clinicians in their daily practice creates a constant necessity to prioritise work and its distribution amongst the practice staff. In pharmacies this is primarily co-ordinated by the pharmacist in charge. Like all prioritisation processes there is an assessment of what is most important and the impact of non-completion. This process often includes a judgement on the number of people that will benefit as this affects the perceived importance. Any heath literacy assessment instrument that is only designed for a sub section of the local population will be judged as of lower importance than an instrument that can be used on all the population. Therefore, in terms of suitability criteria, the generalisability of the health literacy instrument was deemed to be an important characteristic.

The importance of using a single health literacy instrument that can be used in all circumstances for the local population is a pivotal consideration, in assessing the suitability of health literacy instruments, for this systematic review. Training clinicians to use to a single instrument to assess health literacy is far more practical than learning several different instruments that are only suitable for a specific sub section of their practice patients e.g. only for diabetic patients (123). The more instruments that are introduced into practice the greater is the risk that the wrong instrument will be used in the wrong circumstances. A single instrument would also be preferable from a patient's perspective as it minimises assessment burden.

2.2.9.2 Text and numerical elements within a health literacy instrument

The literature review carried out at the beginning of this thesis identified, at an early stage, the variation in health literacy instruments in assessing numeracy as well as literacy skills. As discussed in the previous chapter, inclusion or exclusion of a numeracy element produces a different approach to measuring and defining health literacy.

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Patients accessing pharmacy services and taking medications need both numerical and prose skills in order to access information and understand and use the information effectively. If the health literacy instrument measures both numeracy and prose skills then it will be more beneficial to a larger proportion of the local population who may have different health literacy needs. From the clinician's perspective the inclusion of both numeracy and prose elements to the suitability criteria ensures that the health literacy instrument benefits the maximum number of people accessing their services.

2.2.9.3 Time required to complete the assessment

Over the last decade, the number of prescriptions dispensed in community pharmacy has increased by 44.6% (124) whilst staffing levels have remained static or decreased slightly (125). In GP practices in the UK, an average consultation with a doctor lasts ten minutes (126). These time constraints mean that if health literacy assessments are to occur within clinical practice then the time required to test should be kept to a minimum. An arbitrary marker of five minutes was agreed by the research team as acceptable from the clinicians' perspective as this constitutes half of the GP consultation time and is approximately the length of a detailed pharmacy over the counter consultation (127). Any test that takes longer reduces the willingness of the clinicians to participate due to the impact on daily practice. It is possible that many clinicians may still feel, under the existing contractual framework in which they operate, that five minutes is too long to administer. Whilst this may be the case it was judged to be important to set some marker to differentiate between those health literacy instruments that were very time intensive compared with those that are quicker to administer.

Research into patient reported acceptability of survey completion by Hoerger in 2010 (128) indicated that patients prefer shorter duration requests on their time to complete surveys and that the longer the activity took the lower was the uptake rate. Applying this to being asked to complete a health literacy assessment would suggest that the duration of the assessment may also be a concern for patients.

2.2.9.4 Validated for use in an English speaking population

As previously stated an objective of the systematic review was to identify existing health literacy instruments that can be used in clinical practice in the UK. It is recognised that the systematic review is likely to identify instruments that have a varying amount of evidence to support their usage in different environments. Some instruments may only have information on the validation of a new instrument whereas others may also have extensive evidence of instrument use after its development. Instruments that have already been validated for an English population, as described earlier, was an important factor.

2.2.9.5 Assess more than domain of health literacy

Chapter one discussed how Raztan and Parker's definition of health literacy (20) comprised of three distinct domains these being; accessing, understanding and applying information. These are different cognitive processes that combine to describe the full complexity of health literacy. There is no research evidence to suggest that anyone that has limited health literacy is equally weak in all three domains and in the absence of this evidence it cannot be assumed that measuring only one domain will provide an accurate assessment. Based on this it could be argued that the acceptability criteria should be that a health literacy instrument should measure all three domains of health literacy. This, without doubt, would be the optimum outcome; however, it was decided to set the criteria as more than one domain as the initial literature review had indicated that the number reaching the full criteria was likely to be very low. Setting this minimum level would still capture all those instruments that measured all three domains but also recognise instruments that were more than unidimensional.

2.2.9.5.1 Self-assessment

Self-assessment instruments have the advantage of reducing the time required by clinicians to administer the test and can be used in postal surveys. There are however, disadvantages associated with them. There is the issue of consistency in the way the instrument is administered. Unless the test is supervised there is the possibility that the participant may get help in completing the assessment. There may also be a big variation in the time taken to complete the assessment. This

may not be an issue with single questions or a small number of questions that just rate their perception of their abilities but can be with the more complicated or detailed instruments.

The biggest risk to self-assessment is self-presentation bias; participants over estimating their health literacy to hide deficiencies in their ability. The American advisory health literacy group (129) indicate that patients try to hide poor reading ability.

Not all researchers accept that self-assessment instruments are inferior to tests that attempt to assess an individual's health literacy. A systematic review (130) of health literacy instruments to use for individuals with diabetes, by Al Sayah et al. in 2013, favoured self-assessment instruments as they caused less embarrassment to patients and were quick to use. They did acknowledge, however, that self-assessment instruments only provided information on an individual's confidence with certain skills and did not measure these skills. They described these instruments as indirect measures compared to direct measures. Due to the concerns over reliance on self-assessment the suitability criteria chosen was that the health literacy instruments should not solely rely on self-assessment.

2.2.9.6 Scoring suitability criteria

One point was allocated if the criterion was met and zero if not. Therefore, giving a total score zero to six, with a score ≤ 2 representing poor; a score between three and four representing medium; and a score ≥ 5 representing high.

2.3 Results

The selection process is shown diagrammatically in figure 2.1. Six hundred and twenty-six abstracts were identified and of these 64 papers were selected for the systematic review.

2.3.1 Study selection

One additional paper was identified through the hand search of references within the accepted published papers.

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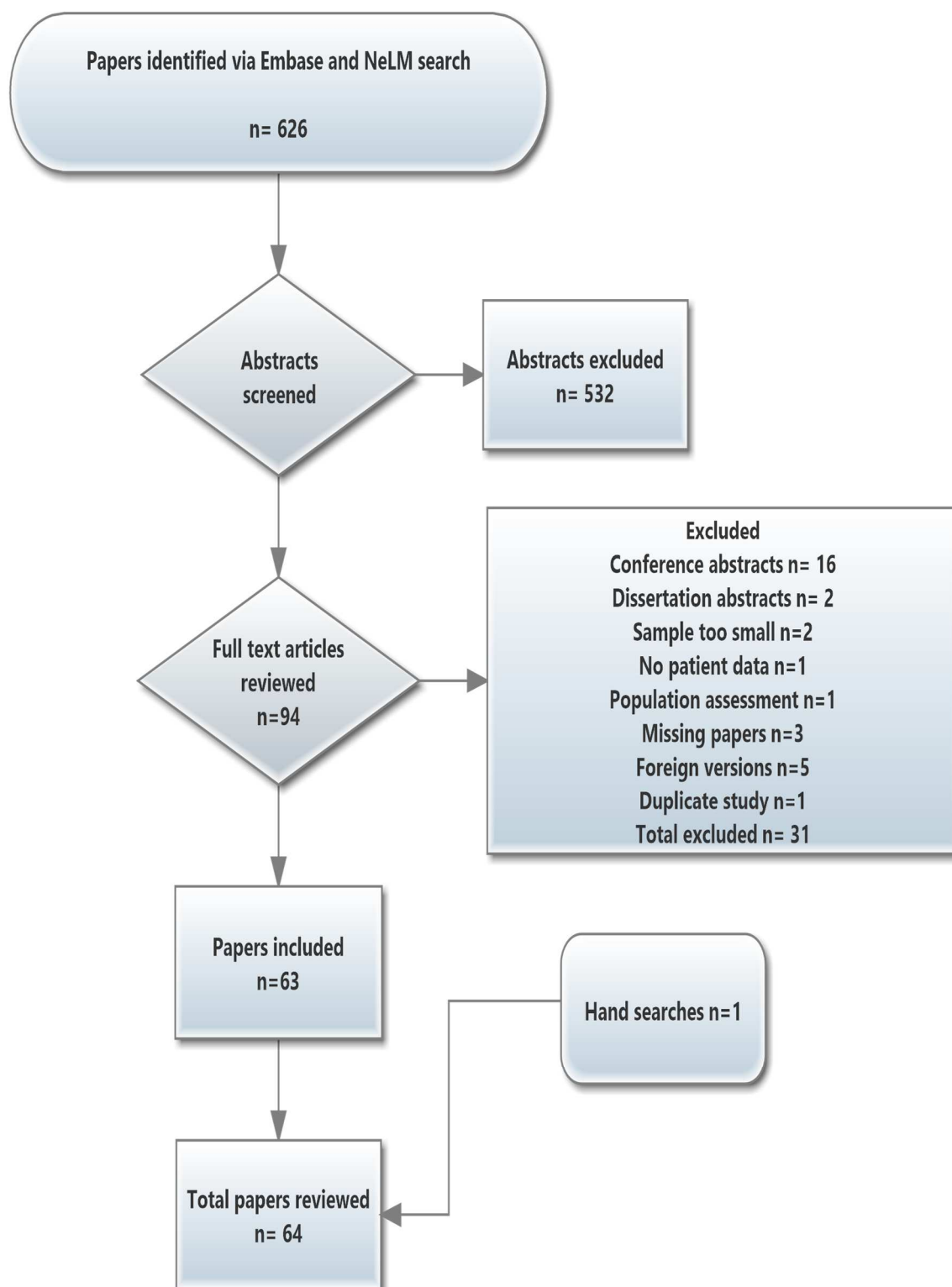
FIGURE 2.1 STUDY SELECTION PROCESS

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2.3.2 Study exclusion

31 papers were excluded at the full text screening stage. Sixteen were of conference abstracts, two were dissertation abstracts and five were foreign translations of existing instruments. One paper was a duplicate study, one a population assessment instrument and one provided no patient data. Two studies had sample sizes below the defined cut off point of 50 participants.

Three full text articles could not be obtained and the authors were not contacted to request a copy of the paper. Two were specific to the condition of rheumatoid arthritis and the third evaluated an oral health instrument. Whilst being far from ideal, the decision was taken to exclude these studies. Factors considered in deciding not to contact the authors were the large number of papers that were available and that the studies were comparable to conference abstracts where insufficient information was available at the time of the study to include.

2.3.3 Description of included studies

Papers were published between 1998 and 2013 with 68.8% (n=44) published between 2009 and 2013. Since 2012 eighteen studies were published which accounts for 28.1% of the total papers reviewed.

Table 2.1 (pages 38 to 43) reports for each paper the year it was written, the sample size and average age of participants. It also reports the country of origin and describes the location of the studies. The sample size varied from 50 to 3186 participants with 38 (56%) studies reporting a sample size between 50 and 300 participants. The reviewed papers came from 13 different countries and considered health literacy using nine different languages. The USA generated 71.9% (n=46) of the papers and only 4.7% papers (n=3) originated from the UK.

There were a variety of exclusion criteria listed for the studies. Table 2.2. (pages 44 to 50) shows the most commonly reported exclusion criteria by studies. Reduced health capacity was a common theme with reduced visual, hearing, cognitive function and critically ill all reported on numerous occasions. Age limits and language difficulties were also regular exclusions.

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Forty-three different health literacy instruments were identified during the review. Nine of these instruments created derivative versions of the original instrument. These included four different versions of the Rapid Estimate of Adult Learning in Medicine (REALM) instrument (131), six different versions of the Wide Range Achievement Test (WRAT) (132), and seven variations of Test of Functional Health Literacy in Adults (TOFHLA). In total 64 health literacy instruments were found in all the studies.

Since 2010 nineteen new health literacy instruments had been created accounting for 44.2% of the instruments identified (n=43). All of the new instrument studies are listed in table 2.3 (pages 51 to 55). The table identifies the instruments' acronym, whether the studies reported psychometric evaluation and lists the health literacy instruments used for validation purposes.

Studies that developed health literacy instruments for a specific health condition accounted for 17.2% (n=11) of the papers. There were 11 different health conditions identified in the papers, the most common condition being diabetes which accounted for 12.5% (n=8) of the articles.

2.3.4 Rationale for studies

Studies that were designed to assess or validate a new version of an existing instrument are reported in table 2.4 (page 56). All tested the psychometric properties of the new instrument and most compared against other health literacy instruments.

Table 2.5 (page 57) reports studies studies that had varying objectives but used more than one health literacy instrument to measure health literacy.

Table 2.6 (pages 58 & 59) reports studies that used multiple health literacy instruments to evaluate the studies objectives.

First author	Year	Study size	Average age	Location Not stated	Location Clinic, practice, hospital	Location Other	Country
Baker, D. (89)	1998	211	44		X		USA
Aguirre, A. (133)	2004	2370	45			X	USA
Sanders, L. (134)	2004	163	28		X		USA
Apter, A. (135)	2005	73	47		X		USA
Weiss, B. (90)	2005	500	41		X		USA
Buchbinder, R. (136)	2006	80	60		X		Australia
Lee, S. (137)	2006	403	44		X		USA
Zun, L. (138)	2006	105	Not stated		X		USA
Baron-Epel, O. (139)	2007	119	56		X		Israel
Chisolm, D. (140)	2007	50	15			X	USA
Diamond, J. (141)	2007	341	Not stated		X		USA

Table 2.1 Overview of population

First author	Year	Study size	Average age	Location			Country
				Not stated	Clinic, practice, hospital	Other	
Gong, D. (142)	2007	102	35		X		USA
Hibbard, J. (143)	2007	303	37			X	USA
Hoffman-Goetz, L. (144)	2007	140	Not stated			X	USA
Lee, J. (145)	2007	202	45		X		USA
Von Wagner, C. (146)	2007	719	48			X	UK
Cavanaugh, K. (147)	2008	398	55		X		USA
Huizinga, M. (148)	2008	398	54		X		USA
Ishikawa, H. (149)	2008	190	43			X	Japan
Ishikawa, H. (150)	2008	138	65		X		Japan
Huizinga, M. (151)	2009	164	46		X		USA
Jeppesen, K. (152)	2009	225	Not stated		X		USA

Table 2.1 Overview of population continued

First author	Year	Study size	Average age	Location			Country
				Not stated	Clinic, practice, hospital	Other	
Ko, Y. (153)	2009	164	43		X		Singapore
Lee, T. (154)	2009	411	73		X		Korea
Miller, M. (155)	2009	154	57			X	USA
Oettinger, M. (156)	2009	163	Not stated		X		USA
Rawson, K. (157)	2009	155	63		X		USA
Sabbahi, D. (158)	2009	100	39		X		Canada
Weld, K.K. (159)	2009	155	54			X	USA
Yost, K.J. (160)	2009	231	Not stated	X			USA
Clayman, M. (161)	2010	330	54		X		USA
Golbeck, A. (162)	2010	143	Under 18			X	USA
Kumar, D. (65)	2010	182	26		X		USA

Table 2.1 Overview of population continued

First author	Year	Study size	Average age	Location			Country
				Not stated	Clinic, practice, hospital	Other	
Lee, S.D. (163)	2010	202	44		X		USA
Ohl, M. (164)	2010	147	41		X		USA
Ozdemir, H. (165)	2010	456	36		X		Turkey
Sarkar, U. (166)	2010	296	55			X	USA
Ferguson, B. (167)	2011	150	60		X		USA
Galesic, M. (168)	2011	987	67				USA
Kim, M. (169)	2011	386	71		X		X
Kirk, J. (170)	2011	593	60-69		X		USA
McNaughton, C. (171)	2011	207	46		X		USA
Patel, P. (172)	2011	62	73		X		USA

Table 2.1 Overview of population continued

First author	Year	Study size	Average age	Location			Country
				Not stated	Clinic, practice, hospital	Other	
Pendlimari, R. (173)	2011	61	64			X	USA
Robinson, S. (174)	2011	612	66			X	USA
Apolinario, D. (175)	2012	226	74		X		Brazil
Bann, C. (176)	2012	889	Not stated			X	USA
Chinn, D. (177)	2012	146	32		X		UK
Dunn-Navarra, A. (178)	2012	154	29			X	USA
Ghaddar, S. (179)	2012	261	16			X	USA
Haun, J. (180)	2012	378	62		X		USA
Helitzer, D. (181)	2012	161	Not stated	X			USA
Schapira, M. (182)	2012	1000	Not stated			X	USA
Shonna Yin, H. (183)	2012	171	28		X		USA

Table 2.1 Overview of population continued

First author	Year	Study size	Average age	Location			Country
				Not stated	Clinic, practice, hospital	Other	
Tzu-I, T. (184)	2012	323	47			X	Taiwan
Wolf, M. (185)	2012	832	63			X	USA
Wu, A. (186)	2012	275	Not stated			x	Canada
Jordan, J. (187)	2013	350	56		X		USA
Koay, K. (188)	2013	93	Not sated		X		Australia
Miser, W. (123)	2013	226	54		X		USA
Osborn, C. (189)	2013	205	55		X		USA
Rowlands, G. (190)	2013	337	Not stated			X	UK
Sun, X. (191)	2013	3186	Not stated			X	China

Table 2.1 Overview of population continued

First author	Not stated	Limited language ability	Exclusion criteria Reduced visual capacity	Reduced hearing capacity	Reduced cognitive function	Critically ill	Age limits	Other
Baker, D. (89)		X			X	X	X	X
Aguirre, A. (133)		X	X	X	X			
Sanders, L. (134)		X						
Apter, A. (135)	X							
Weiss, B. (90)			X		X			
Zun, L. (138)		X					X	
Lee, S. (137)				X	X			X
Buchbinder, R. (136)	X							
Baron-Epel, O. (139)	X							
Chisolm, D. (140)							X	
Diamond, J. (141)	X							

Table 2.2 Overview of health literacy studies - exclusion criteria

| First author | Not stated | Limited language ability | Exclusion criteria | | Reduced cognitive function | Critically ill | Age limits | Other |
			Reduced visual capacity	Reduced hearing capacity				
Gong, D. (142)	X							
Hibbard, J. (143)	X							
Hoffman-Goetz, L. (144)							X	
Lee, J. (145)			X	X	X			X
Von Wagner, C. (146)		X	X				X	
Cavanaugh, K. (142)			X		X		X	
Huizinga, M. (148)			X		X			
Ishikawa, H. (144)								X
Ishikawa, H. (150)								X

Table 2.2 Overview of health literacy studies - exclusion criteria continued

First author	Not stated	Limited language ability	Exclusion criteria Reduced visual capacity	Reduced hearing capacity	Reduced cognitive function	Critically ill	Age limits	Other
Huizinga, M. (151)	X							
Jeppesen, K. (152)		X	X		X			
Ko, Y. (192)		X	X	X	X		X	
Lee, T. (154)			X	X	X			
Miller, M. (155)		X	X					X
Oettinger, M. (156)			X		X			
Rawson, K. (157)	X							
Sabbahi, D. (158)		X			X			

Table 2.2 Overview of health literacy studies - exclusion criteria continued

First author	Not stated	Limited language ability	Exclusion criteria Reduced visual capacity	Reduced hearing capacity	Reduced cognitive function	Critically ill	Age limits	Other
Weld, K. (159)		X	X		X			
Yost, K. (160)			X		X			
Clayman, M. (161)		X			X	X		
Golbeck, A. (162)	X							
Kumar, D. (65)			X		X			
Lee, S. (158)				X	X			X
Ohl, M. (164)		X	X		X		X	
Ozdemir, H. (165)		X			X			
Sarkar, U. (166)	X							
Ferguson, B. (167)			X	X	X			

Table 2.2 Overview of health literacy studies - exclusion criteria continued

First author	Not stated	Limited language ability	Exclusion criteria		Reduced cognitive function	Critically ill	Age limits	Other
			Reduced visual capacity	Reduced hearing capacity				
Galesic, M. (168)	X							
Kim, M. (169)	X							
Kirk, J. (170)					X	X		
McNaughton, C. (171)		X				X		
Patel, P. (172)			X	X	X			
Pendlimari, R. (173)								X
Robinson, S. (174)		X			X	X		
Apolinario D. (175)		X						
Bann, C. (176)	X							

Table 2.2 Overview of health literacy studies - exclusion criteria continued

| First author | Not stated | Limited language ability | Exclusion criteria | | Reduced cognitive function | Critically ill | Age limits | Other |
			Reduced visual capacity	Reduced hearing capacity				
Chinn, D. (177)	X							
Dunn-Navarra, A. (178)	X							
Ghaddar, S. (179)							X	X
Haun, J. (180)	X							
Helitzer, D. (181)		X						X
Schapira, M. (193)	X							
Shonna Yin, H. (183)			X		X			
Tzu-I, T. (184)	X							

Table 2.2 Overview of health literacy studies - exclusion criteria continued

First author	Not stated	Limited language ability	Exclusion criteria		Reduced cognitive function	Critically ill	Age limits	Other
			Reduced visual capacity	Reduced hearing capacity				
Wolf, M. (185)		X		X	X			X
Wu, A. (186)	X							
Jordan, J. (194)	X							
Koay, K. (188)					X	X		
Miser, W. (123)		X	X				X	
Osborn, C. (189)			X		X			
Rowlands, G. (190)		X	X		X			X
Sun, X. (195)	X							

Table 2.2 Overview of health literacy studies - exclusion criteria continued

First author	Year	Name of instrument	Acronym	Psychometric evaluation	Comparison instrument(s)
Aguirre, A. (133)	2004	Short Test Of Functional Health Literacy in Adults	S-TOFHLA	Yes	None
Sanders, L. (134)	2004	Not named – single question	None	Yes	S-TOFHLA
Apter, A. (135)	2005	Asthma Numeracy Questionnaire	ANQ	No	S-TOFHLA variant and REALM
Weiss, B (90)	2005	Newest Vital Sign	NVS	Yes	TOFHLA
Lee, S. (137)	2006	Short Assessment of Health Literacy for Spanish speaking Adults	SAHLSA	No	REALM
Baron-Epel, O. (139)	2007	Hebrew Health Literacy Test	HHLT	Yes	None
Diamond, J. (141)	2007	Nutritional Literacy Scale	NLS		S-TOFHLA variant
Gong, D. (142)	2007	Test Of Functional Health Literacy in Dentistry	TOFHLiD	No	TOFHLA and REALM

Table 2.3 Overview of health literacy studies - studies for new health literacy instruments

First author	Year	Name of instrument	Acronym	Psychometric evaluation	Comparison instrument(s)
Lee, J. (145)	2007	Rapid Estimate of Adult Literacy in Dentistry	REALD-30	No	TOFHLA and REALM
Cavanaugh, K. (142) and Huizinga, M. (148)	2008	Diabetes Numeracy Test	DNT	No	REALM and WRAT
Ishikawa, H (149)	2008	Not stated	None	Yes	None
Ishikawa, H. (150)	2008	Not stated (different to [50])	None	Yes	None
Jeppesen, K. (152)	2009	Short Literacy Survey	SILS	Yes	S-TOFHLA variant
Lee, T. (154)	2009	Korean Health Literacy Scale	KHLS	Yes	None
Rawson, K. (157)	2009	Medical Term Recognition Test	METER	No	REALM
Sabbahi, D. (158)	2009	Oral Health Literacy Instrument	OHLI	No	S-TOFHLA

Table 2.3 Overview of health literacy studies - studies for new health literacy instruments continued

First author	Year	Name of instrument	Acronym	Psychometric evaluation	Comparison instrument(s)
Yost, K. (160)	2009	Talking Touchscreen	None	Yes	S-TOFHLA and REALM and CLOZE
Clayman, M. (161)	2010	Ask, Understand, Remember Assessment	AURA	No	S-TOFHLA
Kumar, D. (65)	2010	Parental Health Literacy Activities Test	PHLAT	No	S-TOFHLA and WRAT
Lee, S. (163)	2010	Short Assessment of Health Literacy	SAHL	No	TOFHLA and REALM
Galesic, M. (168)	2011	Graph	None	Yes	S-TOFHLA
Kim, M. (169)	2011	High Blood Pressure – Health Literacy Scale	HBP-HLS	No	TOFHLA and NVS
Ko, Y. (192)	2011	Health Literacy Test for Singapore	HLTS	No	NVS
McNaughton, C. (171)	2011	Subjective Literacy Scale	SLS	No	S-TOFHLA variant and REALM and WRAT
Pendlimari, R. (173)	2011	Assessment of Colon Cancer Literacy	ACCL	No	NVS

Table 2.3 Overview of health literacy studies - studies for new health literacy instruments continued

First author	Year	Name of instrument	Acronym	Psychometric evaluation	Comparison instrument(s)
Apolinario, D. (175)	2012	Short Assessment of Health Literacy for Portuguese Adults	SAHLPA	Yes	None
Chinn, D. (177)	2012	All Aspects Health Literacy Scale	AAHLS	Yes	None
Helitzer, D. (181)	2012	TALKDOC	None	Yes	HALS
Schapira, M. (193)	2012	Numerical Understanding in Medicine instrument	NUMi	No	S-TOFHLA variant and WRAT
Tsai, T (184)	2012	Mandarin Health Literacy Scale	MHLS	Yes	None
Wu, A. (186)	2012	Not stated	None	Yes	None
Jordan, J. (187)	2013	Health Literacy Management Scale	HeLMS	Yes	None

Table 2.3 Overview of health literacy studies - studies for new health literacy instruments continued

First Author	Year	Name of instrument	Acronym	Psychometric evaluation	Comparison instrument (s)
Miser, W. (123)	2013	Spoken Knowledge in Low Literacy Diabetes	SKILLD	No	S-TOFHLA variant and NVS
Osborn, C. (189)	2013	General Health Numeracy Test	GHNT	No	REALM and WRAT
Rowlands, G. (190)	2013	Newest Vital Sign – UK version	NVS	Yes	TOFHLA
Sun, X. (191)	2013	Not stated	None	Yes	None

Table 2.3 Overview of health literacy studies - studies for new health literacy instruments continued

Author	Year	Name of instrument	Acronym	Psychometric evaluation	Comparison instrument(s)
Baker, D. (89)	1998	Short Test Of Functional Health Literacy	S-TOFHLA	Yes	TOFHLA and REALM
Chisolm, D. (140)	2007	Test Of Functional Health Literacy - Reading	TOFHLA-R	Yes	REALM and WRAT
Bann, C. (176)	2012	Health Literacy Skills Instrument – Short Form	HSLI-SF	Yes	None
Yin, H. (196)	2012	Parental Health Literacy Activities Test (Spanish)	PHLAT Spanish	Yes	S-TOFHLA variant and WRAT and PHLAT-10
Rowlands, G. (190)	2013	Newest Vital Sign for UK use	NVS	Yes	TOFHLA

Table 2.4 Overview of health literacy studies - studies to validate a new version of an existing health literacy instrument.

Author	Year	Comparison instrument(s)
Buchbinder, R. (197)	2006	TOFHLA and REALM
Zun, L. (138)	2006	S-TOFHLA and REALM
Weld, K. (159)	2009	S-TOFHLA and REALM
Ozdemir, H. (165)	2010	REALM and NVS
Sarkar, U. (166)	2010	S-TOFHLA
Kirk, J. (170)	2011	S-TOFHLA, NVS

Table 2.5 Overview of health literacy studies - assessing health literacy using multiple instruments.

First author	Year	Study Outcome	Comparison instrument(s)
Hibbard, J. (198)	2007	Assessment of consumer competencies	Patient Activation Measure (PAM) and TOFHLA variant
Donelle, L. (144)	2007	Determine the relationship between health numeracy skill, prose health literacy and math anxiety	S-TOFHLA, General Context Numeracy Assessment (GCNA), Health Context Numeracy Assessment (HCNA), Abbreviated Math Anxiety Scale (AMAS)
Von Wagner, C. (146)	2007	To determine limited health literacy prevalence in the UK and examine associations with health behaviours	TOFHLA (UK version) and psychometric evaluation
Cavanaugh, K. (199)	2008	Association between numeracy and diabetes control	Diabetes Numeracy Test (DNT), REALM and WRAT
Huizinga, M. (148)	2009	To compare literacy, numeracy and portion-size estimation skills	Diabetes Numeracy Test (DNT), REALM and WRAT
Miller, M. (155)	2009	To assess the comprehension of written pharmacy materials	CLOZE and S-TOFHLA variant
Oettinger, M. (156)	2009	To assess the impact of colour –coding body mass charts	WRAT and S-TOFHLA variant
Golbeck, A. (162)	2010	Assessing the association between numeracy and reading comprehension in adults with limited health literacy	Numeracy section of TOFHLA v prose section.

2.6 Overview of health literacy studies - comparing health literacy scores with an outcome**.**

First author	Year	Study Outcome	Comparison instrument(s)
Ohl, M. (127)	2010	To assess brief screening questions and provider perceptions of low health literacy in HIV clinics	S-TOFHLA variant and Single Item Literacy Screener (SILS)
Ferguson, B. (167)	2011	To assess patients' views on health literacy measurement	REALM and S-TOFHLA
Patel, P. (172)	2011	To assess the utility of the NVS in older African-American adults	NVS and S-TOFHLA
Robinson, S. (174)	2011	Assessing health literacy in heart failure patients with and without time limits to the health literacy measurement	S-TOFHLA time limited and not time limited
Dunn-Navarra, A. (178)	2012	Assessing the association between health literacy, knowledge and beliefs regarding upper respiratory infections	S-TOFHLA variant and NVS
Haun, J. (180)	2012	To assess measurement variation across health literacy assessments	S-TOFHLA variant, REALM and Brief Health Literacy Screening Tool (BRIEF)
Wolf, M. (185)	2012	Assessing, literacy, cognitive function and health	TOFHLA, REALM and NVS
Koay, K. (188)	2013	To assess poor health literacy and distress with head and neck cancers	S-TOFHLA variant and the Health Literacy Management Scale (HeLMS)

Table 2.6 Overview of health literacy studies - comparing health literacy scores with an outcome continued

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2.3.5 Frequency of instrument use

New instruments were validated in 56.3% (n=36) of the studies. The Short Test of Functional Health Literacy in Adults (S-TOFHLA) (89) was used in 43.8% (n=28) of the studies as either the comparison instrument for validation or as the sole assessment instrument for assessing health literacy. The S-TOFHLA prose only version was more commonly used than the full version. It was used at least 71.4% of the time the instrument was used (n=20). The exact figure is unclear as a few papers did not indicate which version was used. The full S-TOFHLA version (numeracy and prose) was used in at least in 7.8% of the studies (n=5).

REALM was the second most frequently reported instrument being used in 28.1 % of the papers (n=18). The Newest Vital Sign (NVS) (90) was the third most popular instrument being quoted in 15.6% of the papers (n=10). Both TOFHLA and WRAT were used in 14% of the papers (n=9).

2.3.6 Comparison of frequently used instruments

Tables 2.7 to 2.9 (pages 61 to 63) show studies that assessed health literacy within their study population using at least two of the four most popular instruments, TOFHLA, S-TOFHLA, REALM and NVS, and compared the assessment of limited, marginal and adequate health literacy within their participants. Golbeck et al. (200), in 2011, compared the TOFHLA instrument results using two different versions of the instrument, one that only used the prose passages and one that only used the numeracy section. Two studies compared three different instruments.

The S-TOFHLA was the most commonly used instrument in these comparisons being used in ten of the twelve papers (83.3%). Only one of these used the full S-TOFHLA version consequently in most cases the comparison with REALM is the comparison between two prose assessment instruments.

Instrument	STUDY								
	Apter	Haun	McNaughton	Macek	Kirk	Dunn-Navarra	Buchbinder	Wolf	Golbeck
S-TOFHLA	11	9	7	12	15.5	20.8			
REALM	16	7	9	26	10.3		1.3	8.9	
TOFHLA							3.7	12.5	
NVS					21.5	42.9		28.9	
TOFHLA prose									23.8
TOFHLA numeracy									19.0

Table 2.7 Comparison of percentage of limited health literacy scores for study populations using different health literacy instruments

NB. Not all the reported studies collected data for all health literacy levels with the health literacy instrument.

Instrument	STUDY								
	Apter	Haun	McNaughton	Macek	Kirk	Dunn-Navarra	Buchbinder	Wolf	Golbeck
S-TOFHLA	13.7	8	4	8	13.3	14.9			
REALM	30	30	11	32	27.2		8.8	15.4	
TOFHLA							5.1	16.8	
NVS					28.3	40.9		22.9	
TOFHLA prose									10.5
TOFHLA numeracy									20.2

Table 2.8 Comparison of percentage of marginal health literacy scores for study populations using different health literacy instruments

NB. Not all the reported studies collected data for all health literacy levels with the health literacy instrument.

Instrument	STUDY											
	Apter	Haun	McNaughton	Macek	Weld	Kirk	Dunn-Navarra	Patel	Buchbinder	Wolf	Ozdemir	Golbeck
S-TOFHLA	75.3	83	89	80	99.6	71.2	64.3	50				
REALM	54	63	80	42	94.6	62.5			90.0	75.7	58.7	
TOFHLA									91.1	70.7		
NVS						50.2	16.2	42		48.2	28.1	
TOFHLA prose												65.7
TOFHLA numeracy												60.8

Table 2.9 Comparison of percentage of adequate health literacy scores for study populations using different health literacy instrument

NB. Not all the reported studies collected data for all health literacy levels with the health literacy instrument.

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In the six papers that compared REALM adequate literacy against the S-TOFHLA adequate literacy assessment, all found a higher level of adequacy when using S-TOFHLA. The full S-TOFHLA version was also one of the six comparisons.

The NVS instrument, when compared against other instruments, identified more participants with limited literacy and found less had adequate health literacy. The biggest variation was described by Dunn-Navarra et al. (178), in 2012, where the difference of adequate literacy detected by S-TOFHLA varied by 48.1% compared with the NVS instrument for the same Latino population. There was also a variation of 26% between the two assessments of limited health literacy with a higher proportion being detected by the NVS instrument. In the Golbeck et al. (162) study, in 2011, the prose version gave a higher assessment of adequate health literacy than the numeracy only version found. Golbeck et al. found that 20% of patients had higher numeracy skills than reading ability and a further 20% had higher reading ability than numeracy skills.

2.3.7 Paper quality

All of the studies were cross sectional in design and the majority presented no significant risk of design or reporting bias. Table 2.10 (pages 65 to 67) reports the assessed level of bias for the five criteria for each study.

Selection and detection bias were the most frequently identified risk of bias. Selection bias was introduced through limited inclusion and exclusion criteria and detection bias through tests not being applied consistently. A third of the studies did not report any exclusion criteria.

Author, Year	Selection	Performance	Detection	Attrition	Reporting
Aguirre, 2004	+	+	+	+	+
Apolinario, 2012	+	+	+	+	+
Apter, 2005	○	+	+	+	+
Baker,1998	+	+	+	+	+
Bann, 2012	+	+	+	+	+
Baron-Epel, 2007	+	+	+	+	+
Buchbinder, 2006	○	+	+	+	+
Cavanaugh, 2008	+	+	○	+	+
Chinn, 2012	○	+	+	+	+
Chisolm, 2007	○	+	+	+	+
Clayman, 2010	+	+	+	+	+
Diamond, 2007	+	+	○	+	+
Dunn-Navarra, 2012	+	+	+	+	+
Ferguson, 2011	+	+	+	+	+
Galesic, 2011	+	+	+	+	+
Ghaddar, 2012	+	+	+	+	+
Golbeck, 2010	+	+	+	+	+
Gong, 2007	○	+	+	+	+
Lee, 2007	+	○	+	+	+
Lee, 2006	+	+	+	+	+
Lee, 2010	+	+	+	+	+
Lee, 2009	+	+	+	+	+
Macek, 2009	+	+	+	+	+
McNaughton, 2011	+	+	+	+	+
Miller, 2009	○	+	+	+	+
Miser, 2013	+	+	+	+	+
Oettinger, 2009	○	+	+	+	+

Table 2.10 Quality of studies

Key low risk of bias ⊕ uncertain / moderate risk of bias ○

Author, Year	Selection	Performance	Detection	Attrition	Reporting
Ohl, 2010	🟢	🟢	🟢	🟢	🟢
Osborn, 2013	🟢	🟢	🟡	🟢	🟡
Ozdemir, 2010	🟢	🟢	🟢	🟢	🟢
Patel, 2011	🟢	🟢	🟢	🟢	🟢
Pendlimari, 2011	🟢	🟢	🟢	🟢	🟢
Rawson, 2009	🟢	🟢	🟢	🟢	🟢
Robinson, 2011	🟢	🟢	🟢	🟢	🟢
Rowlands, 2013	🟢	🟢	🟢	🟢	🟢
Sabbahi, 2009	🟢	🟢	🟡	🟢	🟢
Haun, 2012	🟢	🟢	🟢	🟢	🟢
Helitzer, 2012	🟢	🟢	🟢	🟢	🟢
Hibbard, 2007	🟢	🟢	🟢	🟢	🟢
Hoffman-Goetz, 2007	🟡	🟢	🟢	🟢	🟢
Huizinga, 2009	🟢	🟢	🟢	🟢	🟢
Huizinga, 2008	🟢	🟢	🟢	🟢	🟢
Ishikawa, 2008	🟢	🟢	🟢	🟢	🟢
Ishikawa, 2008	🟢	🟢	🟢	🟢	🟢
Jeppesen, 2009	🟢	🟢	🟢	🟢	🟢
Jordan, 2013	🟢	🟢	🟢	🟢	🟢
Kim 2011	🟢	🟢	🟢	🟢	🟢
Kirk 2011	🟢	🟢	🟡	🟢	🟢
Ko, 2011	🟢	🟢	🟢	🟢	🟢
Koay, 2013	🟢	🟢	🟢	🟢	🟢
Kumar, 2010	🟢	🟢	🟡	🟢	🟢
Sanders, 2004	🟢	🟢	🟢	🟢	🟢
Sarkar, 2010	🟢	🟢	🟢	🟢	🟢
Schapira, 2012	🟢	🟢	🟡	🟢	🟢
Shonna Yin, 2012	🟢	🟢	🟢	🟢	🟢
Sun, 2013	🟢	🟢	🟢	🟢	🟢
Tzu-I, 2012	🟢	🟢	🟢	🟢	🟢
Von Wagner, 2007	🟢	🟢	🟢	🟢	🟢

Table 2.10 Quality of studies continued

Key low risk of bias 🟢 uncertain / moderate risk of bias 🟡

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Author, Year	Selection	Performance	Detection	Attrition	Reporting
Weiss, 2005	+	+	+	+	+
Weld, 2009	+	+	+	+	+
Wolf, 2012	+	+	+	+	+
Yost, 2009	+	+	○	+	+
Zun, 2006	○	+	+	+	+

Table 2.10 Quality of studies continued

Key low risk of bias + uncertain / moderate risk of bias ○

2.3.8 Psychometric analysis

The analysis of the psychometric properties of the health literacy instruments is reported in table 2.11 (pages 74 & 75). Assessment identified that a quarter (12/43) were of high quality, half (22/43) were classified as of medium quality, and a fifth (9/43) were of poor quality. All the studies reported the reliability of the instrument and all but two instruments reported the item generation mechanism. Just over a third of the studies did not use any form of factor analysis to generate construct validity.

Health literacy instrument	Expert panel	Items from the literature	Focus group derived	Exploratory factor analysis	Confirmatory factor analysis	Cronbach's alpha or ICC	Score	Quality rating
AAHLS	1	1	1	1	1	1	6	High
e-HEALS	1	1	1	1	1	1	6	High
KHLS	1	1	1	1	1	1	6	High
MHLS	1	1	1	1	1	1	6	High
SAHLSA	1	1	1	1	1	1	6	High
DNT	1	0	1	1	1	1	5	High
HBP-HLS	1	1	1	0	1	1	5	High
HeLMS	0	1	1	1	1	1	5	High
NLS	1	1	1	0	1	1	5	High
PHLAT	1	1	1	1	0	1	5	High
PAM	1	1	1	0	1	1	5	High
SAHL	1	1	0	1	1	1	5	High
BRIEF	0	1	0	1	1	1	4	Medium
CMOHK	1	1	0	0	1	1	4	Medium
HALS	1	1	0	0	1	1	4	Medium
HLSI	1	0	1	0	1	1	4	Medium
NVS	1	1	1	0	0	1	4	Medium
NUMi	1	1	0	0	1	1	4	Medium
REALD-30	0	1	1	1	0	1	4	Medium
SAHLPA	0	1	0	1	1	1	4	Medium
SNS	0	0	1	1	1	1	4	Medium
TALKDOC	1	0	1	1	0	1	4	Medium
TOFHLiD	1	1	0	1	0	1	4	Medium
ANQ	1	1	0	0	0	1	3	Medium

Table 2.11 Psychometric assessment

Key * indicates no information found so treated as a negative response

Health literacy instrument	Expert panel	Items from the literature	Focus group derived	Exploratory factor analysis	Confirmatory factor analysis	Cronbach's alpha or ICC	Score	Quality rating
AURA	0	1	0	1	0	1	3	Medium
CLOZE	1	1	0	0	0	1	3	Medium
GHNT	1	1	0	0	0	1	3	Medium
HCNA	0	1	0	1	0	1	3	Medium
HHLT	1	1	0	0	0	1	3	Medium
OHLI	1	1	0	0	0	1	3	Medium
SILS	0	1	0	0	1	1	3	Medium
S-TOFHLA	0	1	0	0	1	1	3	Medium
TOFHLA	1	1	0	0	0	1	3	Medium
WRAT	1	1	0	0	0	1	3	Medium
ACCL	0	1	0	0	0	1	2	Low
GCNA	0	0	0	1	0	1	2	Low
HLTS	0	1	0	0	0	1	2	Low
METER	0	1	0	0	0	1	2	Low
REALM	0	1	0	0	0	1	2	Low
SLS	0	1	0	0	0	1	2	Low
TORCH	0*	1	0*	0*	0*	1	2*	Low
GRAPH	0	0	0	0	0	1	1	Low
SKILLD	0*	0*	0*	0*	0*	1	1*	Low

Table 2.11 Psychometric assessment continued

Key * indicates no information found so treated as a negative response

2.3.9 Suitability criteria

2.3.9.1 Population

There were 11 instruments (17.2%) that were designed to assess participants' understanding of a disease state and therefore they cannot be used as a generic health literacy measurement. Many studies, 60.4% (n=26), only assessed prose comprehension or numeracy ability.

2.3.9.2 Time

One study by Robinson et al. (174) in 2011, assessed the impact of setting a time limit for the completion of the prose version of S-TOFHLA compared to having the test with no time restrictions. The study, of 612 rural-dwelling Americans, found 27% of patients improved by more than one literacy level when the time limit was removed (p<0.001). It identified that 17% went from inadequate to marginal and 10% went from marginal to adequate.

There were four (9.3%) health literacy instruments that set no time limit to complete the assessment and participants could take as long as they wished. The DNT instrument created by Huizinga et al. (148) was one of these and the time taken to complete ranged from 10 minutes to 105 minutes. There were 22 health literacy instruments (51.1%) that did not specify the time taken to complete and it is unclear if a time limit was set or not. Within these papers, it is possible to assess the approximate time required to complete. The approximation is based on the number of questions within the instrument and on the complexity of the questions described within the papers. It is estimated that 16 instruments (37.2%) could be completed within five minutes, seven of the instruments (16.3%) were confirmed by the authors to take less than five minutes to complete.

2.3.9.3 English

Table 2.12 (pages 71 to 81) documents the health literacy instruments found within the studies. Of these, six (13.9%) were designed for populations that could not read in English and each would require validating in English before they could be used in the UK.

70

Name	Self-Assessment	Disease specific	Validation		Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
			Test	Result					
All Aspects Health Literacy Scale AAHLS Chin (177)	X		Cronbach's alpha	0.75	X		14	Not stated	4
Assessment of Colon Cancer Literacy ACCL Pendlimari (173)	X	X	Other		X		10	3	2
Asthma Numeracy Questionnaire ANQ Apter (135)		X	Pearson coefficient	0.47 with S-TOFHLA Prose 0.41 with REALM	X	X	4	Not stated	5
Ask, Understand, Remember Assessment AURA Clayman (161)	X		Cronbach's alpha	0.75	X		4	Not stated	4

Table 2.12 Suitability of health literacy instruments

Name	Self-Assessment	Disease specific	Validation Test	Validation Result	Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
BRIEF Haun (180)	X		Cronbach's alpha Pearson coefficient	0.77 0.4 with REALM 0.61 with S-TOFHLA Both P<0.001	X		4	Not stated	3
CLOZE Miller (155)			Pearson coefficient	0.71 with S-TOFHLA P<0.001	X				3
Comprehensive Measure of Oral Health Knowledge CMOHK Macek (201)		X	Fischer's exact	REALM p<0.01 S-TOFHLA P=0.62	X		44	Not stated	3
Diabetes Numeracy Test DNT Huizinga (148)		X	Kuder Richardson	0.95	X	X	43	10-105 Average 33	4

Table 2.12 Suitability of health literacy instruments continued

Name	Self-Assessment	Disease specific	Validation Test	Result	Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
GRAPH Galesic (168)			Cronbach's alpha	0.85	X	X	42	21	3
e-HEALS Ghaddar (179)	X		Cronbach's alpha	0.90	X		8	Not stated	4
General Context Numeracy Scale GCNA Schwartz (144)			Pearson coefficient	S-TOFHLA r=0.23 P=0.002		X	3	Not stated	4
Health Activities Literacy Scale HALS Helitzer (181)			Not known	Not known	X		Not stated	Not stated	2
High Blood Pressure - Health Literacy Scale HBP-HLS Kim (169)			Kuder Richardson	0.98	X	X	13	10-15	4

Table 2.12 Suitability of health literacy instruments continued

Name	Self-assessment	Disease specific	Validation Test	Result	Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
Health Context Numeracy Assessment HCNA Donelle (144)			Pearson coefficient	S-TOFHLA r= 0.43 P<0.01		X	8	Not stated	3
Health Literacy Management Scale HeLMS Jordan (187) Table 2.11			Cronbach's alpha	0.82	X		37	Not stated	4
Health Literacy Management Scale HeLMS Jordan(187)			Cronbach's alpha	0.82	X		37	Not stated	4
Hebrew Health Literacy Test HHLT Baron-Epel (139)			Cronbach's alpha	0.98	X		13	Not stated	2

Table 2.12 Suitability of health literacy instruments continued

Name Disease	Self-assessment	Disease specific	Validation Test	Result	Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
HEALTH Literacy Skills Instrument HLSI Bann (176)			Cronbach's alpha	0.70 For 10 item Test 0.86 for 25 item test	X	X	10 or 25	5-10 For 10 item version	5
Medical Term Recognition test METER Rawson (202)			Cronbach's alpha Pearson coefficient	0.93 R=0.74 to REALM P<0.001	X		80	2	4
Health Literacy Test For Singapore HLTS Ko (153)			Cronbach's alpha other	0.87	X	X	40	10	3
Korean Health Literacy Scale KHLS Lee (154)			Cronbach's alpha	0.89	X	X	24	15-20	3

Table 2.12 Suitability of health literacy instruments continued

Name	Self-assessment	Disease specific	Validation Test	Result	Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
Mandarin Health Literacy Scale MHLS Tzu-I (184)			Cronbach's alpha	0.97	X	X	50	25	4
Nutritional Health Literacy NLS Diamond (141)			Cronbach's alpha Pearson coefficient	0.84 0.61 to S-TOFHLA prose	X		28	No time limit	4
Newest Vital Sign NVS Weiss (90)			Cronbach's alpha	0.76	X	X	6	3	6
Numerical Understanding in Medicine instrument NUMi Schapira (182)			Cronbach's alpha Spearman	0.86 R=0.43 to S-TOFHLA prose P<0.001 0.73 to WRAT-A P<0.001	X	X	20	Not stated	5

Table 2.12 Suitability of health literacy instruments continued

| Name | Self-assessment | Disease specific | Validation | | Prose test | Numeracy test | Number of test items | Time to complete minutes | Assessment score |
			Test	Result					
Oral Health Literacy Instrument OHLI Sabbahi (158)		X	Cronbach's alpha Pearson coefficient	0.85 0.61 with TOFHLA	X	X	57	20	4
Parental Health Literacy Activities Test PHLAT Kumar (65)		X	Kuder - Richardson	0.76 for 20 item 0.70 for 10 item	X	X	20 or 10	No time limit	4
Patient Activation Measure PAM Hibbard (143)			Pearson coefficient	TOFHLA prose P > 0.05	X		13	Not stated	4
Rapid Estimate of Adult Literacy in Dentistry REALD-30 Lee (145)		X	Cronbach's alpha Pearson coefficient	0.87 0.64 with TOFHLA 0.86 to REALM P<0.05 for both	X		30	Not stated	3

Table 2.12 Suitability of health literacy instruments continued

Name	Self-assessment	Disease specific	Validation		Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
			Test	Result					
Rapid Estimate of Adult Learning in Medicine REALM Davis (85)					X		66	1-2	4
Short Assessment of Health Literacy SAHL Lee (163)			Pearson coefficient	0.94 to REALM and 0.68 to TOFHLA Both p<0.05	X		18	2-3	4
Short Assessment of Health Literacy for Spanish-speaking Adults SAHLSA Lee (203)			Cronbach's alpha Pearson coefficient	0.92 0.86 Test-retest 0.65 to TOFHA	X		50	Not stated	3
Single Item Literacy Screener SILS CHEW (204, 205)			AUROC Help reading Help with forms	0.87 0.80	X		1	Not stated	4

Table 2.12 Suitability of health literacy instruments continued

Name	Self-assessment	Disease specific	Validation Test	Result	Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
Spoken Knowledge in Low-Literacy Diabetes SKILLD Miser (123)		X	Cronbach's alpha	0.72	X		10	Not stated	3
Short Literacy Survey SIL McNaughton (171)	X		Cronbach's alpha Spearman	0.74 0.36 to S-TOFHLA and 0.38 to REALM P<0.001 for both	X		3	Not stated	4
Subjective Numeracy Scale SNS McNaughton (171)	X				X		8	Not stated	3
Short Test of Functional Health Literacy in Adults S-TOFHLA Baker (89)			Cronbach's alpha Spearman	0.68 for numeracy items 0.97 for the 36 prose items 0.80 to REALM	X	X – in full version	40 36 in prose only version	12 or 7	5

Table 2.12 Suitability of health literacy instruments continued

Name	Self-assessment	Disease specific	Validation		Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
			Test	Result					
TALKDOC Helitzer (181)	X	X			X		119	60-75	3
Test of Functional Health Literacy in Adults TOFHLA Parker (87) Von Wagner UK version (146)			Cronbach's alpha	0.98 (Parker)	X	X	67	22	5
Test of Functional Health Literacy in Dentistry TOFHLiD Gong (142)		X	Cronbach's alpha Pearson coefficient	0.63 0.52 to TOFHLA and 0.53 to REALM P< 0.05 for both	X	X	67	Not stated	4
Test Of Reading Comprehension TORCH Buchbinder (136)			Pearson coefficient	0.36 to REALM and 0.39 to TOFHLA P<0.05 for both	X		14	15-20	4

Table 2.12 Suitability of health literacy instruments continued

Name Disease specific	Self-Assessment	Validation		Prose test	Numeracy test	Number of test items	Time to complete minutes	Assessment score
		Test	Result					
Wide Range Achievement Test WRAT Wilkinson (132)				X	Depends on version		Linked to age	5

Table 2.12 Suitability of health literacy instruments continued

2.3.9.5 Study design - linkage to Ratzan and Parker's domains

Figure 2.2 shows pictorially the relationship between the health literacy instruments and the three health literacy domains described by Ratzan and Parker. Of the 43 instruments identified 34.9% measure understanding and using health information (n=15); 7.0% measure accessing, understanding and using health information (n=3); 2.3% (n=1) measure accesing and using health information and 2.3% measure accessing and understanding health information. The remaining 53.5% (n=23) only measure understanding health information.

2.3.9.5.1 Study design self-assessment

Nine (20.9%) health literacy instruments relied on the patient's assessment of their health literacy rather than attempting to measure health literacy.

Accessing health information

Understanding health information

AURA (31

S-TOFHLA (prose) (24), TOFHLA (77), REALM (84), SNS (59), WRAT3 (86), CMOHK (58), METER (68), OHLI (70), CLOZE (60), ACCL (67), SAHLSA(55), TOFHLiD (39), TORCH (27), SAHLPA (22), REALD-30 (54), HLTS (51), KHLS (57), BRIEF (40), GCNA (33), HALS (41), HHLT (26), SAHL (56), SILS (47), SKILLD (61), SLS (59), TALKDOC (41)

e-HEALS (37), Ishikawa (45), AAHLS (29)

Graph (36), Wu (81), NVS (78), Ishikawa (46), PHLAT (53), ANQ (23), HBP-HLS (49), MHLS (76), DNT (44), GHNT (64), HCNA (33), HeLMS (48), HLSI (25), NLS (32), NUMi (73)

AURA (31)

Using health information

FIGURE 2.2 STUDIES AND THE HEALTH LITERACY DOMAINS MEASURED

2.3.9.6 Feedback on acceptability

Only three studies, (167);(170);(123) reported on patients' views on using the health literacy instruments. The first of these studies was a cross-sectional survey study, by Ferguson et al. in 2011 (167), that reported that there was no patient preference over completing REALM to S-TOFHLA. The other two studies compared the S-TOFHLA and the NVS. One of these, by Kirk et al. in 2012, was a cross-sectional study that utilsed in-person inverviews in Carolina (170). It reported that S-TOFHLA was a better instrument for older adults to use compared to the NVS due to the better completion rates obtained. Only 73% (n=280)

completed the NVS compared with 87% completing the comprehension section of S-TOFHLA and 92% completing the numerical assessment (n=563). The final study was carried out in Ohio by Miser et al. in 2013 (123). The study reported that 24.3% of patients thought that the NVS was very hard or hard to complete compared with 3.6% of patients using S-TOFHLA. In this study, it was observed that many patients found that the immediate use of arithmetic in the NVS instrument was intimidating and were uncomfortable with percentages.

2.3.9.7 Suitability criteria scores

Table 2.11 (pages 68 & 69) shows how each of the instruments scored on each dimension of the suitability criteria. Only the NVS fulfilled all of the suitability criteria thus achieving the maximum score of 6. The TOFHLA, S-TOFHLA (full version), WRAT, NUMi, GHNT and the ANQ scored five out of six and accounted for 16.3% of the assessed instruments.

2.4 Discussion

2.4.1 PICOS

2.4.1.1 Study population and sites

Most the studies identified for the systematic review used participants that were attending hospital clinics or accessing services from primary health care settings. The use of these discrete populations reduces the generalisability of the findings. Berkman et al. (206) indicated in their review that they were concerned over the transferability to other settings of such studies. However, the quality assessment did not indicate that the studies were of poor design and were appropriate for testing new health literacy instruments.

2.4.1.2 Types of interventions

All the papers were focused on either developing, testing or validating health literacy instruments. Validation was by either comparison with at least one existing health literacy instrument, by psychometric analysis or a combination of both.

The number of questions that constituted the assessment of health literacy within the instruments varied significantly from the single question instruments to the

TALKDOC instrument that has 119 test items. The number of items within the instrument was not always an indicator of the complexity of the test and of the amount of time required to complete the assessment. Whilst the TALKDOC is a complicated assessment and takes on average 60 to 75 minutes to complete the Medical Term Recognition Test (METER) contains 80 words that the patient is asked if they recognise and can be completed in a couple of minutes.

Scoring categories and cut off points between different levels of health literacy ability varied from instrument to instrument. The updated systematic review of health literacy and outcomes in 2011 by Berkman et al. (206) raised concerns over 'inconsistent approaches to creating health literacy and numeracy levels or thresholds in analyses, hampering comparisons between studies'.

2.4.1.3 Comparison

Comparison with existing instruments was a popular mechanism for validation of new instruments with S-TOFHLA being the comparison instrument of choice in nearly half the papers. The rationale for using this instrument is that it is well established and is much quicker to use than the full TOFHLA instrument. However, S-TOFHLA instrument has two versions one that measures both numeracy and prose and one that only measures prose. Reporting in the studies of which version was used was poor and where this information was provided, the prose only version was frequently used. This indicates that the researchers believe that the two instruments are interchangeable and give consistent results. The acceptance that the two versions are interchangeable is challengeable as different constructs underpin the two versions. If the S-TOFHLA is being used as the criterion for validity assessment it is essential that the same outcome performance measure is used.

2.4.1.4 Outcomes

As described in the previous section validity was often based on assessment against an existing heath literacy instrument. This is an accepted validation method if the instrument being used as the comparator has been verified as a gold standard assessment (112). In practice the assessment instrument has been one of the earliest developed instruments which did not necessarily score highly

against the psychometric standards set for this review. Consequently, it is unclear if any variation against the set 'standard' indicates a poorer outcome in terms of accurate assessment of limited health literacy.

2.4.1.5 Study design

Many studies excluded patients with reduced cognitive function, poor hearing or vision, poor language proficiency or limited the age range of participants. Whilst excluding these patients made the test easier to perform it may well reduce the number of patients that may have limited health literacy. The excluded patient groups are regularly seen in clinical environments and hence it reduces the generalisability of the health literacy instruments tested in the studies.

2.4.2 Quality assessment

Since all the studies were cross sectional in design there was no recognised quality assessment tool to use and therefore there were no set reporting standards. Consequently, the information searched for within the papers was not always present which resulted in a non-definitive assessment being made on many occasions. Despite this there was little evidence to suggest the studies were poorly conducted.

2.4.2.1 Psychometric analysis

A critical appraisal (207) by Jordan et al. in 2011 evaluated nineteen instruments established before 2008. They considered the psychometric properties of the available health literacy instruments and found that there were 'varying underlying constructs, narrow content and psychometric weaknesses'. REALM and TOFHLA were thought to have the best psychometric properties. The content validity of the NVS was thought to be low due to the results obtained against TOFHLA and REALM. It is surprising that Jordan el al. compared the content validity against REALM as the domain content of both are very different and are effectively measuring different constructs. The results obtained against TOFHLA were comparable to many other health literacy instruments.

2.4.3 Suitability

2.4.3.1 Incorporation of numeracy within the instrument

A problem identified within the systematic review was the inconsistent inclusion of a numeracy measuring element within the included health literacy instruments. TOFHLA was the first health literacy measure that assessed numeracy alongside literacy. The shortened version also included a numeracy element. However, most papers that used the S-TOFHLA version omitted the numeracy element of the test thus using a purely prose version. This can easily cause confusion over the version used in studies. It is surprising that some studies then chose to use the prose version to compare another health literacy instrument that did contain a numerical element to it, indicating again that many researchers do not acknowledge the comparison against a different construct.

2.4.3.2 Comparison of instruments on patients

Only five papers (135, 171, 208-210) provided sufficient data to compare S-TOFHLA health literacy measurement against REALM. On each occasion S-TOFHLA gave a higher estimate of adequate health literacy. Only Macek et al. in 2010 (210) used the full version of S-TOFHLA as the others all used the prose version and limited the time required for completion of the tests. Although there is little evidence identified it does fit with an understanding of differences between the two health literacy tools. REALM is a word comprehension test. The prose version of S-TOFHLA uses two prose passages with the hardest FOG score test prose removed from the original TOFHLA. It also gives the participant a 1 in 4 chance of guessing the missing word from the list of words provided. Consequently, as acknowledge by others (65, 211) it tends to under estimate inadequate health literacy. When REALM, TOFHLA, and S-TOFHLA were compared against NVS the NVS was better at identifying limited literacy. S-TOFHLA over inflated the adequate literacy level whereas NVS did not. REALM was used on a number occasions to compare against numeracy instruments. On each of these occasions the REALM identified more people having adequate health literacy than the numerical instrument. This finding is in keeping with evidence from a 2003 USA study by Kutner et al. (212) that indicates

lower levels of numeracy skills are more prevalent than low literacy skills. Psychometric data on assessment of new instruments tended to show that there was greater content validity when prose tools were compared against tools such as REALM or numerical tools against TOFHLA.

Incorporation of a numeracy element provides a more accurate health literacy assessment as functional, communicative and critical health literacy involve numeracy as well as literacy. There needs to be a greater level of agreement on the value and role of numeracy within measuring health literacy.

2.4.3.3 Time taken to measure health literacy

A randomised clinical trial, of 612 rural dwelling American adults, by Robinson et al. in 2011 (174), demonstrated that allowing a test to have no time limit for completion was associated with higher health literacy levels being obtained. It is therefore a reporting limitation of many studies that the time taken to undertake a test was infrequently reported.

The issue of time to administer for many clinicians is the biggest concern in using an instrument in their clinical practice. Researchers are aware of this and several the instruments identified in the systematic review have a number of derivatives. Each new addition tries to reduce the amount of time required to complete the test to improve the acceptability of the health literacy instrument.

2.4.3.4 Validated in English

Health literacy instruments were identified in this review that were created for non-English speaking individuals. Whilst they were included in the study to gain a better understanding of the range of health literacy instruments available, without translation and validation into an English version they are unsuitable for wider adoption.

2.4.3.5 Health domains

The mapping of health literacy tools against the three health literacy domains demonstrated that most fall within the one domain of understanding health information. It is clear that there is some discrepancy in how terminology is used within health literacy with regard to interpreting health literacy domains, as

previously reported (213). Other researchers (19) and (214) acknowledged the importance of creating a shared terminology within health literacy.

Only three tools were identified that measure all three health literacy domains, however, none are currently suitable for use in a UK clinical setting. The first of these instruments (215) was reported in a Japanese research paper by Ishikawa et al. in 2008. It asked a series of questions and was a self-reporting assessment of health literacy. Whilst translated into English the instrument has not been validated in English. The critical appraisal of health literacy instruments by Jordan et al. (194) believed that the instrument failed 'to fully measure a person's ability to seek, understand and use health information'. The second instrument by Ghaddar et al. in 2012 (179) was an electronic instrument designed only for use with adolescents and was only reported in one research paper and was described as an instrument under development. The final health literacy instrument by Chinn et al. in 2013 (177) was a self-assessment instrument that lacks sufficient evidence to currently warrant its use.

There were screening questions to assess health literacy identified within the systematic review. These do not easily align with a health literacy domain and depended on the specific questions asked.

2.4.3.5.1 Use of self-assessment

As described earlier in this chapter due to self-reporting bias any study that solely relied on self-assessment was scored lower than an instrument that had no or only partial self-assessment. Screening questions that do not require byself-assessment would therefore be better for use in practice as they are by nature very quick and relatively easy to incorporate into a consultation and therefore a possible solution to the systematic review question.

2.4.4 Suitability scoring

Whilst the studies were dominated by S-TOFHLA and REALM they failed to fulfil all the assessment criteria regarding suitability for use in the clinical setting due to failing in their breath of measurement and time required to complete. The TOFHLA and S-TOFHLA (numeracy versions), WRAT and NUMi all scored well but did not

achieve the maximum score due to taking longer than five minutes to complete. The ANQ also scored well but was not a generic instrument. The REALM might have been expected to score highly scored less than the instruments mentioned as it missed the two criteria that considered the tools breadth. It only measures reading comprehension and only measures communicative health literacy. The best performing tool against the criteria was the NVS which recorded a perfect score.

2.4.5 Limitations

All of the studies reviewed were cross sectional which are lower in the hierarchy of evidence. The quality assessment carried out rated all of the studies as being of medium overall quality. A weakness within the systematic review was that if information was absent within the paper the authors were not contacted to find out if the information was available and just not reported in the study or had not been evaluated. This resulted in potentially indicating the studies were of a poorer quality or of lower psychometric validity than indicated by the published papers. There was little evidence found to support patients' acceptability for measuring their health literacy with these tools and more work is required to assess the use of the NVS tool in clinical practice.

2.4.5.1 Confounders

Not all of the papers reported the impact that confounders such as education level, race, sex, age on the instruments tested. Consequently, it was not possible to assess the impact this had on the results obtained.

2.4.5.2 Time limits

As described during the study many studies did not enforce a time limit on completing the tests or specify the test order used when a number of tests were used and considered the impact it would have on the individuals' concentration.

2.5 Conclusion

There are a wide range of health literacy instruments available but there is no one universally accepted gold standard. In part this can be explained by the variation in the definition of health literacy used. The systematic review (216), by Sorensen et

al. in 2012 identified multiple definitions of health literacy and emphasised the importance of developing an accepted standard definition for health literacy. Berkman et al. (19) accepted the argument that a lack of consensus over a definition could handicap progress but also argued that the complexity of the health literacy construct and different definitions allow different goals to be achieved. An Australian review in 2006 reported the findings of a systematic review (78) and identified that health literacy varied depending on the context and the setting and consequently the context was pivotal to whether an individual's skills contributed to their health literacy assessment.

Most health literacy instruments were found to only assess understanding health information. Instruments that combined numeracy and health literacy were perceived as being more effective at identifying inadequate health literacy. There has been a rapid growth in the number of newer instruments to assess health literacy but none of these have yet got sufficient evidence to warrant their use over more established instruments. Little evidence exists on acceptability and feasibility of the existing instruments. However, there is an established recognition of the importance of keeping the time to complete the test to a practical level.

The NVS instrument is the most practical health literacy instrument to use until a more encompassing health literacy instrument is developed and can demonstrate its effectiveness. The rationale for the NVS for being the instrument of choice is that it assesses critical and communicative health literacy, is quick to use and assess both numeracy and literacy both of which are important elements of health literacy. Further work, however, is required to test the use of the NVS in a community pharmacy setting in the UK. This work should assess the acceptability and feasibility of using the NVS in practice from both patient and pharmacy staff perspectives and the following chapters will describe this assessment.

Chapter Three

Decision making and heuristic theory

3 Decision making and heuristic theory.

3.1 Introduction

The systematic review in Chapter 2 identified an existing validated health literacy instrument that addressed all of the criteria required for use in practice. Consequently, assessing use of the NVS in community pharmacy will form part of the thesis analysis and the methodology for this is described in Chapter 4.

Chapter 1 identified that there is a belief amongst researchers that healthcare practitioners should not formally assess health literacy ability (8, 9) in healthcare environments. Primarily the concerns relate to causing patient embarrassment and harm by testing their ability (66, 217). Heuristics are fully definied in section 3.2.2.4.1 (page 106) but are essentially are simple judgement rules that reduce the assessment process. The creation of a decision making or informal heuristic assessment mechanism that does not create embarrassment or harm would provide a solution to this problem.

This chapter introduces the current major theories on decision making and heuristics. It examines the literature to demonstrate how these theories are used in clinical decision making and sets these in context of existing primary care and community pharmacy practice. The literature review describes how heuristics can provide effective decision making and be used as an alternative to a formal assessment.

Most studies, on the application of decision making theories in health care practice, focus on doctor or nurse environments and there is a paucity of research in the pharmacy setting. In part, this is due to the differences in the professional roles and the extent to which clinical decision making is a function of daily activity for pharmacists. Existing community pharmacy practice is primarily associated with medicine supply, providing patient support with their medicines and support for self-care (218). The UK government wishes to see this support to patients to be expanded through the development of more clinical services in pharmacies (219, 220).

Chapter 1 identified patient behavioural characteristics which were associated with limited literacy. Chapter 5 will explore the potential for these characteristics to be used as a heuristic assessment of health literacy. The

creation of an informal assessment mechanism would be less intrusive for patients and should generate less barriers to implementing in practice.

The theories have been organised in this chapter into the two constructs of bounded and unbounded rationality. This has enabled similar theories to be considered collectively and that the two different constructs to be juxtaposed. Dual process theories which seek to amalgamate these two constructs are also introduced. Both paradigms place a different emphasis on the role of rationality within decision making. The main theories that will be discussed are shown in figure 3.1. The figure shows pictorially the sub division of rationality theories between bounded and unbounded rationality.

Unbounded rationality

Information processing theory
Dual process
Hypothetico-deductive theory
Bayes' theory and decision making
Bayes' decision trees

Dual system theory

CEST

Bounded rationality

Pattern recognition - expertise
Probalistic mental models theory
Fast and frugal hueristics
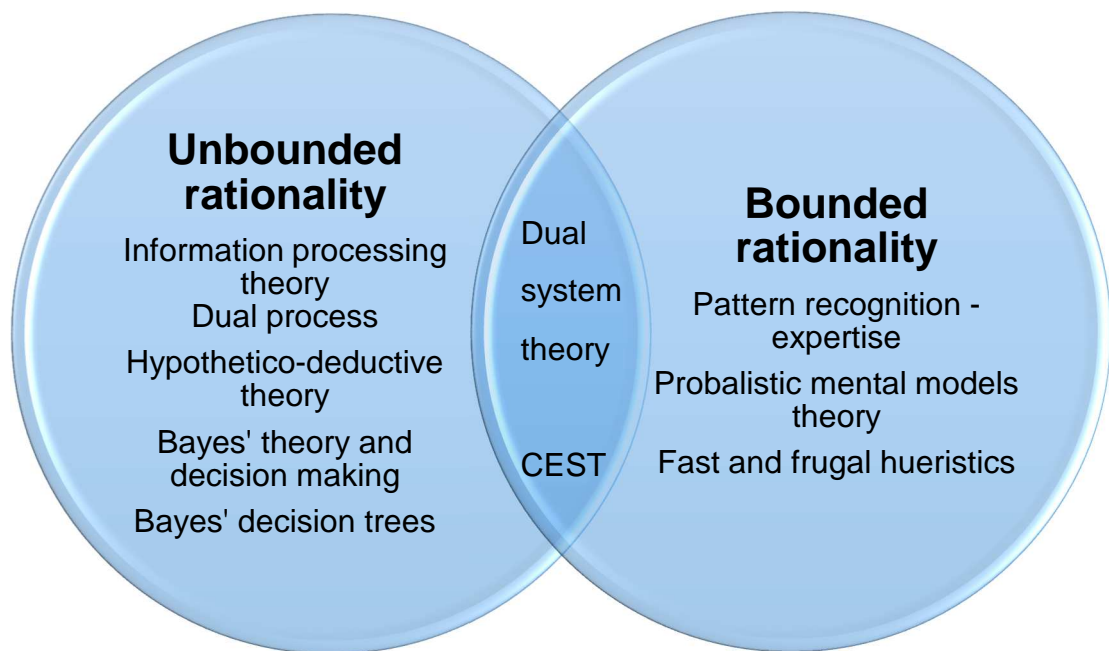
FIGURE 3.1 DECISION MAKING THEORIES

The chapter explains how these theories underpin the remaining research studies in the thesis.

3.2.1 Decision making theories

The dictionary definition of 'decision' is 'a conclusion or resolution reached after consideration' (221). Hence it is a cognitive process to choose between different options available.

3.2.1.1 Normative decision making

The concept of rationality, that is the ability to use reason to make decisions, is described as normative decision making. The term stems from the work of Savage (222) who first described statistical process as logical and taking a normative or rational approach. These normative theories assume that it is possible to make perfect decisions by following distinct processes and assessing every piece of information. There is an assumption that rationality is unbounded (223) and that an infinite amount of information could be processed with sufficient time. Whilst this is a theoretical stance it does have major implications for application in practice if this process was to be adopted in a clinical environment. The main implication being the length of time it would require resolving a complex medical case and the impact this would have on managing workloads. The second paradigm of theories relate to the construct that rationality is not unbounded is discussed in 3.2.2.

Rational decision making forms the backbone of healthcare decision making. Professional guidance for pharmacists recommends that decisions 'demonstrate clear and logical thought' (224). There is also an expectation that an evidence based practice approach is applied (225-227). The implementation of an evidence based approach demonstrates a rationale for adopting specific decisions in a patient's healthcare management plan. Consequently, pharmacists are expected to apply normative decision making to daily practice.

3.2.1.2 The information processing theory

The information processing theory originates from cognitive psychology work in the 1950s and equates human thinking to that of a computer and describes a system for analysing information in a structured way. The theory provides a rationale for how information is stored and processed and retrieved over time. It is based on the assumptions that information is processed in stages and that there are human limitations on the amount of information that can be processed at any

stage. It describes how these limitations are managed and how interactive the model is by building on previous knowledge and experience.

In 1968 the theory was called 'The Stage Model' by Atkinson and Shiffrin (228). It states that external stimuli are received by the sensory register in the brain, which has an enormous capacity to take data in an unprocessed form and store it for up to three seconds. Recognition and attention are responsible for the transfer of this information to the short-term memory. The new information is compared with information already stored in the long-term memory and selective elements chosen to be further assessed in the short-term memory.

Numerous researchers have postulated on distinguishing between different forms of long term memory. Declarative memory or explicit memory has been defined as 'the sum of stored information that can be readily retrieved and put into words in conscious thought and sharing' (229). It is considered to have two sub divisions which are semantic and episodic memory. Semantic memory is concerned with abstract information such as concepts, strategies and facts whereas episodic memory is associated with remembering specific actions or events. Procedural memory is associated with knowing how to do things. This is sometimes referred to as implicit memory as it involves unconscious or autonomic memory.

The information processing theory identifies the importance of both conscious and unconscious memory in the ability to utilise existing knowledge when faced with a dilemma so that a decision can be made to resolve the problem. The theory suggests that as health care practitioners develop their existing knowledge and build up their experience they become more effective at information processing. The theory has also been used to explain how nurses store and recall information from their short term and long term memory to solve problems (103).

3.2.1.3 Hypothetico-Deductive Reasoning Model

Kemeny (230) defined induction as the 'process by which the scientist forms theory to explain the observed facts, it is a reasoning drawn from the past to the future in the expectation that the future will continue to behave in the same manner as the past'. It starts with specific observations which are used to construct general scientific principles.

Chapter 3 Decision making and heuristic theory

The hypothetico-deductive model forms the backbone of modern diagnostic training. The model is credited to the philosopher Karl Popper who argued against the scientific process of induction to formulate theories (231). Popper's view (232) was that the starting point was a problem which should be followed by a theory or a tentative explanation or solution and that by experimentation or observation the theory is tested. If the theory could be refuted it would be dismissed or if collaborated, then further tested until it was either disproved or found to be correct under the observed parameters. Popper dismissed the idea that the observations could occur prior to theory production. The model builds on the deductive principles devised by Aristotle which promotes the use of general ideas to deduct specific outcomes and the testing of this through observation. The process has its roots in scientific reasoning but this is developed further within the medical profession to use these principles to formulate a process for diagnosing and treating illness. Clinical reasoning involves identification, interpretation, hypothesis generation, and hypothesis testing (233). Interpretation and hypothesis generation involves the assessment of the likely probability of potential conditions.

Pharmacy education differs fundamentally from medical education in that pharmacy courses are treated as being a science based degree rather than a clinical based degree. The medical training is now very focused on the importance of problem solving and structures learning to facilitate this approach (234). In recent years, more clinical elements have been added to pharmacy degree courses. The introduction of problem based learning has expanded the clinical skills of practising pharmacists but this is still different to trainee medical students practice. Pharmacy education with its scientific basis develops professionals that are trained to utilise a normative approach to decision making with the emphasis on taking an evidence based approach. Consequently, pharmacists use less probability assessment within their decision making process compared to doctors. A qualitative study, by Whyte in Toronto in 2015, of twelve community pharmacists participating in clinical case studies found that the pharmacists preferred a rules based approach that involved a step-wise analysis / pathway progression process to problem solving (235). They were confident in their content knowledge but less confident in using this knowledge to make clinical decisions.

Chapter 3 Decision making and heuristic theory

The hypothetical-deductive reasoning model is an important component of modern day clinical practice and emphasises the importance of normative decision making within clinical practice. It is considered as the 'gold standard' approach to decision making for assesing patients.

3.2.1.4 Bayes' Theory and Decision Analysis

The hypothetical-deductive reasoning model's process of testing a theory is dependent on being able to refute or corroborate via tests or experiments. This requires an understanding of the probability of the accuracy of evidence obtained. Bayes' theorem provides a mathematical model to assess the likelihood that 'given the number of times in which an unknown event has happened and failed: Required the chance that the probability of its happening in a single trial lies somewhere between any two degrees of probability that can be named' (236).

The theorem describes variables that are required for the probability to be calculated. These are described in table 3.1. The table provides definitions of the variables and demonstrates how they are calculated.

A gold standard is used as the reference point for categorisation of the test results into having the condition or not. The use of Bayes' theorem allows clinicians to be able to predict with a level of mathematical certainty the likelihood of an individual test result being accurate and therefore used to help validate or refute the hypotheses for the diagnosis.

Variable	Definition	Formula
Sensitivity	The sensitivity is the true positive (TP) rate divided by the total number of positive cases identified (true positives plus false negatives (FN)).	Sensitivity = TP/(TP+FN)
Specificity	The specificity is the true negative (TN) rate divided by the total number of negative cases (true negatives plus false positives (FP).	Specificity = TN/(TN+FP)
False-negative rate	This is the number of false negative cases divided by those with the condition (true positives plus false negatives).	False negative rate = FN/ (TP+FN)
False-positive rate	This is the number of false positive cases divided by those without the condition (true negatives plus false positives)	False positive rate = FP/(TN+FP)
Predictive value of the positive test	This is the frequency of the condition in those with a positive test result	Predictive value of positive test = TP+FN/ TP+FP
Predictive value of the negative test	This is the frequency of not having the condition in those with a negative test result	Predictive value of negative test =FP+TN/FN+TN
Likelihood ratio (LR)	This is for a positive test result is the ratio of the probability of the test result in those with the condition to the probability of the test result in those without the disease	LR for a positive result = sensitivity / (1-specificity) = TP/(TP+FN)/ (1-(TF/(TF+FP)) LR for a negative result = (1-sensitivity)/ specificity
	Key TP= true positive cases; FN= false negative cases; TF= true negative cases; FP= false positive cases	

Table 3.1 Bayes' theory variables

Bayes theorem can be applied to clinical decision making and used to create a decision analysis process to clinical care. It is a very systematic approach that considers potential outcomes at each stage of the pathway and assesses the

probability of occurrence for each. Decision analysis trees pictorially show the process. The function of the decision tree is to show the progression of choices and consequences. The branches of the tree are different directions that can be taken based on decisions made at the nodes. Bayes' decision trees vary from other decision trees in that outcomes are based on probabilities whereas other decision trees may include the branches that provide subjective outcomes or benefits which are referred to as utilities (237).

The use of Bayes' theorem and clinical decision trees encapsulates the normative approach to decision making, that despite the complexity of the situation rational decision making is possible and should be applied to practice. A qualitative study by Phansalkar et al. in 2009 (238) demonstrated that American hospital pharmacists used data to generate hypotheses about potential adverse drug events by a process described as 'a forward reasoning approach' which was found to be linked to an application of the Bayes theorem.

The use of normative decision making consequently, underpins the scientific approach used by healthcare professionals to make everday decisions in the management of patients. The emphasis is on applying rules and folowing a systematic approach to consider all the information. The reliance of taking short cuts is not accepted as good practice. The next section describes an alternative view to how decisions can be made in clinical practice.

3.2.2 Bounded rationality based decision making

The second paradigm of theories relate to the construct that rationality is not unbounded.

3.2.2.1 Bounded rationality

Herbert Simon postulated that the application of normative thinking was not practical and realistic for individuals having to make decisions in the 'real world' and that their level of rationality was limited or bounded (223). 'Human rational behaviour ... is shaped by a scissors whose two blades are the structure of the task environments and the computational capabilities of the actor' (239). He argued that it was therefore important to create a theory that fitted their practical approach to decision making. Simon proposed that individuals used 'satisficing heuristics' to make decisions that is they searched through a sequence of

alternative solutions until they found one that met their needs. Although Simon did not define 'satisficing heuristics' other researchers have created their own interpretation, which have a similar content. Bazerman and Moore (240) define it as 'choosing an alternative which is not the optimal solution but is a solution which is good enough'.

3.2.2.2 Pattern recognition in expertise and intuition

3.2.2.2.1 Expertise

Early theories on the construct of expertise proposed three elements to its development; motivation, perseverance and innate ability (241). Later researchers challenged the necessity for innate ability and argued that extensive 'deliberate practice' over a long period (minimum of ten years) were the only requirements (242). Deliberate practice was described as 'an exerted effort to improve performance by repeatedly performing the same or similar tasks'. Feedback on the performance of the task was deemed to be essential to improve performance levels.

The literature provides two different schools of thought on the effectiveness of clinical expertise in decision making. The first is that of normative researchers who argue that experienced clinical judgement is 'inferior to algorithms or statistical approaches due to inconsistency and lack of statistical attention to the base rate of outcomes' (243). Some of the argument relates to concerns that rather than using learnt experience judgements are made by inappropriately using heuristics (244). It is acknowledged, in this paradigm, that whilst practitioners may sometimes demonstrate expertise in some areas it is not seen across the whole range of their practice which has been termed 'fractionated expertise' (244).

The other school of thought promotes intuitive naturistic decision making. The difference in diagnostic decision making between medical students and experienced medical practitioners was investigated by Schmidt et al. in 1990 (234) during the creation of a theoretical framework that describes the development of experienced based cognitive thinking. The theoretical framework consists of four stages of knowledge development:

Stage 1 – 'Development of elaborated causal networks'

In this first stage, cognitive models are developed to provide structure and meaning to newly learnt information. The created causal networks explain 'the causes and consequences of disease in terms of general underlying pathophysiological process' (234). The networks link cues that are related.

Stage 2 – 'Complication of elaborated networks into abridged ones'

The knowledge base is converted by compiling information to create simplified models. Higher level concepts are distilled to provide an explanation of signs and symptoms.

Stage 3 – 'Emergence of illness scripts'

Schmidt defined a script as 'a scenario of events that occur in a certain order'. In this stage, rather than storing knowledge by causal groups the knowledge is stored in 'list-like structures called illness scripts'. The formation of illness scripts is based on growing experience of having encountered patients displaying similar or comparable symptoms. Each script builds up examples of how disease manifestations vary providing a broader perspective of the phenomena observed in practice.

All scripts have a consistent structure that provide rules for cognitive recognition of diseases. Each script contains enabling conditions; fault descriptions and consequences. Enabling conditions are described as 'factors that make the occurrence of certain diseases more likely'. Fault description describes the reason for the illness and consequences are the symptoms created by the fault.

Schmidt argues that problem solving at stage 3 involves the searching for potential illness scripts, identifying the correct script and then validating that the script selected was appropriate. In this theorem, the generation of illness scripts are dependent on the cases observed in practice and consequently provides an explanation of why different practitioners do not all become experts in the same fields. This supports Kahneman's concept of fractionated expertise.

Stage 4 – Strong patient encounters as instance scripts.

At this final stage memories of previous patient encounters are stored as individual cases and not merged by cause. Hence the theorem is that pattern recognition is not just a short cut to decision making but is a skill requirement to compare the

similarity of retained cases to new examples. This is directly opposed to the normative assumptions that recognition bias is a fundamental flaw in intuitive naturistic decision making.

Schmidt's model describes the development of medical practitioners and provides an explanation for the development of expertise within the profession. There are visible comparisons to be made with the development of experienced pharmacists. Pharmacy graduates on completion of their University degree qualification have developed cognitive processes to manage complex sets of information on a variety of pharmaceutical skills including training on the use of medicines to treat diseases.

A quantitative survey of 114 third year pharmacy students in America, by McLaughlin et al. in 2014, examined their preference for rational based decision making compared to their preference for fast and intuitive decision making (245). The study found that the pharmacy students preferred rational decision making compared to intuitive decision making. This result is in keeping with the concept that intuitive decision making develops as practitioners gain experience and recognise that uncertainty occurs in real-life situations. The training of students has been predominately in a theoretical environment where examples used lack the complexity and uncertainty seen in practice. It is in the pre-registration year and early years of practice that the young professional starts to build up a pattern recognition process of the use of medicines in the lives of individual patients where side-effect recognition of commonly prescribed drugs moves beyond the earlier learnt University based teaching. Similarly, with the progression of working experience the pharmacist develops cognitive recognition patterns that recognise patient characteristics associated with many long-term conditions and with carrying out minor ailments advice and treatment. This in turn can lead to modified decision making practices where previous cases are remembered for comparison. A qualitative study, by Phansalkar et al. in 2009, involving five very experienced American pharmacists captured their perspectives of their decision making during reviewing cases for adverse drug events (238). The pharmacists used a method of think aloud analysis to address four hypothetical scenarios during a focus group session. The researchers compared decision making strategies and unmet information needs for adverse drug events. During the think aloud analysis the

pharmacists asked questions about information they perceived as being implicit and made implicit judgements which the researchers attributed to pattern recognition within their memory from previous cases. The researchers referred to the work of Schmidt and the possibility that the pharmacists may be using instance scripts.

A quantitative study, by Hicks et al. in 2003, of 54 nurses, using the validated Decision Analytic Questionnaire, reported that experienced critical care nurses had a greater likelihood than less experienced nurses of having consistent accurate decision making in low complexity tasks. In high complexity tasks, intuitive based decisions were safer interventions than those based on more analytical methods (246).

3.2.2.2.2 Role of intuition

A dictionary definition of intuition is that of 'revelation by insight or innate knowledge' (221). A clinical interpretation of this is 'an understanding which is derived from personal clinical experience' (247). Simon (248) provides further clarification by describing intuition as the 'advanced pattern recognition skills within the memory'. Simon's argued that 'the situation provided the clue: this cue has given the expert access to information stored in the memory, and the information provides the answer. Intuition is nothing more and nothing less than recognition'. This definition is supported by McConnell (249) who states that 'the use of intuition relies on an exquisite sensitivity to patterns and cues'. Simon's work, along with the other definitions of intuition indicate the link between intuition and experience and that advanced pattern recognition is associated with expertise. Studies of chess grandmaster's (250) indicate that they can recognise extremely complex patterns quickly. Kahneman states that skilled intuition attainment requires two conditions to be met; 'an environment of sufficiently high validity and adequate opportunity to practice skills' (244). The first condition recognises that the environment must have some predictability so that the experience will be seen on different occasions so that experiential learning can occur. The second of these conditions supports the arguments made regarding the development of expertise that practise is a pre-requisite of intuition development.

Similarly, to the discussion on expertise, the normative theory researchers are negative about the role of intuition within clinical decision making. A review of

intuitive decision making and uncertainty described intuition as 'a cognitive short circuiting' (251).

Despite the lack of support for the role of intuition in clinical decision making, there is a recognition within some researchers that uncertainty remains within clinical practice and that a greater understanding of intuition and how it used is vital to minimise poor decision making. The literature review on intutive decision making and it's link with the development of clinical expertise provides an alternative process to making decisions within clinical practice. The reduction of complex problems into comparisons with prior experience offers an alternative mechanism to quickly resolve problems that would otherwise be difficult to manage in a brief clinical encounter.

3.2.2.3 Dual System theory

The Dual System theory states that information is processed in one of two ways – system 1 or system 2. System 1 is characterised by thought processes that are automatic, intuitive, fast, frugal and effortless. The thought processes use pattern recognition, shortcuts, heuristics and mind maps. They are developed by prior learning, experience and repetition (252, 253). In contrast, system 2 processing involves structured, considered rational analysis and evidence based evaluation. In effect the dual systems mirror the two different approaches described within the normative and non-normative constructs.

3.2.2.3.1 Four stage conscious competence model

The model describes four forms of competence that can exist for an individual at varying stages of knowledge in a subject area that alter as expertise is developed. The four stages are:

- **Consciously incompetent.** This occurs when an individual is faced with a task they have never done before and they know cannot do this without learning new skills.
- **Consciously competent.** Knowledge has been learnt and practised but it still requires full concentration and effort to perform appropriately.
- **Unconsciously competent.** Continued practice builds the actions into a part automated process allowing the task to be performed with minimum effort and conscious thought.

- **Unconsciously incompetent.** The skill set needs to be kept up to date with the latest best practice and failure to do this can create a situation where the practitioner may unknowingly make errors.

The four stages of conscious competence have been linked into the dual system processes. The consciously incompetent phase is said to require system 2 processing to gain the requisite knowledge and skills required to perform the task. Similarly, the consciously competent phase requires system 2 processing to achieve the task. The unconsciously competent stage is a system 1 process as the delivery of the task becomes more automated and fast. The unconsciously incompetent stage is also associated with system 1 processing. Keeping up to date would require system 2 processing to move back to a competent stage.

3.2.2.3.2 Cognitive Experiential Self Theory model

The Cognitive Experiential Self Theory (CEST) is very like the four-stage conscious competence model (254). It also proposes that there are two information processes a rational based one and an experiential one which is automatic and intuitive. This model differs in that, it is believed, that both processes operate simultaneously and sequentially and that individuals have a preference and use the preferred style consistently.

3.2.2.4 Role of heuristics

3.2.2.4.1 Definition

The word heuristics comes from Greek and means 'serving to find out or discover'. There are various definitions of heuristics which revolve around a common theme that underpins non-normative theory that when uncertainty exists decisions are made using rules of thumb. Todd (255) argues that its original use in the English language is a 'useful, even indispensable cognitive process for solving problems that cannot be handled by logic and probability theory alone'. Tversky and Kahneman in 1974 (256) described heuristics as 'methods for simplifying complicated likelihood judgements about different outcomes by use of short cuts or rules of thumb which still lead to reasonably accurate probability estimates'. A more simplistic definition defines heuristics as 'subjective probability judgements' (257). Donyai in their definition excludes the issue of uncertainty and complexity and describes heuristics as 'strategies based on readily available mental

representations of the world, which can be evoked during decision making' (258). Others have focused on the non-normative approach of using less information to make a decision and defined heuristics as an 'efficient cognitive process, conscious or unconscious, that ignore part of the information' (259). The simple heuristic definition of heuristics, that fits with non-normative theory, is that of a 'rule of thumb'.

3.2.2.4.2 Cognitive Bias and heuristics

The normative principle of assessing all of the relevant information and making an informed choice is at the heart of clinical training programmes across the healthcare professions. These programmes are based on the active use of the conscious mind to analyse information and deliver evidence based outcomes. The concept of using subconscious thought patterns or heuristics is thought inappropriate by many researchers, as they are believed to be subject to cognitive bias, inaccurate and to produce poor clinical decisions (260, 261).

Cognitive bias has been described as 'a pattern of deviation in judgement that occurs in particular situations' (253). This deviation focuses on a single factor that takes precedence in the decision-making analysis.

The biggest criticism of heuristics is based on the weaknesses of some cognitive biases described in table 3.2. The table describes reported biases and provides brief explanations of the causes of the biases. These biases are frequently referred to in commentaries and research papers to demonstrate the danger of relying on intuitive thinking based on heuristics. The seminal paper on heuristics and biases focused on the three cognitive biases of representativeness; availability; adjustment and anchoring (256). It argued each of these cognitive biases could cause systematic errors in making probability judgments when uncertainty existed. Each bias had examples of failure to obtain an accurate assessment due to not giving recognition to statistical rules when faced with limited information and giving over emphasis on a memory recollection.

Bias	Deviation
Anchoring	Emphasis on information provided at the start of the consultation
Ascertainment	Decision influenced by prior expectation
Availability	Emphasis on recall of recent past-experience
Blind spot	Not recognising ability to make cognitive biases
Gambler's fallacy	That a sequence of similar cases cannot continue rather than treating each as an individual case
Omission	Emphasis on inaction rather than action as acts of omission are deemed as less harmful than acts of commission
Search satisficing	Stopping a search too early without reviewing all the information
Sutton's slip	Jumping to the obvious conclusion without checking
Confirmatory	Look for cues to fit with pre-existing expectations
Representativeness	Overestimate of a likelihood by comparing to a group that is perceived as having similar characteristics

Table 3.2 Cognitive biases in clinical practice

The cognitive biases and heuristics most directly related to pattern recognition are the representativeness and the availability heuristics. Tversky and Kahneman focused in depth on these in their challenge to intuitive decision making. They described the representative heuristic as a situation where an assessment is made on the probability that A belongs to class B. If it assessed that A is highly representative of B then it is assumed that it belongs to that class. Their criticism of this was that it did not take into consideration the prior probability of being in class B and consequently this created a cognitive bias towards incorporation of A into B. That is, it is not taking into consideration the base rate frequency of being in class B. If this is compared to Schmidt's theory it would indicate that the validation element of the illness script is not occurring by deciding too early that the patterns match.

The availability heuristic is described as 'the ease by which instances or occurrences can be brought to mind' (256). Consequently, instances within larger

classes will be remembered quicker and faster than instances of less frequent cases. A bias is created by associating the current case with the easily recalled cases and inappropriately aligning the new case with the easily remembered one. In Schmidt's model this is effectively a situation where the wrong illness script has been selected and then inappropriately validated. There is some synergy between these two opposing theories on the validity of intuitive thinking as the issue identified by Tversky is the lack of consistency in interpretation of information rather than of two incompatible theories.

A systematic review, by Blumenthal-Barby and Kreiger in 2015, of cognitive biases and heuristics in medical decision making reviewed 213 studies and identified that 77% based their conclusions on hypothetical vignettes and were concerned over the applicability of the studies' findings on influencing the use of heuristics (262). Other scholars such as Marewski and Gigerenzer (259, 263) argue that heuristics have an important role to play in decision making provided that they are 'ecologically rational'. 'Ecological rationality' being described as 'adaptive behaviour resulting from the fit between the mind's mechanisms and the structure of the environment in which it operates'. The argument focuses on identifying in what circumstances to use a heuristic rather than assuming it will provide the universal truth to any question being asked. This approach fits with the work of Tversky and Kahneman's, as described earlier, who are perceived as being major researchers in the cognitive and heuristic biases camp. Whilst the bulk of their original paper identifies weaknesses with heuristics and biases the paper does acknowledge that 'not all intuitions that arise in heuristics are always incorrect, only that they are less trustworthy than intuitions that are rooted in specific circumstances'.

3.2.2.4.3 Probabilistic Mental Models Theory (PMM)

The probabilistic mental model theory states that probability cues are used to make inferences about unknown states of the world (264). It provides a theoretical basis to the development of heuristics. The theory has three aspects that provide a rationale for the process of using inductive referencing. The three elements are:

- The reference must consider natural environments in which it is being used. This concept fits within the idea of ecological rationality.

- The inductive reference uses satisficing algorithms, that is algorithms to generate 'good enough solutions'. This idea links to Simon's work on bounded rationality (section 3.2.2.1).
- It is based on frequencies of events in a reference class.

3.2.2.4.4 Fast and frugal heuristics

The development of the concept of bounded rationality led to the creation of the terminology of fast and frugal heuristics. The terminology arising from the concept that heuristics, in controlled circumstances, can with limited time and information be fast and frugal.

Ecological rationality requires the creation of an 'adaptive tool box' with each heuristic. It has been described as 'the collection of specialised cognitive mechanisms that evolution has built into the human mind for specific domains of inference or reasoning'. The use of the tool box allows each heuristic to be modified to fit a specific decision making environment. The tool box can be applied to a large selection of heuristics. Modification of the heuristic creates a 'cognitive niche' for each heuristic (265). Marewski classified heuristics in the adaptive toolbox into four groups depending on how the heuristic functioned and the environment it was intended to be used. They were non-exclusive groups that identified important considerations to the heuristics use.

- The process of how the heuristic assigns varying importance to information in the model
- The social domain to which the heuristic is applicable
- The inductive inference properties of the heuristic
- Exclusivity of memory recall to the heuristic

Heuristics consist of building blocks and usually have three or more. The three main blocks are a search rule which dictates how information is searched for, a stopping rule that dictates when the search should end and a decision rule that specifies how decisions will be made (266). All fast and frugal heuristics must restrict the search process for information or objects by using simple searching stopping rules and simple decision rules (255).

The choice of fast and frugal heuristics is situation specific. An information rule is required to set what cues are looked for. Consideration must be given to the

number of cues that exists for a specific decision and on the number chosen to make that decision. Heuristics for decision making can, if desired, use just one cue or reason regardless of the potential number of cues or reasons that exist. The simplest version being where one option is chosen from a possible two options, for a criterion. Where multiple cues exist a stopping rule is required to decide when sufficient information has been collected to make the decision.

Fast and frugal trees are simple decision aid instruments as they are easy to understand and use. Unlike Bayes' decision trees there is no probability attached to each branch.

The three rules usually used, to create a fast and frugal decision tree, are:

- Search rule – View predictor variables in order of importance
- Stopping rule – stop search as soon as the predictor allows it
- Decision rule – use final position as selected outcome

The fewest number of question nodes are required to be a fast and frugal heuristic decision or categorisation tree. It has been said that it can only be a fast and frugal categorisation tree if it has 'at least one exit at each level' (267). The trees work on the basis that cues are considered one at a time and are not combined.

Another fast and frugal decision rule is known as 'take the best' (268). It is based on the Probabilistic Mental Model (264). The decision rule is based on choosing the cue that has the greatest validity through a process of ranking. The idea being 'take the best ignore the rest'. The search rule states search through the predictor variables in order of their validity. The stop rule is to cease searching when the first predictor is identified that can discriminate between the cues. The decision rule is to assume the positive predictor is the best choice (266, 268). A study, by Berg et al. in 2010, of 100 American economists assessed how they decided to have a PSA screening or not (269). Two thirds reported that they did not weight the pros and cons and decided to just trust their doctor's advice. Faced with the complexity of trying to assess the value of each criteria and weight them they opted for what they perceived to be the strongest one and ignored the rest.

The tallying heuristic is a simple heuristic where the following three steps are followed:

- A decision is made on what information to search and review
- Each cue is assessed to see if it provides positive evidence. If positive, it scores one point
- Once the set number of cues have been reviewed a tally is made of all positive scores. The object with the highest tally score is the one to use.

The tallying heuristic equally weights each cue. A modified version of this heuristic follows the procedure above until tallying occurs. At this point each positive cue is weighted 'according to its ecological validity' (268) and given a score based on the weighting. Scores are then tallied and the highest scored item is the one that is chosen. This heuristic is known as the weighted tallying heuristic. The study described in section 3.2.2.4.5 (270) is an example of a tallying heuristic.

3.2.2.4.5 Use of fast and frugal heuristics in clinical practice

It is advocated that fast and frugal decision making can work effectively (268). A frequently cited example reports its use to assess patients with suspected heart disease for admission to a critical care unit (271, 272). The American hospital had a succession of problems regarding who should be admitted. Originally the doctors were performing defensive medicine and were over referring using a 'protect from suing' decision process. The hospital then introduced a complicated chart, called the Heart Disease Predictive Instrument (HDPI), that used logistic regression to calculate risk based on 50 parameters to decide if a patient should be sent to a critical care unit. Physicians used it infrequently as they did not trust it and found it difficult to use. A frugal and fast decision tree was created and used instead. It asked only three questions:

- Is there an anomaly in the electrocardiograph reading?
- Is pain the primary symptom?
- Are other factors such as myocardial infarction or nitroglycerin used for chest pain?

The searching strategy was to ask the questions listed in the order of the bullet points. The decision rule was to refer to the critical care unit if any question had answer of yes. The stopping rule for this decision tree was if any question generated a positive answer then no further questions would be asked.

The fast and frugal heuristic was compared against the HDPI and the physician's independent decisions. The study reported the heuristic had fewer false positives and less false negatives than both the HDPI and physician's estimates which were only slightly better than chance.

A qualitative study, by Wackerbarth et al. in 2007, of semi-structured interviews of 66 primary care physicians (273) analysed how they used fast and frugal heuristics to formulate plans for colorectal screening recommendations. The semi-structured interviews were reviewed to create decision trees for the heuristics of 'when to screen' and 'how to screen'. The results indicated that when the 'when to screen heuristic' was used the physicians compared their decision against their inclusion and exclusion criteria to see if the decision needed changing. It indicated that the physicians were instinctively using an ecologically rationale approach to the heuristics use. Four variants of the 'when to use' heuristic were identified. All considered age of 50 to be the best heuristic. The variations were expansions of the simpler version; age 50, earlier if family history; age 50, if family history, then at age 40; age 50, if family history, then adjust relative to reference case.

In the how to screen analysis the most common approach was based on a take the best heuristic approach. Options were ranked by their perceived validity and the best one chosen. If the patient was not willing to take the physician's recommendation the heuristic was amended to if not the best to take the next. This is an excellent example of how the rule of thumb 'if not the best take the next' appears to have no scientific basis yet is formulated by a standard set of rules of information selection, stopping process and decision making that takes the environment it is being used in into consideration. It is a form of naturistic decision making.

A prospective epidemiological study by Jenny et al. in 2013, reported the use of a fast and frugal tree for diagnosing clinical depression (274). The study involved 1382 young women between the ages of 18 to 25. The Beck Depression Inventory was used to assess for clinical depression and the results were compared to a fast and frugal process and a complex compensatory logistic regression model. The fast and frugal tree asked up to four binary questions (yes / no answers). Any no answer resulted in the stop rule being applied with the assessment of not clinically depressed. The results indicated that the fast and frugal tree was highly frugal with

the search stopping after 1.3 cues (SD=0.66). The fast and frugal process outperformed the logistic regression model.

A review of decision making in end of life care for dementia patients, by Mathew et al. in 2016, searched for the use of heuristics to aid decision making (275). Twelve papers were identified that used terminology of decision tools; guidelines, principles or algorithms to describe how decision making could be simplified. The reviewers believed that they all used mechanisms that were compatible to the heuristic decision making despite not be labelled as heuristics. An example of this was a study on swallowing and eating difficulties (276) by Gilick in 2001. The authors created stepwise process for American care homes explaining what was required when a dementia patient stopped eating. In effect this was a fast and frugal decision tree that gave a decision making process for care staff.

A prospective cohort study, by Fischer et al. in 2002, of 253 children in the USA used Receiver Operating Curves to compare the predictive capabilities of two models to assess the need for macrolide antibiotics to treat community acquired pneumonia (277). One model was a scoring system derived from logistic regression analysis and the other a fast and frugal decision tree. The heuristic model asked up to two questions. Is the duration of the fever equal to or less than two days? If the answer was yes, the decision was that there was a low risk of Mycoplasma pneumoniae and macrolide antibiotics should not be prescribed. If the answer was no an additional question was asked: are they aged three or less? If yes, the decision was that was a moderate risk and the antibiotics should not be prescribed. If the answer was no the risk the decision was the risk was high and macrolide antibiotics should be prescribed. Consequently, the heuristic rule created was 'prescribe macrolides only if child is older than 3 years and has had the fever for more than 2 days, otherwise do not prescribe macrolides'.

The study found that 32 (13%) of the children had mycoplasma pneumonia. The scoring system model predicted that 75% of these cases were at high or very risk of having the illness compared to 72% rated as high risk by the heuristic model. The ROC analysis gave a predictor value of 0.84 (95% confidence interval CI 0.77-0.91) for the scoring system and 0.76 (95% confidence interval CI 0.70-0.83) for the heuristic. Both predictor models were estimated to be able to reduce

existing macrolide prescribing by 75% and 68% respectively for the scoring system and heuristic models.

The authors argued that 'the simplicity of the trees arises from the specific choice of variables and cut offs: these allow physicians to rule out or rule in a particular disease … by deliberately accepting a small false-negative (or false-positive) rate'(277). This view highlights the importance of understanding the ecological rationality of the situation and assessing the impact that a small false negative or false positive rate has on the implementation of the heuristic rule for the patients being treated.

An Italian study, by Riva et al. in 2011, assessed 70 patient's decision making when purchasing over the counter medicines (270). Participants were trained to use a touch screen and completed simulated tasks that assessed the heuristics used to decide on either an over the counter medicine for a cold or for pain. It has been postulated that two different exploration paths exist to decide product choice either a feature-wise or global-wise (278). The feature-wise approach requires considering just one feature of the product and comparing that between various treatment options (this has been called Cue-wise by Riskamp (279)). The global-wise process considers all the features of an individual product together before following the same process with another product (also called alternative wise by Riskamp). The study identified that for both scenarios the global-wise approach predominated (23 out of 35 in the pain group and 33 out of 36 in the cold group).

Tallying was identified as a key heuristic. Treatment features were converted into positive (scores 1) or not (scores 0) and the selected number of features tallied to provide the choice of product. Predominately used features were side effects, doctor's advice, price, brand and availability. Participants that had previous experience of the problem used less cues to make their decision.

Analysis of the results indicated that 78% of the participants' decisions could be predicted using a simple combination of a tallying rule and a fast and frugal decision tree.

The alternative side to the dilemma of which over the medication to purchase is that seen within the pharmacy where the pharmacy personnel are asked to

provide advice on the most appropriate treatment for minor ailments. Community pharmacy practice in the UK advocates that pharmacy staff use of a mnemonic to aid decision making for advising on treatment options for over the counter medication (280). Whist it is not termed in practice as a heuristic it follows the three-rule design and takes account of the environment it is used in.

The mnemonic WWHAM provides a reminder of the information selection rule.

W - Who is it for?
W - What are the symptoms
H - How long have the symptoms been present
A - Action taken
M - Medication taken

There are stop rules applied that inform medicine counter staff when to refer to the pharmacist or for the pharmacist to refer to the GP. A common stop rule is linked to the duration of the symptoms. A decision rule of symptom y greater than x days requires referral to the GP practice (281).

If all the selected information is collected the rule of thumb used is a variant of take the best. The modification considers treatments already tried and existing medication prescribed. The process is ecologically rationale as it considers red flag symptoms (another stopping rule) and provides safety netting advice with the medication sale for example if no better within y days then come back to the pharmacy or make an appointment with your GP.

3.2.2.4.5 Use of heuristics in health literacy

It can be argued that Chew's single assessment question (204) that was identified during the systematic review constitutes a simple heuristic assessment of health literacy. Chew's question asks ''how confident are you filling out medical forms by yourself?'' The question is treated as a binary outcome of confident or not confident. The decision rule would be that confidence equates to adequate health literacy and stop rule that the process ends when the predictor discriminates confidence.

From the systematic review this single assessment question did not score highly on the assessment criteria which does not provide a strong evidence base for its inclusion in a potential pharmacy solution. The single assessment question would

be a very unusual question in ask in a pharmacy setting in the UK as medical form filling is not something that occurs with any major frequency in any healthcare setting. Consequently, inclusion of this validated single question into a pharmacy research study was not a realistic option.

There were no research papers found that used heuristics to assess health literacy. A study, Bass et al. in 2002, of American resident physicians assessed their ability to predict limited health literacy amongst 182 patients (282). All the patients were assessed using the Rapid Estimate of Adult Literacy in Medicine – Revised (REALM-R) assessment instrument. The instrument identified that 42% (77) had limited health literacy however the residents were only able to predict 10% of these patients (18). Indicating that they had not developed an accurate pattern recognition process to identify health literacy.

There were three papers that used health literacy heuristic rules of how to simplify information for the creation of web based applications designed for individuals with limited health literacy (283-285). Heuristic rules used included keep information simple; use large font; limit the amount of information provided, all of which are based on best practice advice for supporting individuals with limited health literacy (286-288).

Non-normative theories provide an evidence base to indicate that a heuristic approach to health literacy is justified and could provide a simple 'rule of thumb' to help clinicians identify individual's health literacy ability.

3.2.3 Summary

The role of recognition within cognitive functions is critical to both normative and non-normative theories and is linked to both learning and retrieval of information. The differences, between normative and non-normative theories, occur in beliefs on the underlying processes and the variance on how systematic each approach is and to what extent they demonstrate an empirical evidence base for use in practice.

The literature reviewed on the development of expertise and the use of intuitive pattern recognition provides two schools of thought on its impact on patient care. The normative approach in general does not recognise any positive utilities whereas the naturistic approach believes that experienced practitioners can use

pattern recognition skills effectively to provide better quality care. As there are no research papers to indicate if pattern recognition is applied to health literacy assessment it is unclear if healthcare professionals can have an innate or learnt ability to do this heuristically.

Both the normative decision making theory researchers and those that advocate a naturistic decision making basis are searching for an approach to improve the consistency and quality of health care professionals' decision making particularly in situations of high uncertainty and complexity. The research into heuristics aims to demystify the decision-making processes used and create rules to provide a standardised approach which is more aligned to rational decision making. The emphasis of ensuring heuristics are used with ecological rationality confirms that there is a recognition that they cannot be expected to be used in every situation and maintain the same level of accuracy. In this sense, there is not such a great deal of difference between the two paradigms as the literature initially suggests.

The literature reviewed provides examples (272, 289) where heuristics have been shown to have a rational decision making analysis underpinning their design. The heuristic is a simplified explanation of a best fit from a logistical regression model and or based on the Bayes' theorem of assessing the probability of the diagnostic instrument. This might be a 'take the best' interpretation or a tallying heuristic used to create the heuristic rule. Ultimately, it provides the combination of both approaches to a short cut to decision making that has a strong empirical foundation.

The final study in this thesis will use normative theories to test a hueristic approach to assessing health literacy. Logistic regression and Bayes' theorem and the creation of Receiver Operating Curves will be used to assess the creation of a diagnostic instrument to assess health literacy that is based on non-normative theories of ecological rationality and fast and frugal heuristics. It will therefore use both normative and non-normative constructs to identify a new assessment process. The rationale for this approach is that both normative and non-normative methods are valid and can co-exist in a scientific methodology.

Chapter 3 Decision making and heuristic theory

The next chapter describes the methods for the study to assess the potential use of the NVS health literacy instrument in community pharmacies and for the study to assess the development of a heuristic health literacy instrument.

Chapter 4

Assessing Health literacy in a community pharmacy using the NVS

4 Assessing health literacy in a community pharmacy using the NVS

4.1 Introduction.

The objective of this thesis is to identify a mechanism to assess health literacy in a healthcare environment such as a community pharmacy setting. The systematic review described in chapter 2 identified the Newest Vital Sign as the most appropriate health literacy instrument to test in this environment. This chapter will provide the rationale for the methodology chosen and presents the results of testing the NVS in community pharmacies.

4.1 Methodology

4.1.1 Philosophical positioning of the thesis

Kuhn (290, 291) posited the concept of paradigms. His initial definition was around the idea of researchers having an agreement on 'exemplars of high quality research and thinking'. Alternative definitions have since been developed and include: the shared beliefs among a community of researchers; an epistemological stance and a commonly quoted definition of 'a world view' (292, 293). Hall (294) described the world view as a collection of stances that incorporated each of the elements of ontology, epistemology, axiology and methodology.

Ontology is concerned with beliefs about reality and what is true. The consensus on ontological view-points ranges from a realism approach that one truth exists and is context free, and the relativism approach which is that meaning can only be found within individual experience and is bound by context. Realism is described in terms of being objective and of being able to be measured and of being a static truth. Whereas relativism is described as subjective and dynamic. The terminology 'quantitative research' is associated with the paradigm of realism whilst 'qualitative research' is associated with social construction and relativism.

Research within community pharmacy predominately aligns with a realism perspective. This is consistent with pharmacy being a physical science based profession where universal truths underpin pharmacy training. There is a body of pharmacy research that aligns to the relativism perspective and this relates to

developing an insight into the complexities that exist in practice where individuals and the external environment effect the application of theory and new service delivery into practice.

Historically within research, realism and relativism, were thought to be diametrically opposed paradigms (295) and that research had to be confined within a single paradigm. Over recent years an alternative view (294, 296, 297) has developed in that it is possible to have a mixed method research based around a pragmatic paradigm that combines the two original paradigms.

Epistemology is defined in terms of the relationship the researcher has to the research. The realism paradigm is based on an objective approach that requires the researcher to minimise the potential influence of the researcher on the research topic whereas the relativism paradigm is based on embracing the researcher's contribution to the research topic. The epistemological stance within health care research and specifically within community pharmacy research is dependent on the research question(s).

Axiology is defined as the study of the researcher's values or ethics in the scientific process (298). Realists believe that individual's values should not influence the research and the methods should be designed to limit personal values affecting outcomes. Whereas relativists encourage the involvement of 'lived experiences' within the study.

Where answering the research question involves the study of quantitative data to search for relationships or to predict the potential outcomes of an intervention or assessment then a realism paradigm approach is taken so that the researcher minimises potential bias. Much of pharmacy research is of this nature. If the research question requires consideration of identifying the 'best' course of action, there is an assumption about what the 'truth' might look like but this is context specific and the evaluation of the context that this research question answers requires a different approach namely that of that within the relativism paradigm. This approach allows the researcher to bring their perspective to the context analysis.

Johnson et al. (297) argue that the choice of method or combination of methods should be based on what works best to answer the research question. They also

quote Pierce, James and Dewey who were the initial advocates of using a pragmatic approach to research to assess the practical consequences of phenomena in a 'real world'. The emphasis was on helping to decide what action should be taken next to address the question under investigation. This ethos is very like the approach taken in this thesis in that the research is driven by the desire to identify a health literacy assessment instrument that can be applied to existing community pharmacy practice. Addressing the 'real world' application requires an understanding of some of the potential barriers to implementation and a qualitative approach provides greater opportunity to capture individual perspectives of their experiences of using the NVS in the pharmacy environment and give an indication of the transferability.

A quantitative approach is also required to generate empirical data that can demonstrate the potential feasibility of the NVS instrument. Consequently, the research approach used in this thesis is based on a pragmatic paradigm.

The approach taken has been described as complementarity mixed method as the objective is 'to seek; explore; enhance; illustrate and clarify the results from one method with the results from the other method' (297). It varies from triangulation (299) in that the objective is not to validate a theory or generate a hypothesis, through a triangulation of information. Rather it is to provide an explanatory narrative to the quantitative findings. Consequently, both the feasibility of using the NVS study in chapter 5 and the heuristic study in chapter 6 use a combination of quantitative and qualitative approaches. The process used was to carry out the quantitative elements first and then collect the qualitative data so the interpretative analysis was informed by the personal experiences of participation.

4.2 Assessing health literacy in a community pharmacy using the NVS

4.2.1 Study overview

The study objective is to provide empirical data on the use of the NVS in a community pharmacy setting. The primary research question is: 'can the NVS be used in a community pharmacy to assess health literacy?' The systematic review in chapter 2 provided a structured assessment of the psychometric properties and validity of the instrument. Little information was evidenced on the clinician's or patient's perspective of assessing and being assessed in a practice environment. A

subsequent question, therefore, to inform the answer to the primary question is: 'what are the perspectives of pharmacists and participants on using the NVS in a community pharmacy?' This question could be assessed from both a quantitative and a qualitative perspective. A quantitative approach via questionnaires would provide generalisability from the sample but would be dependent on the wording of the questions. Alternatively, the use of a qualitative approach would allow for a more in depth analysis of personal experiences. Consequently, a qualitative approach was adopted for the study.

There were two distinct phases to the study. The first was quantitative and involved community pharmacies in Suffolk recruiting eligible patients, administering the NVS and collecting demographic data. Patients and pharmacists that completed the study provided feedback via patient focus groups or pharmacist interviews in the qualitative second phase.

4.2.1.1 Describing Participants

The word participant could be used in these studies to refer to two groups: patients accessing pharmacy services who agree to participate in the study and pharmacy staff who deliver the assessments. To remove the potential for confusion participant will only be used when referring to both groups collectively. Patients will refer to those accessing services at the pharmacy who joined the study and pharmacists or pharmacy personnel refers to the pharmacist and the wider team carrying out the assessments.

4.2.2 Aims and Objectives

The aim is to determine whether the NVS is appropriate for use in community pharmacies to assess health literacy.

The objectives of the assessment of the NVS were to estimate the following:

- Proportion of patients willing to complete the NVS
- Average time taken to complete the NVS

The NVS test can be completed within 3 minutes however the systematic review described in chapter 2 indicated it is unclear from the literature if this is the case for the majority of the population and if patients with lower health literacy require longer.

Recording the time taken will give a better understanding of the actual time required to complete the NVS.

- Distribution of the level of health literacy within the population

This is the first time that health literacy has been measured in community pharmacies in the UK and so will give an initial assessment of the extent of limited health literacy in a community pharmacy environment.

From the focus group discussions, the following will be elicited:

- Facilitators and barriers to completing and distributing the NVS from the patient and pharmacy staff perspective respectively.

4.2.3 Pharmacy identification and recruitment

Ethical approval was obtained for the study from the South Central Berkshire B Research Ethics Committee and NHS R&D approval from Norfolk & Suffolk Primary & Community Care Research Office.

All 120 pharmacies within two Clinical Commissioning Group (CCG) areas in Suffolk (Ipswich and East CCG and West Suffolk CCG) were invited to participate in the research project. Data from the NHS choices website crossed referenced with data published in the Suffolk Pharmaceutical Needs Assessment were used to identify all eligible pharmacies.

Each pharmacy was sent an information sheet inviting both the community pharmacist(s) and medication counter assistant(s) to be involved in the study. A follow up request was sent to improve the study uptake.

4.2.4 Anticipated number of pharmacies

A previous study (300) indicated that an uptake rate of 30% would be a likely response rate to a questionnaire. This study requires a greater level of engagement and is more labour intensive for the participant hence a conservative uptake rate of 20% was initially anticipated; giving a target of 22 pharmacies participating.

4.2.5 Pharmacy staff training

Each participating pharmacy was sent the NVS paperwork which included prepared written scripts for the staff to follow. The scripts described how to invite patients to

participate and how to carry out the assessment (appendices 4.1 & 4.2 pages 250 & 252). Staff were advised to familiarise themselves with the NVS label and questions and carry out a trial run of inviting patient participation and carrying out an assessment with the researcher. Any further learning needs were then addressed. Training sessions were held at the pharmacies.

4.2.6 Patient identification and recruitment

Each participating pharmacy was given 50 invitation packs to recruit patients in the pharmacy. All patients prescribed at least one medication for the treatment of hypertension and aged over 18 years and not having a severe mental health condition were eligible for the study. The rationale for the choice of hypertension was that hypertension has a higher prevelance than other common conditions and consequently all pharmacies would have sufficient number of patients to invite into the study. Requiring only one medicine would increase the potential number of patients that could participate. Severe mental health conditions were excluded due to the concern that having their health literacy ability assessed may cause them to have increased anxiety and stress.

The person(s) responsible for labelling dispensed medicines identified the patients who fulfilled the eligibility requirements, via the patient medication records and attached a sticker to the dispensed prescription bag. This indicated that a study invitation pack was to be provided when the dispensed medication is handed to the patient. The patient medication record was annotated to ensure that the patient was not re-approached. The invitation pack comprised of a patient information sheet and consent form.

Trained staff members used a script prepared (appendix 4.1) by the principal investigator when patients come to collect their prescriptions marked with the sticker. The script said that the pharmacy was participating in a University of East Anglia research project to understand how easily facts about health could be understood by patients. They were told that once they had agreed to participate the study would require them to answer a few questions in the consultation room and would take 5 to 10 minutes of their time. For most patients that would be the end of the study. A small number of patients might be contacted again and asked to join a small discussion group. Patients were given the Patient Information Leaflet (appendix 4.3

page 255) and consent form (appendix 4.4 page 259) and asked to complete the consent form if they wished to participate. Patients that completed the consent form were then invited to either make an appointment or complete the assessment straight away.

The patient information leaflet did inform patients that answering the questions would involve the use of maths but did not directly tell them that they would have their health literacy tested. This was a deliberate decision as there were concerns that those who had limited health literacy may not agree to participate if they knew they were being tested. The issue of not fully informing the patients was discussed in detail with the ethics committee at an ethics committee meeting before approval was granted.

4.2.7 Patient activity

Consenting patients were invited into the pharmacy consultation room by a trained member of pharmacy staff who followed a prepared script which is shown in appendix 4.3. The pharmacy member of staff then explained that the participant would have to confirm a few details about themselves before they were given a short information leaflet about the contents of an ice cream tub. They were told that the leaflet could be read to the participant if they preferred. They were also told that they would be asked to answer up to six questions about the leaflet and would be timed on how long it took to answer the questions. The patient was asked if they were okay with the process and if they had any questions. They were also informed that they could stop at any time they wished without giving a reason. If for any reason, they were upset with any aspect of the study they could contact the project supervisor whose details were on the Patient Information Leaflet.

Each patient was asked to confirm their age and state at what age they left full time education. This information was collected as the literature indicates that there are associations between the level of education of an individual and their health literacy ability and between the individuals age and health literacy level. The staff member recorded the answers along with the patient's gender. Patients were asked if they were also prepared to take part in the discussion groups and if so that they were happy with their contact details being passed on to the researcher. Figure 4.1 (page

129) shows the Newest Vital Sign information leaflet, that was given to the patient to read.

Staff used their mobile phones to measure the time taken. When the participant was ready the start time was recorded. The staff member read the questions, which are shown in figure 4.2 (page 130) and recorded the answers provided and recorded the time when the last question was answered. The patient was thanked for taking part and reminded that (if they agreed to group work) that they might be contacted to take part in the small group discussions. They were given a £5 voucher for participating. The use of financial incentives was based on previous work undertaken by the supervisory team who found that a small payment acted as an incentive to participation without influencing patient's responses to study objectives. The method was particualrly common within psychological research at the University.

Nutrition Facts

Serving Size	1/2 cup
Servings per container	4

Amount per serving

Calories 250	Fat Cal 120

	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

* Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

FIGURE 4.1 NVS INFORMATION SHEET

	ANSWER CORRECT?	
	YES	NO

READ TO SUBJECT: This information is on the back of a container of a pint of ice cream.

QUESTIONS

1. If you eat the entire container, how many calories will you eat?

    Answer ❏ 1,000 is the only correct answer

2. If you are allowed to eat 60 g of carbohydrates as a snack, how much ice cream could you have?

    Answer Any of the following is correct:

    ❏ 1 cup (or any amount up to 1 cup)

    ❏ Half the container

    Note: If patient answers "2 servings," ask "How much ice cream would that be if you were to measure it into a bowl?"

3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes 1 serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?

    Answer 33 is the only correct answer

4. If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?

    Answer 10% is the only correct answer

Pretend that you are allergic to the following substances:
Penicillin, peanuts, latex gloves, and bee stings.

5. Is it safe for you to eat this ice cream?

    Answer ❏ No

6. (Ask only if the patient responds "no" to question 5): Why not?

    Answer Because it has peanut oil.

                                         Total Correct _____

FIGURE 4.2 NVS QUESTIONS

4.2.8 Pharmacy sample size

With an estimated 22 participating pharmacies, ten completed NVS assessments per pharmacy provides a sample of 220 completed assessments. A sample size of this magnitude would be, acording to an audit of sample size for pilot and feasibility studies (301), adequate for providing an early indication of the likely prevalence of sub-optimal health literacy within the patient population prescribed anti-hypertensive medication.

4.2.9 Quantitative Analysis

The study is a feasibility study and is not powered. The study aims to provide an initial assessment of the potential use of the NVS in clinical environments. As described in 4.2.1 the primary research question for this study is: 'can the NVS be used in a community pharmacy to assess health literacy?' To answer the primary question additional quantitative research questions were devised. These were:

- Will patients consent to complete the NVS in a community pharmacy?
- Will pharmacies be willing to assess health literacy in pharmacies?
- How long on average does it take to complete the NVS in a community pharmacy?

Additional questions were generated to provide a community pharmacy perspective on health literacy research. The results obtained from the feasibility study would not be powered but might give an indication of an answer to the following questions:

- Is there an association between health literacy level and the time taken to complete the NVS?
- Are age, sex or educational levels confounders of health literacy?
- What is the level of limited health literacy in a community pharmacy setting?

The associations between NVS score and time for completion were calculated using Spearman's correlation coefficient.

Descriptive statistics were used to report:

- Pharmacy consent rate
- Patient consent rate
- Age, sex, education level of the patients

- NVS self-administered or read by pharmacy staff member
- NVS score
- NVS level (limited; marginal; adequate)
- Time for NVS completion
- Non-completion rate including reason

To compare the nominal level data of sex, percentages were used to describe the variation in number of patients between males and females whereas consideration of age differences between the genders was treated as interval data. The dispersion of the data was reported using standard deviations for all interval data and inter-quartile ranges for ordinal level data (NVS levels).

Depending upon the observed variation in participant characteristics, associations between NVS score, non-completion rate and demographic data were explored, using Spearman's correlation coefficient, except for sex which used a Mann-Whitney test. Spearman's correlation is preferred to Pearson's coefficient in these studies since it can be used with ordinal level data such as the NVS level (302). Spearman's correlation is less prone to influence of outliers or non-normal distribution, but is less powerful than a parametric test (303).

4.2.10 Focus groups and interviews

Observational techniques were ruled out as it was not deemed possible to observe the assessment in an unobtrusive manner and from an epistemological position there was a concern that it would alter the normal patient / pharmacist dynamics.

Also from a practical perspective the assessments would occur on a random basis in the pharmacies at a time that suited the pharmacist rather than the researcher which would make the observations extremely difficult to fit into pharmacy visits.

Questionnaires were a potential option but were discounted due to concerns over appropriate design to fully capture the perspectives and experiences of individuals and the lack of opportunity to further explore issues as they arose. Also as the topic concerns health literacy ability there was the added complication of writing it in a way that would be comprehended correctly by all patients and ensuring those with limited health literacy would not be put off from completion.

Interviews and focus groups were both potential processes that could be used. Data would have to be collected from patients with different health literacy abilities and a concern was to minimise any reticence to disclose information due to not wanting to expose their lack of ability. It was felt that individuals with limited health literacy may not be very communicative and keep their answers brief. Whilst one-to-one interviews would facilitate not having to share information with a wider group, they still might feel uncomfortable sharing information with a researcher. Focus groups were deemed to be more suitable as the intention was to only have individuals with similar health literacy abilities in each group so that there was the opportunity to share similar experiences and not feel isolated and different (304). It was also hoped that this would stimulate greater debate as they became more comfortable amongst peers to share their experiences and feelings. The collective response would then give a perspective for that health literacy level which is under reported in the literature.

The option of interviews or focus groups were considered to collect pharmacist data. Due to the geographical distribution of participating pharmacies, individual interviews were more feasible relative to trying to find a suitable time and location for all participating pharmacists.

The location of the focus group meetings was dependent on the location of the patients as the objective was to make attending the focus group as easy as possible. No patient had to travel more than 2 miles to reach the meeting place and for most the venue was within walking distance. Because of this approach all the focus group meetings were held in large towns in Suffolk.

Each of the focus groups had two moderators. The principle moderator ran the focus group sessions and ensured that all the participants had an opportunity to contribute to the discussion. The second moderator was responsible for recording the event; keeping notes and providing support to the principle moderator. The focus group session ended when both moderators agreed the topics had been fully explored. A maximum time limit was set for 90 minutes to allow patients to be fully aware of the possible time commitment associated with participation.

Debi Bhattacharya was the moderator for each focus group. For the first Ipswich focus group Neil Cooper was the principle moderator as Paul Duell had carried out

the NVS assessments for some of the patients at the group. Paul Duell was the principle moderator for the remianing focus groups.

Semi-structured questions were developed to aid the focus group discussions (appendix 4.5 page 261). The rationale for this was to give each group consistency and to ensure that information was collected on individual's perspectives on taking the NVS assessment. An unstructured process was rejected as it was thought this might not capture the breadth of issues associated with completing the assessment. Likewise, a fully structured process was rejected as this could artificially produce outcomes based on the researchers views and biases.

Each focus group discussion was transcribed in full including the introductions and final comments. An intelligent verbatim transcription process was used. Intelligent verbatim transcription is where the transcriber makes an educated assessment on words that are not very audible rather than spending large amounts of time trying to identify the correct word. This decision was influenced by a limited budget to carry out the study.

4.2.10.1 Focus group analysis

4.2.10.2 Analytical approach

As described earlier, a pragmatic methodology underpins this thesis. To answer the aforementioned research questions several different approaches were possible.

The objective was to gain an insight into individuals' perspectives of health literacy assessment in a pharmacy and was not to generate a theory consequently a grounded theory approach was discounted.

Interpretative Phenomenological Analysis (IPA) is concerned with the experience of individuals and the impact the phenomena had on their mental and physical states. It is less concerned with gaining an understanding of the process or the activity itself. Whilst this was a possible approach to take the research question does involve an assessment of the process so this technique was not adopted.

A narrative analysis approach was discounted as a collection of holistic understanding of individuals' personal histories and perspectives was deemed an unsuitable way to answer the research question. Thematic analysis was adopted as

it 'a method for identifying, analysing and reporting patterns (themes) within data' (305).

The analysis described in this chapter is inductive as it uses a 'bottom up' approach of using the data to create the theme rather than starting from a theoretical perspective. It is also semantic in that it is only looking at explicit or surface meanings within the data and does not try to find a hidden inner meaning within the data.

The epistemological stance is essentialist / realist as it reviews the data set and accepts the meaning of the experience at a face value level and does not look to understand the social context within the data.

Three patient focus groups were convened; one focus group consisting of patients with limited health literacy, one with marginal literacy and one with patients with adequate health literacy.

4.2.10.3 Patient selection

All patients who agreed to join a focus group were considered. Pharmacies located in Ipswich and Hadleigh had enough potential participants to generate a focus group so participants in these locations were invited to attend one of the focus groups.

All patients in the focus groups were offered travelling expenses and were given a £20 Marks & Spencer Voucher.

4.2.10.4 Pharmacy personnel selection

The initial plan was to choose pharmacy focus group membership from all pharmacy staff consenting to the study, and have two focus groups with pharmacists and one pharmacy staff focus group meetings. The rationale for keeping the staffing groups separate was to ensure that participants felt at ease and free to speak from their perspective without bringing in the potential dynamics of hierarchical management.

During the study, the low number of pharmacies participating and their large geographical variation required the study plan to be modified. A substantial amendment request was made to the ethics committee to change from pharmacist and pharmacy staff focus groups to pharmacist only interviews. Explanation of the predicted difficulty of arranging focus groups with the small number of pharmacy

personnel resulted in a substantial amendment approval being obtained to allow pharmacists to be interviewed at their pharmacies. Paul Duell interviewed all the pharmacists.

As the primary researcher who is an experienced and well known pharmacist in East Anglia my involvement in the study potentially could add bias. A direct impact was that some of the pharmacists that participated were well known to me and the professional relationship may have influenced their decision to participate in the study. However, the use of interview scripts kept the conversations consistent and the transcripts indicate that they did not respond differently to those I did not know. I did carry out some NVS assessments in one pharmacy so that I was personally aware of the issues of assessing patients, but I have only reported the views of the pharmacists.

4.2.10.5 Data analysis

4.2.10.5.1 Process

The process followed was that recommended by Braun and Clarke (305) and involves six stages:

1. Familiarisation with the data
2. Generating initial codes
3. Searching for themes
4. Reviewing themes
5. Refining and naming themes
6. Producing the report

Familiarisation with the data started by listening to each of the focus group recordings several times and then the transcription was read whilst listening to the recordings.

Printed copies of the transcriptions were systematically reviewed and text highlighted and annotated with initial codes to reflect the subject content. Further readings occurred to ensure a complete set of initial codes were generated.

All of the identified codes were added to a mind map (appendix 4.6 page 264) and the codes were then rearranged to bring together codes that had a similar content.

Similar codes were then compared to identify patterns or themes. These patterns were then allocated a title that reflected the theme.

Once all of the codes had been linked to themes the transcriptions were reviewed again to provide a reality check to the work. The data was shared the qualitative expert of the supervisory team to sense check the original work and to provide feedback on the assessment.

All of the agreed themes were reassessed to identify if any alterations were required and to see if the identified themes were sub-themes of a bigger pattern. If changes were required, then the themes were renamed to more accurately reflect the content of the data.

4.3 Quantitative results

4.3.1 Consent rates

4.3.1.1 Pharmacy consent rate

The figure 4.3 shows both the pharmacy and patient consent rates. Of the 120 pharmacies invited, nine (7.5%) agreed to participate and seven (5.8%) collected data. Three of the participating pharmacies were independent pharmacies and the remaining six were from the same multiple chain (Boots). One independent and one Boots branch were unable to collect any data. Both pharmacies cited insufficient time and staffing pressures as barriers to collecting data.
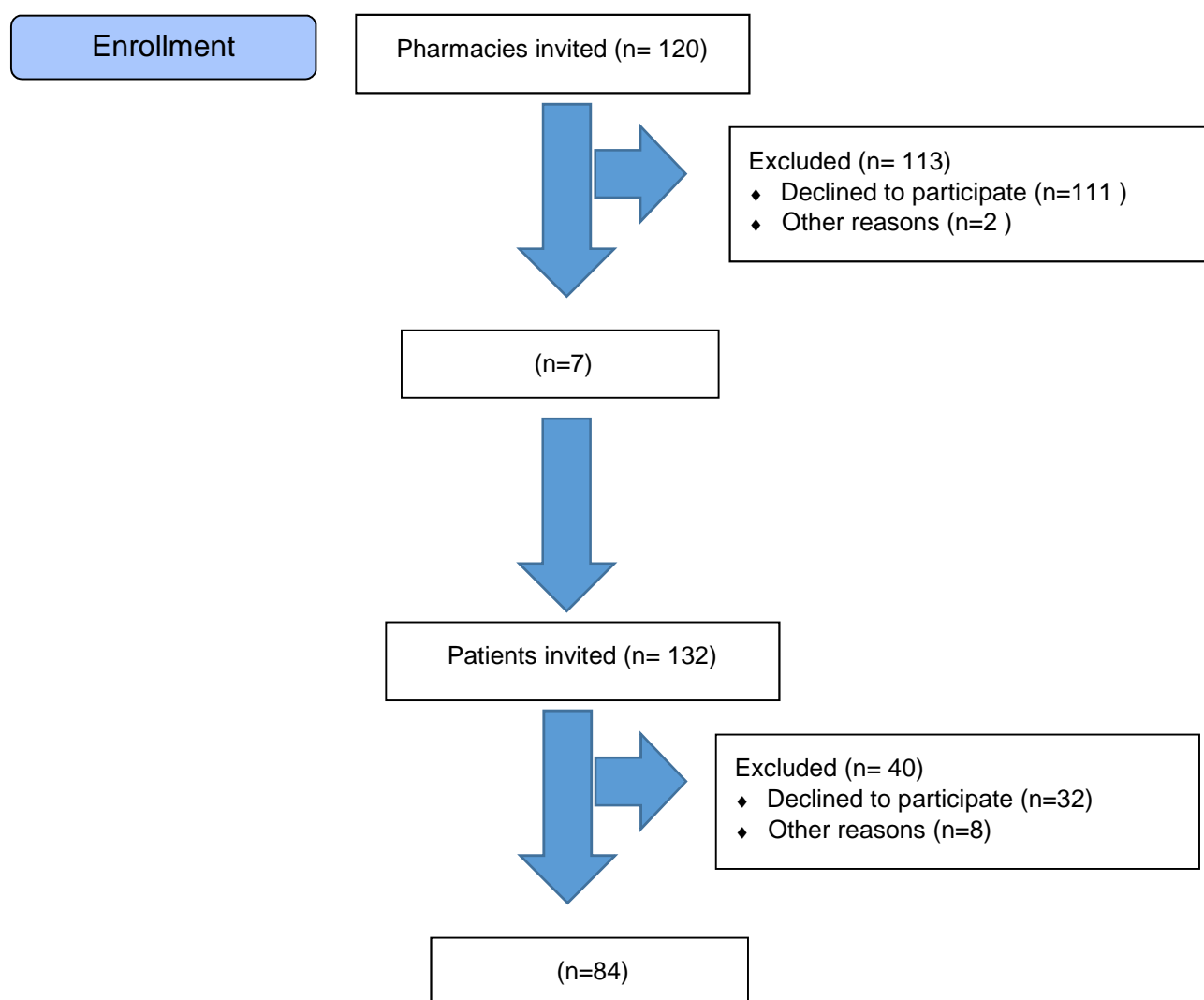
FIGURE 4.3 CONSENT RATE CONSORT DIAGRAM

4.3.1.2 Patient consent rate

Three of the seven pharmacies recorded patient consent rate data as per protocol, on a recording sheet in the pharmacy. From the 132 patients known to be invited to participate, 92 accepted. One independent pharmacy recruited 34.5% (29) of the patients to the study. This pharmacy had an acceptance rate of 70.1% (29/41) compared with acceptance rates for the two Boots branches of 28.6% (8/28) and 30.7% (8/26). Eight patients (8.7%) signed up to the study but did not complete the NVS assessment. Non-completion of the NVS was only reported in two of the seven pharmacies and no written data was collected on the reason for the non-completion.

4.3.2 Age, gender, education level of the participants

The age range of the participants was 38 to 88 years. The interquartile range was 15 years and the median age of the sample was 67. The distribution was negatively skewed but still approximates to a normal distribution.

The gender mix of the sample population was nearly equally divided between the sexes with 51% of the sample female. Both males and females had a similar education profile with a median interquartile range age for leaving education of 16 (3) years for both sexes. Ages, leaving education, ranged from ten to twenty-six years of age and the distribution had a positive skew.

4.3.3 NVS score

Figure 4.4 provides the NVS scores for the sample population. The median NVS score was 4. The scores were not normally distributed with the distribution being negatively skewed, with the skewness more than twice the standard error (skewness -0.54; standard error 0.26). Nearly a third of the sample scored the maximum score of 6 compared with 6% scoring zero.
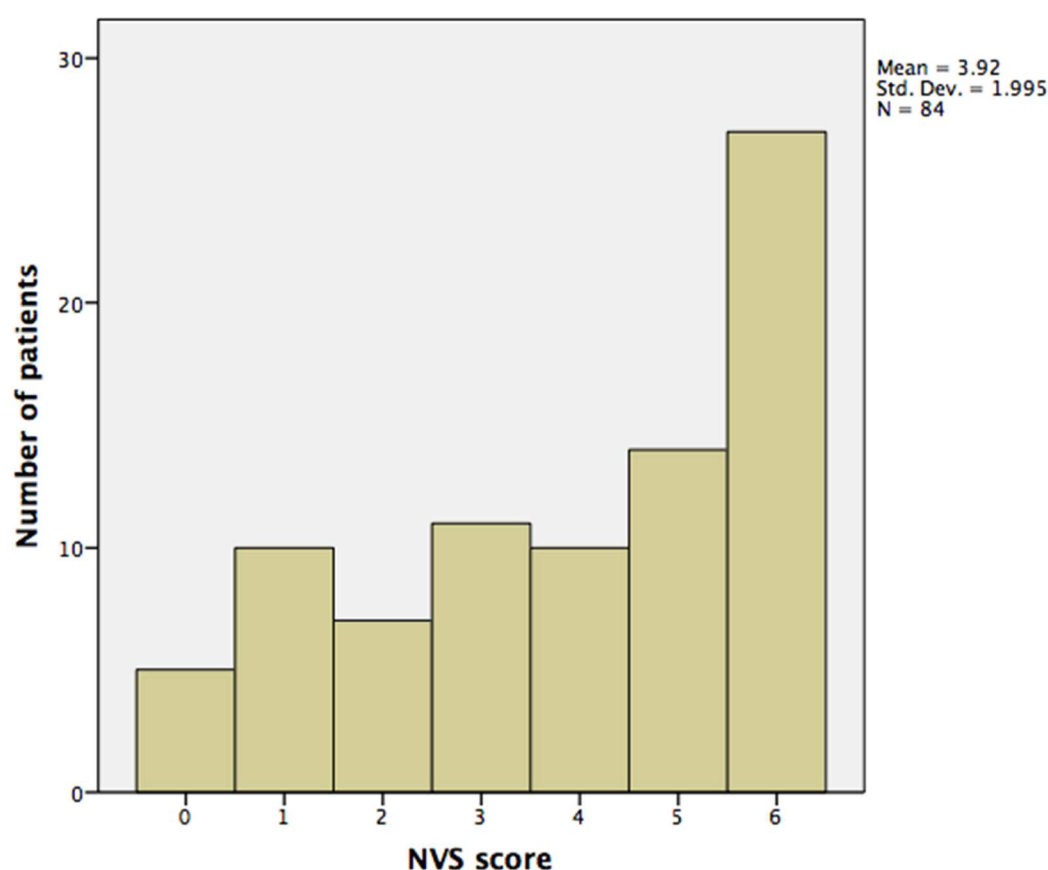
FIGURE 4.4 HISTOGRAM OF NVS SCORE

4.3.3.1 NVS score, age and gender

There was a moderate negative correlation between NVS scores and age of patients with a Spearman's rho correlation of -0.51 (p< 0.001).

Figure 4.5 shows the box plots for NVS scores versus age bands. None of the sample in the 18 to 54 age group had a health literacy score on the NVS below 3 compared with the over 75 age group that had 3 as the mean score. The 18-54 group had one mild outlier (greater or equal to 1.5 interquartile ranges below the lower quartile).
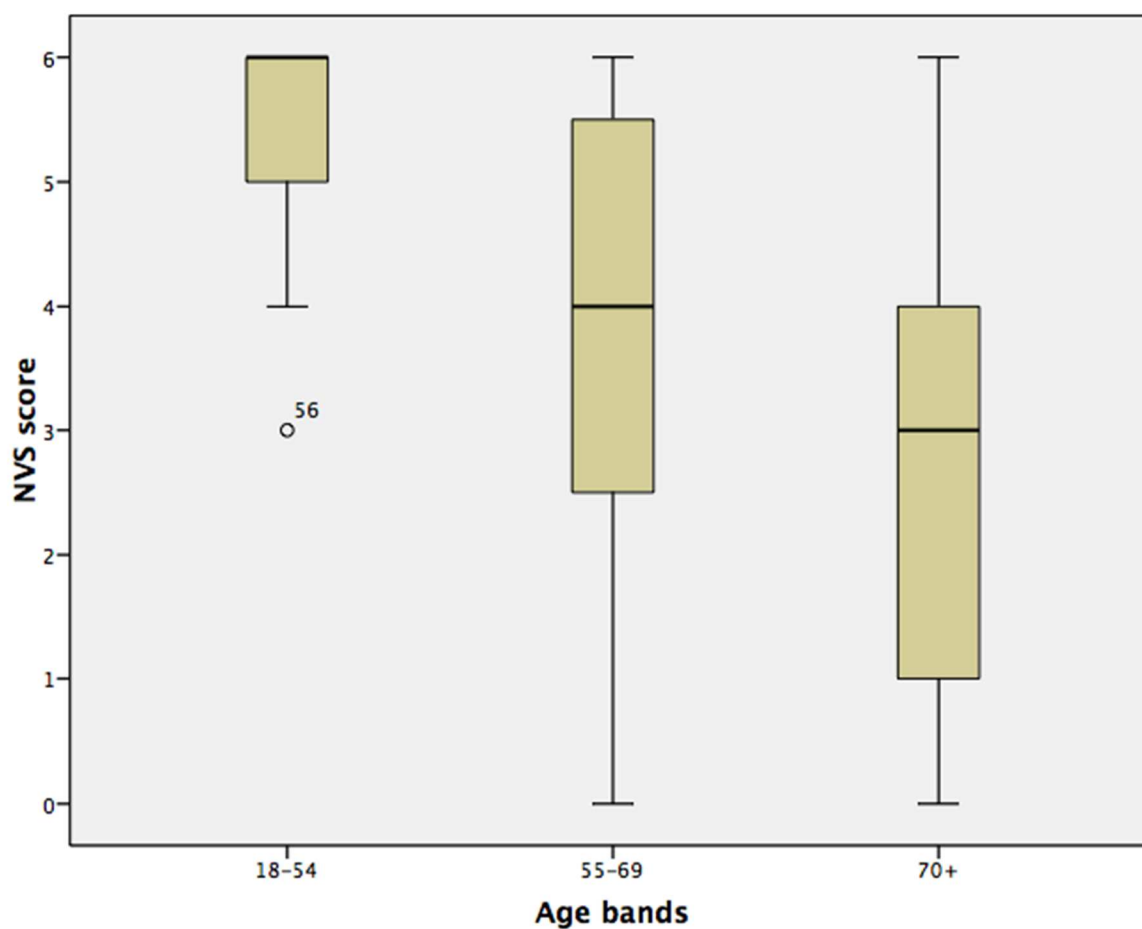
FIGURE 4.5 BOX PLOT OF NVS SCORE VERSUS AGE BANDS

There was no significant difference found in the sample population between NVS score and gender. The Mann-Whitney U value was 785.5 and the significance was p=0.38.

4.3.3.2 NVS score and age participants left education

A significant, moderate positive correlation was identified between NVS score and age of leaving education (R= 0.41, p< 0.001). The correlation was positive indicating that those with a higher score also tended to have spent longer in education.

Figure 4.6 shows the box plots for NVS score and the age the patients left education. The secondary school plot contains individuals leaving school up to and including sixteen years of age; the sixth form plot of seventeen and eighteen year olds and the higher education box plot for ages nineteen and over. The higher education group had one mild outlier below the lower quartile.
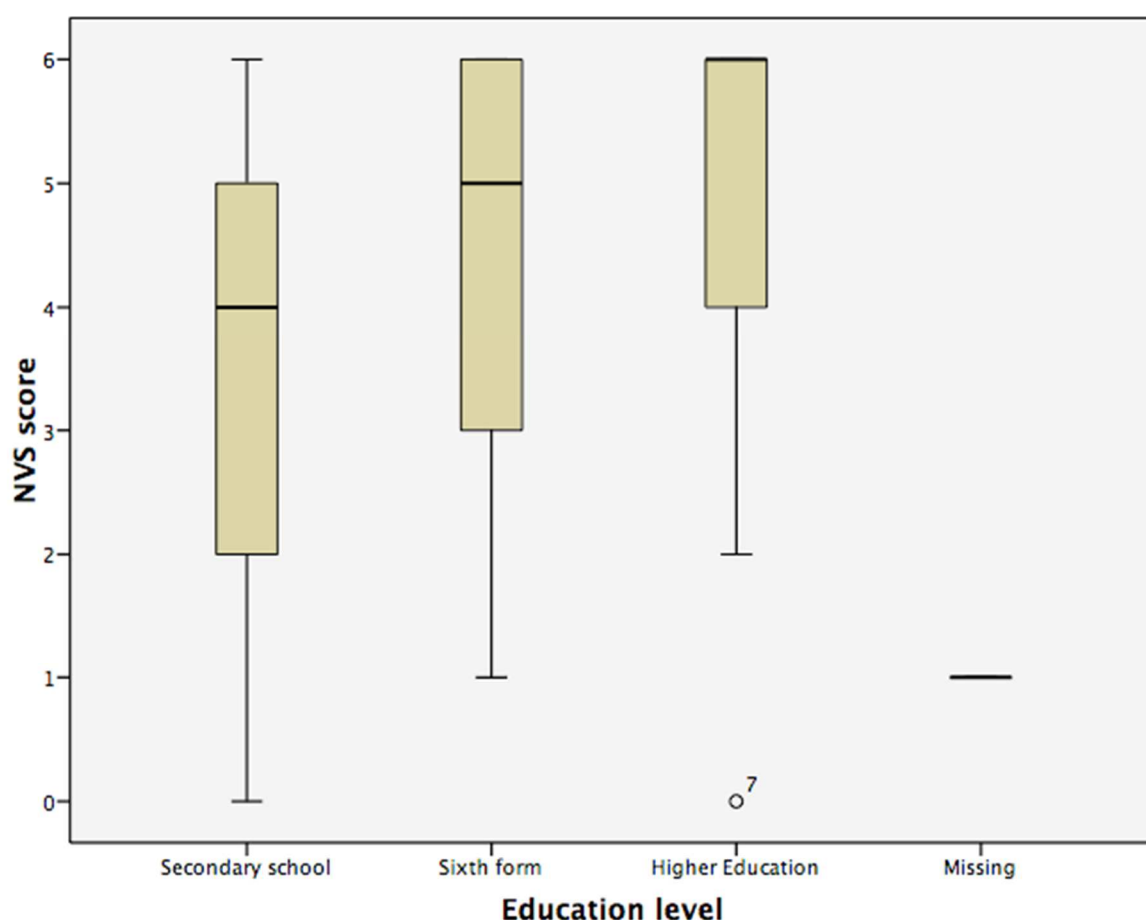
<small>F</small>IGURE 4.6 B<small>OX PLOT OF</small> NVS <small>SCORE VERSUS EDUCATION LEVEL.</small>

4.3.3.3 Time for NVS completion

Data was collected from 83 participants on the time taken to complete the NVS assessment. Nearly two-thirds of patients took longer than 3 minutes to complete the NVS. The median (IQR) was 4 minutes 9 seconds (2 minutes 40 seconds). Completions time ranged from one minute sixteen seconds to ten minutes.

Figure 4.7 shows the variation in the number of individuals obtaining each NVS score depending on the time taken to complete.
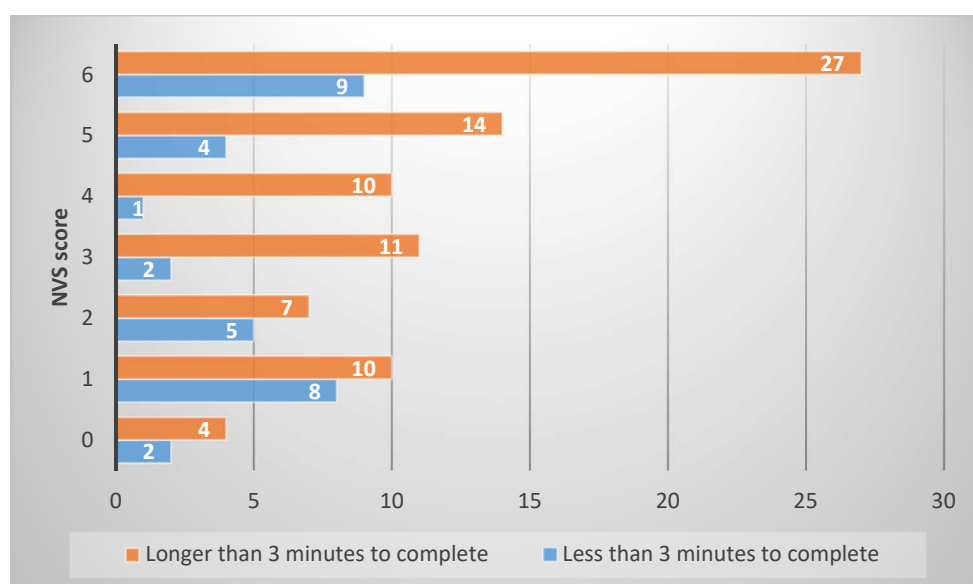
FIGURE 4.7 NVS SCORE AND TIME TO COMPLETE

The median score for those that completed in less than 3 minutes was 3 whereas the score for those taking longer than 3 minutes the median was 5. The NVS score was weakly positively associated with the time taken to complete the assessment. The Spearman's rho correlation was 0.23 (p=0.04).

4.3.4 Health literacy levels

Sixty-one percent of the patients were assessed as having adequate health literacy compared with twenty-one percent having marginal and eighteen percent limited health literacy.

4.3.5 Focus group participation

The lower number, than anticipated, of completed NVS assessments reduced the number of people that had given consent to participate in the focus group. Forty of the 84 patients (47.6%) expressed an interest in attending a focus group meeting. Thirty-three of these lived in the two Suffolk towns of Ipswich and Hadleigh. The remaining seven were scattered across the large geographical county of Suffolk. All the thirty-three individuals living in Ipswich and Hadleigh were invited to attend a focus group meeting. Three focus group events were held, two in Ipswich and one in Hadleigh. In total 10 people attended, five attended a limited literacy focus group, three an adequate health literacy group and two a marginal health literacy group. Only one of the attendees, in the limited health literacy group, was a female.

Using the green, yellow and red cards to indicate good, neither good or bad and bad respectively, two of the ten patients rated the experience of completing the NVS as red; four yellow and four green.

All three patients in the adequate health literacy focus group rated it as a positive experience and the two in the marginal group were ambivalent about the process. The limited health literacy group was spilt with two rating it a bad experience; two ambivalent and one positive.

4.4 Qualitative findings

4.4.1 Experiences of completing the NVS

The same three themes emerged from both the focus group transcripts and the pharmacist interview transcripts. The pharmacist and patient experiences have been combined to provide a singular report for each theme.

The first theme can be described as 'being tested in a pharmacy' which consists of three sub-themes of comparison to an examination; lack of preparedness and surprise; performance anxiety. The second theme related to the 'relevance of the assessment material' and the final theme to the 'relationship structure and support' of pharmacy personnel. Table 4.1 provides information on the participant's sex and patient's health literacy level.

Patient identifer	Sex	Health literacy level	Pharmacist identifer	Sex
M1	Male	Limited	P1	Male
M2	Male	Limited	P2	Male
M3	Male	Limited	P3	Male
M4	Male	Limited	P4	Male
M5	Male	Adequate	P5	Female
M6	Male	Adequate		
M7	Male	Adequate		
M8	Male	Marginal		
M9	Male	Marginal		
M10	Female	Limited		

Table 4.1 Participant demographics

4.4.1.2 Being tested

Within the patient transcripts much of the discussion on their experiences of completing the NVS assessment focused on the theme of being tested in the pharmacy. Within this theme there were sub-themes of comparison to an examination; lack of preparedness and surprise; performance anxiety.

4.4.1.2.1 Examination

The pharmacists in their interviews described their perceptions of patients' views on completing the NVS in the pharmacy.

> *'Yeah, it can be a different reactions from the customer because, as I said from the beginning, it's test and the people who come to us, they are not used for that, to test them'* (P3).

 Pharmacist P1 referred to the fact that they were initially surprised by the NVS assessment as they had assumed it was more interpretative in nature and this was reflected in their views of their patient's perspective.

> *'Well, some of them were, especially with the mathematical side to it, which was more than I was really expected it to be to start with, so I thought it was*

just about interpreting the information rather than... they were like, "Oh, it's a maths test" so that's the general sense that I got from them on it'.

Patient M3 referred to the assessment as 'the quiz'. Focus group member M10 said:

'I felt a bit panicky yeah. And that's what I would be like in any exam I think'.

Patient M4, in response to patient M10, continued to discuss the testing theme.

'*I was talking to a guy yesterday who had failed a minibus test and he said, "I hate exams!" I said, just put in your head and say you're gonna do it". That's what you gotta do, innit'?*

The patient also said, when asked about completing the assessment,

'*I just thought plod on hit or miss, I don't care'.*

Pharmacist P2 raised concerns that the timing of the assessment added additional stresses to the patients and added to the idea of being tested

'the idea of them being timed, they felt that they were against the clock'.

4.4.1.2.2 Lack of preparedness and surprise

Patient M9 describes their initial shock of being asked to complete an assessment of their knowledge.

*'I was a little bit apprehensive about it but when I got into it a little bit that weren't too bad, but I weren't sort of jumped into it and I didn't say no, I just thought, well, I'll go into it with caution 'cause the I didn't really know how to answer the questions right away but then when I began to analyse them and look at it and chat… **the pharmacist** explained a few things, they weren't too bad. So, I did go into it a bit cautiously, so I wouldn't say I wouldn't go in and go in fully confident 'cause I'm not fully confident with it obviously'.*

Patient M2 said:

'The thing is we all went in there but none of us knew what we were gonna do!'… 'if we could have took it home with us the night before we'd have got better results'.

Another Patient M8 stated:

> *'Well I think I'd be a bit happier the second time because you'd already done it the first time, you've got a little bit of what to expect'…. 'Have you got ten minutes to spare? and that's caught you unawares, you see'.*

Pharmacist P2 who spoke about how they were unprepared for the difficulty for patients to complete the assessment and their desire to be able to communicate effectively.

> *'The fact that something that I would say was easy and had probably been learnt through years of school in terms of maths I thought was straightforward, actual older people and younger people got questions wrong that I wouldn't expect, so that was my biggest surprise, and somebody I would communicate on a just talking about medicines level where they'd understand their medicines, would find this sort of thing hard. I didn't expect that when their speaking capability is very good and their intellectual… what I can gather from them was straightforward and good but in terms of the test was more difficult'.*

Pharmacist P2 raises an interesting perspective on how the NVS provided them with a different insight into a patient's level of understanding of health-related information and how this differs from what they usually use to assess competency.

4.4.2 Relevance of the assessment material

The subject matter of the assessment – assessing nutritional information had a perceived influence on the overall belief of the value of the process for the individuals. There were two differing sets of views. Those with more limited health literacy ability focused on the lack of importance of calories to them. Patient M4 stated:

> '*When you look at me, and how I've been clapped together like a board all my life, whose worried about calories? That's exactly why I read it. I don't have to bother. To me it was a waste of eight questions or however many there was'.* On further questioning M4 stated '*basically, as I said before, when he asked the question I hadn't the faintest idea, hadn't the faintest idea. That's my answer all the way down, and as I said, I don't have to worry now, I don't read*

my calories, I don't have a problem. I don't pile the pounds on, not even since I retired'.

Justifying the lack of importance of the nutritional information helped to ease, for this participant, the tension of being asked questions they could not answer but it did not fully alleviate the feeling of intellectual failure for others. M10 said:

'*To be honest I'm a bit thick. I didn't understand a lot of it 'cause I don't understand calories. I don't count calories. I do watch what I eat in the way of carbohydrates and fat, but calories I don't understand. So, I was a bit dim'.*

Patients that had adequate health literacy spoke of the educational value of concentrating on assessing nutritional information and considering more how to build it into eating healthily.

'It was an education to me. Thinking oh yeah, perhaps I do need to think more about when I see something or just like that, and I do now actually look at packets at home and think ooh, yes, I can't have that, or I'll have that but only have a small amount. So, it was quite useful in that sense'. (M7)

The conflicting challenge of following healthy lifestyle advice and being able to do this in a real-life environment with time constraints was raised by patient M5.

'*You sometimes think to yourself, should I eat this, should I not eat that and things like that, and they keep saying to you, you should look on the sides of packets when you are looking at things and things like that, but if you done that you'd be in Sainsbury's for eight hours. If you do your shopping "oh, don't know about that" and took a calculator and that on there, you'd be in there way too long. But the general stuff, yeah, I did find it useful'.*

One individual stated that completing the NVS had changed their perspective on the role of the pharmacist in providing nutritional and healthcare advice.

'*I've never had that in my life, somebody actually saying, "here's the information you need" and why it's important. I don't want it regimented 'cause it's a free choice, but if I'd had that many years ago I may not have the issues or problems that I face now, I may have been able to control it earlier. So, I*

found it rather a… road to Damascus I suppose, a conversion, but had that been … in that format as well, somebody just taking that 20 minutes, saying, "read this, what does it mean to you?" (M7).

4.4.3 Relationship structure and support

The importance of the relationship with the participant's regular pharmacist was expressed by the focus group members. During the focus groups, they spoke about the impact of the relationship with the pharmacist had on completing the assessment. The dynamics of the existing relationship with the pharmacist was apparent and it played a major role in the compliance of the individuals to complete the assessment.

Individuals in the focus group spoke of how the pharmacist eased the pressure they felt in completing the NVS assessment and had reassured them with the task**.**

'Yeah, I think he actually made it easy the way he done it, easier than what a lot of people would. Well, he's such a nice bloke, he'll approach you, he doesn't pressurise you into it, he gave you time to think about it, 'cause I tend to panic a bit if I get too much in my head at once, I'm not a brainbox, and I didn't, I just answered them quite quick, I can't see how that would've been any better, no'. (M9)

Individuals in the limited health literacy group spoke highly of the pharmacist who owned the pharmacy and referred frequently to how he was willing to help them, consequently they felt compelled to reciprocate.

'*I think I got involved 'cause **name** down at **pharmacy name,** he asked me, and he's such a nice bloke I'd do anything for him' (*M2). Participant M2 added later '*it's no good people moaning about things unless they put something in to try and put it right. If this is going to help them people like **name** down the road I'd do anything, yeah'.*

Individuals spoke of how the importance of reciprocating to the pharmacists perceived kindness allowed the individual to deal with an unpleasant situation as they were happy to give something back. The demonstration of loyalty and giving outweighed the negative experience to create a more positive outcome. Patient M4,

who used a green card to demonstrate their rating of completing the NVS assessment said:

> '*I just done it for the sake of **Pharmacist name, ...** You know what I mean? (general agreement) I thought that was… I done it for **names** cause'.*
> Interviewer – '*So you were fine with it?'*
>
> '*Oh yeah, didn't worry me. I been stopped by the police quite often!'*

Patient M2 (amber card) said:

> '*Do your best, don't you? That's what you gotta do. Yeah. Make the best of a bad job'.*

The perceived difficulty of the test created a tension for the pharmacists who were uncomfortable in having their patients struggle.

> '*If the customer doesn't have the level of understanding, I definitely have to change it, but some of them was really good and understand quickly, so it depends if they understand it. I didn't move on until they understand fully what is the question'* (P5).

The importance of putting the patients at ease and reassuring them was mentioned.

> '*Some of them, I tried to make it funny so I tried to be… but when I done this survey I tried to make them comfortable, so we had a little bit of fun on it, just make sure they don't feel pressure and they do just try to understand the question, try to answer the question'* (P5).

Another pharmacist (P3) commented on the question order.

> '*Yeah, I kept exactly to the order. The only thing I found with that is most of the people struggled to understand the first part, which is the four servings. Once they understand that, they can answer all the questions easily, but therefore I think… my first or second I did explain that because I can't struggle the people in the beginning, they couldn't understand four servings, so I said this is four servings, this one like this… so it's a bit easier'.*

Pharmacist P1 described the problem they experienced of patients struggling to imagine hypothetical situations.

'A few of the slightly older people were like, they heard it wrong when I'd say, "now imagine yourself as such-and-such a person that's allergic to this", and they'd go, "I'm not allergic to anything though". And it's like, "hypothetically you're going to imagine that you are" …. And then obviously, they'd get a misled from that'.

Carrying out the NVS assessment in the pharmacy changed the usual dynamics between the pharmacist and the patient. The patient was suddenly faced with a situation where rather than getting reassurance from the pharmacist they were being challenged and asked to make their own unsupported decisions. Most of the pharmacists interviewed struggled with this changing dynamic and looked to alter how they could provide reassurance during the assessment process. Pharmacist P5 perceived that their patients were frightened by this new experience,

'because I know, mostly I know them so just… maybe just scared, they were scared or different situation'.

4.4.3.1 Pharmacy staff support

The study was designed so that pharmacy support staff could complete the NVS assessment leaving the pharmacist to carry on with their normal daily activities. This did not happen in most of the assessments and was a surprise outcome to the study. The pharmacists described in their interviews a conscious decision to override the study protocol to manage the work flow within their pharmacy. They described their rationale for completing the assessments themselves rather than delegating to their staff.

'Yeah, it's definitely something that I would have thought that they could do (sic staff), they would have been fine doing it. It's just in terms of the staffing roles that I have available, it's sometimes not consistent with the person that's there, so it's easier for me to lead the study and to complete rather than having a different person every couple of hours on the till' (P1).

A pharmacist who worked for a large company raised concerns over the current workload of their staff and their worries over their ability to manage additional work.

'With my staff is …I have only two and they are really, really busy, they have to do a lot of different things, so I thought I will take the things, it's better than

> *give them more extra things and they cannot tell me "I can't do this because I do this one". So, I took it myself (laughs)'* P3.

This view was also reported by pharmacist P5

> *'Yes, it seems to me they don't have time to do it…. too many things going on and that is part of our job really'.*

The issue of professional responsibility was also picked up by pharmacist P2 when asked their thoughts on involving their staff.

> *'It was a possibility but I thought as I'd signed up to the study I thought it would be better if I conducted it'.*

4.5 Quantitative discussion

4.5.1 Pharmacy and patient consent rate

The pharmacy consent rate obtained in this study was towards the lower end reported in the literature (306, 307). The pharmacy chain Boots has a policy of deciding at a national level whether it wishes to participate in the study and if so which of its pharmacies it wishes to participate. Boots has 22 pharmacies in this area and it allowed six to participate. The central decision making consequently has a direct impact on the percentage recorded for the consent rate.

The actual obtained consent rate of pharmacies was significantly less than the original estimate of twenty-two pharmacies. The initial invitation to participate resulted in no pharmacies agreeing to participate. Increasing the remuneration package from receiving a gift voucher to £15 per patient participant improved the number of pharmacies agreeing to participate. A systematic review of pharmacists' involvement and attitudes toward pharmacy practice research identified that the most frequently reported barriers to carrying out research included insufficient or lack of funds (307). Other factors identified were lack of time and workload and internal support (staff holidays, sickness and corporate). Verbal feedback from the pharmacies that originally consented to the study but were unable to recruit patients indicated that existing workload, pharmacist absences and lack of project prioritisation within the pharmacy when the primary pharmacist was absent were major reasons for not starting the study. A qualitative focus group study (306)

identified the importance of the pharmacist's perception of the purpose of the research. Hence, whilst 32 to 48% of UK pharmacists report to have an interest in participating in research (308) there is a big difference in the number that commit to research. The variation between interest and participation was cited in the factors described in the systematic review.

Not all the pharmacies collected information on the number of people that declined to participate and consequently, the recorded patient consent rate is only an estimate of the true level for this population sample. No explanations were provided for the rationale for not complying with the protocol. In the pharmacies that did collect this data there was a wide variation in consent rates. The variation in consent rates reflects the variation observed in previous studies (309, 310). Different reasons have been identified for this variation in consent rates, such as age and gender of patients (310, 311).

The patients that failed to complete the NVS assessment in the sample were in a pharmacy that demographically has a high proportion of older residents and is in a socially deprived town. As described in the introduction of chapter 1 there is a body of literature that suggests that those with limited literacy try to hide their perceived inadequacies and opt out if possible from situations that they feel may show their deficiencies. Hence, the expectation would be that, if faced with being tested with the NVS they might opt out of the assessment, to hide their actual ability level.

4.5.2 Age, sex, education level of the patients

The median age of the patients in the sample population was consistent with the older profile of the customer base of community pharmacies (312, 313). The older age of pharmacy customers is predominately due to the increasing need for medication to help manage an individual's health as they get older and therefore as age increases so does the need for pharmacy services (314). Whilst the findings may therefore be generalizable to UK community pharmacy users, it is less so to the general population where the median age is much younger.

The sample population that completed the NVS assessment was nearly gender balanced which contradicts national marketing analysis of community pharmacy users that indicates females are more regular visitors and service users (313). This analysis includes accessing pharmacies for retail purposes as well as medication

supply. As described in the previous section on age the need for pharmacy services for males increases with age, so whilst younger males have less need to shop in a pharmacy or collect prescriptions for medication this changes as they get older. The lower proportion of females within this study may make the results less generalisable to the UK population.

The median age of the patients in this sample reflects a generation that predominately left education after secondary school. This was particularly true for the females of this generation. Changing educational policy over the last eighty years has impacted on the minimum school leaving age resulting in an increase in school leaving age in the younger aged participants.

4.5.3 NVS score

The NVS allows individuals to get a third of the questions wrong and still be classified as having adequate health literacy. Consequently, the NVS assessment mechanism is based on individuals failing to answer a large percentage of the questions. The percentage of incorrect answers is higher, compared to longer health literacy assessment instruments, due to the lower number of questions in the NVS. Therefore, whilst the shortness of the assessment is an advantage by limiting the number of test questions, the individual may be more aware they are struggling to accurately complete the test and it could impact on their confidence and influence the acceptability of it as an assessment instrument. If the aim of any assessment is to identify those that are in the greatest need of health literacy support, then the assessment requires the individual to get all answers wrong or a maximum of one question right. This differentiates the NVS from other assessment instruments where the limited health literacy level is not so pronounced within the testing mechanism and is less recognisable to those taking the test.

4.5.3.1 NVS score and age, gender and education

The positive correlation between NVS score and age was consistent with previous research (315-317). There was no correlation found in the sample population between NVS score and gender indicating that the null hypothesis of there being no difference between the NVS score and gender was likely to be true for this sample. However, the sample size obtained may be too small to detect a statistically significant difference that does exist in the sample population. Other studies (318-

320) have indicated that there is an association with females having higher health literacy ability than their male counterparts. The study of young adults in Guatemala (320) assessed health literacy using the NVS and identified that females were significantly more likely to achieve higher scores. As the thesis study is a feasibility study the lack of any association could be due to the fact that the study is underpowered to detect any association or the sample may not be a true reflection of the wider population.

The study found that NVS scores were moderately correlated to the age participants left education indicating that these results was unlikely to have arisen by chance (assuming the null hypothesis to be true). This supports previous studies (315, 321, 322) that identified a similar correlation. Other studies (321, 323-325) have indicated that there is a stronger association between level of education and NVS score than between age and NVS score whereas this was not found with this sample. This could be due the sample size being too small to detect the effect size reported in other studies or that this sample population is not a true reflection of the wider population.

4.5.4 Time for NVS completion

The literature (89, 326-328) indicates that the NVS can be completed in under 3 minutes but no there was no literature reporting what percentage of participants could complete it in this time. Hence, an important characteristic of this study was to measure the time taken to complete and to see if the 3 minutes was a realistic possibility for pharmacy patients. Completing within five minutes was, as previously described in Chapter 2, used as an indicator of the suitability of health literacy assessment instruments. Consequently, this feasibility study set out to check that in practice that it could be completed in the indicated time. The extended time requirement identified in the study was a surprising outcome being greater than a three-fold increase in the standard quoted time.

It is not however, the first study to identify that some patients may require longer to complete the NVS assessment. A previous study reported that the average time for completing the NVS was eleven minutes (172). The study reported that 62 elderly African American (mean age 73.2) were assessed and that the time taken to complete ranged from 6 minutes to twenty-eight minutes to complete.

The median completion time, within the feasibility study, was greater than the suggested 3 minutes for the sample population but within the 5- minute limit set in the systematic review. In terms of feasibility of use within a pharmacy the extra minute in the median time does not necessarily limit its potential use. However, the upper time range, if this was a true reflection of the upper time limit to complete the NVS, is of a concern and could make its use unfeasible in a busy environment. A study of patients in an American emergency department (329) dismissed the use of the NVS in practice due it taking just over three minutes to complete as the authors deemed this too long for use in an emergency department.

The NVS is used as a commercial health literacy instrument by Pfizer in the USA and the guidance, for healthcare professionals, within the tool kit states;

> 'The average time needed to complete all 6 questions is about 3 minutes. However, if a patient is still struggling with the first or second question after 2 or 3 minutes, the likelihood is that the patient has limited literacy and you can stop the assessment' (330).

If the primary objective to assessing health literacy is to identify those with limited health literacy, then this guidance would increase the number of false positive results obtained by assessing health literacy using the NVS in this manner.

The Pfizer guidance is a very different approach to that used in research using the NVS where this methodology has not been described in studies using the NVS. It is unclear where the evidence for 'the likelihood that the patient has limited literacy' comes from to support this recommendation and this is not supported by the sample in this thesis study (see next section). It does raise the question whether it is appropriate to set a time limit for completion of the NVS as a standardised approach to its use and this would require further research to answer.

4.5.5 The associations between NVS score and time for completion

There was a weak positive association between NVS score and the time taken to complete the assessment. There was, however, a 5% chance that a type 1 error may have occurred that is in fact the null hypothesis was true and there is no association between completion time and NVS score. Further investigation is required to assess

if the result obtained is a true reflection and identify if the positive correlation between completion time and NVS score is a population based outcome or specific to the sample population. Further research could also assess the impact this could have on the accuracy of health literacy assessments when no time limit is set to complete the NVS assessment.

4.5.6 Health literacy levels

The present study provides the first report of health literacy levels for patients attending community pharmacies. Two studies (190, 331) have measured health literacy ability in the UK using the NVS. The first (190) validated the NVS for use in the UK. It identified, in its sample population, that the mean NVS score was 3.47 (compared with 3.92 in this study).

A 2016 cross sectional survey, by Protheroe et al., of 972 residents in a town of high deprivation in the North of England (331) reported 28.5% to have limited health literacy; 23.5% marginal and 48% adequate. The mean age of participants was 48.7 years. These figures identify a greater percentage of the sample population lacking adequate health literacy compared to the thesis study, but it is acknowledged that this study sample was much larger which prevents direct comparison. An earlier study (332) when assessing education levels across England identified a variation between the North of England and the South, where the South had higher education obtainment levels compared to the North of England.

An earlier UK interview survey (146) used TOFHLA to assess health literacy in the UK. The 759 participants were younger than the sample population within this thesis study as the mean age was 47.6 years. Only 11.4% had either marginal or adequate health literacy. The study design incorporated a screening process for the sample population. Screening involved assessing visual acuity and basic reading skills and only individuals that got three or more of the four screening questions correct were assessed with the TOFHLA health literacy instrument. Forty individuals were excluded from taking the TOFHLA.

4.6 Qualitative Discussion

The qualitative perspective obtained provides some valuable insights into the complexity of issues regarding the use of the NVS in community pharmacies. The

first theme developed, that of testing patients in a pharmacy, raises concerns over the possible future use of the NVS in this environment within everyday practice. Baker (333) argued that the NVS 'may feel more comfortable and natural for patients than word lists or other instruments that seem more like academic test of reading ability'. However, the reported perspectives of patients in this chapter, do not support Baker's view that the NVS would not be perceived as a test. Other researchers have reported patient perspectives on using the NVS in a non-pharmacy environment (334). The results indicated that 99% of the 179 patients did not feel shameful in completing the NVS unfortunately the issue of being tested was not one of the questions asked. Shame was not a word used by patients within the chapter study and highlights that perceived concerns with NVS participation is more complex than previous studies have indicated.

Testing patients within community pharmacy is a novel concept and based on the experiences described alters the patient-pharmacist relationship. Managing the changing dynamics adds other barrier to the difficulty of changing existing practice so that health literacy assessment becomes standard practice.

The study design, deliberately, played down the fact that the individuals health literacy was being tested and this was reflected in the comments provided on the sub-theme of lack of preparedness and surprise. The rationale for this approach was to minimise the possibility that individuals with limited health literacy would refuse to complete the assessment. Collecting the perspectives of individuals who had completed the NVS was deemed an important outcome of the study. Because of this approach, it captured the perspectives of individuals that suddenly found themselves having to complete the NVS which was the intention within the study design. An additional consequence, of not making the study objective of assessing health literacy explicit was the lack of clarity for the rationale for asking questions around nutrition (sub-theme relevance of assessment the material). Consequently, everyone came to their own conclusion on the relevance of the task.

This unexpectedly, produced comments from those with adequate health literacy about their perceived benefits of highlighting nutritional information as they were forced to consider nutritional information and analyse the impact different activities had on dietary consumption. If assessing health literacy with the NVS became

standard practice, then the purpose of NVS questions would be known and this could take away the positive benefits described and increase the concerns reported concerning performance anxiety.

The remaining theme of the relevance of the relationship structure and support with the pharmacy personnel provide accounts of how it offset some of the general negativity reported around the theme of being tested.

It is not clear to what extent the additional pharmacist support, during the NVS assessment impacted on the health literacy score achieved by the individuals. The time taken to complete the NVS assessment varied from 1 minute forty-four seconds to ten minutes and this variation may be linked to the level of pharmacist intervention. It should not be forgotten that there is only a maximum of six questions in the assessment. The final question only being asked if the fifth question is answered correctly and is a brief explanation of how they came to the answer to the previous question.

Pharmacist P5 mentioned their determination to see a question completed before moving on to the next and trying to reduce the focus on competing against the clock. This does raise the question if a time limit should be set for NVS assessments to ensure that a consistent approach is taken and allow comparison of results in different environments. As this study only used the NVS to measure health literacy ability it would require additional research to find out if pharmacists would feel obligated to provide similar levels of support to patients having their health literacy tested using other health literacy assessment instruments.

This study also raises the question of whether the pharmacist is an appropriate person to carry out the NVS assessment and whether they can carry it out in an objective way without being influenced by the changing dynamics of the pharmacist-patient relationship.

One aspect of this study sample that differs from the wider community pharmacy population in the UK is that all the pharmacies that participated in the study had a pharmacist who had been working at that pharmacy on a full-time basis and had the opportunity to develop the important pharmacist-patient working relationships described by the focus group members. This is not the case for all pharmacies and

any point in time there will be many pharmacies that operate by having different locum pharmacists in the pharmacy each day. Similarly, whilst many patients prefer to use just one pharmacy on a regular basis some prefer the flexibility of accessing numerous pharmacies, on different occasions, depending on their circumstances. Both factors mean that not all community pharmacy users in the UK will have developed the pharmacist-patient relationships that were described by the focus group members as being important in their decision making on the value of completing the NVS.

4.7 Summary

The feasibility study adds to the existing information on the suitability of using the NVS in a routine healthcare environment. The impact on the pharmacist / patient relationship identifies a major barrier to adding to existing practice and the next chapter reports an alternative hueristic approach to assessing health literacy.

Chapter 5

Heuristic assessment of health literacy

5 Hueristic assessment of health literacy

5.0 Introduction

Chapter 4 indicated that the NVS is unsuitable for use in standard care and that a simpler diagnostic method was required if health literacy assessment were to be implemented into current practice.

5.1 Study to assess a heuristic assessment of health literacy

5.1.1 Heuristic study overview

The NVS was used as the 'gold standard' research assessment instrument against which indicators described in section 1.2.6 in Chapter 1 were assessed to identify if a heuristic health literacy instrument can be created. It follows a pragmatic methodology in that the objective was to create a 'real world' solution to health literacy assessment that is non-test like and can be fitted into everyday practice. The methods used in this study build on those used in the previously mentioned study in 4.2 for assessing the feasibility of the NVS instrument in pharmacy practice. Modifications were warranted due to specific outcomes observed in that study.

This study also had two distinct phases. In the first phase, as shown in figure 5.1, a quantitative assessment, by pharmacy support staff, of patient's health literacy ability using the NVS instrument and the subsequent assessment, by a pharmacist, using predictor cues and the comparison of the results obtained.
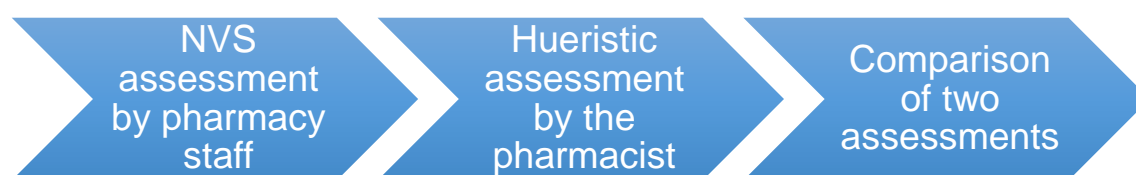
FIGURE 5.1 FLOW DIAGRAM OF QUANTITATIVE PHASE

The second phase was a qualitative analysis of interviews with the pharmacists that explored their perspectives of using a heuristic assessment of health literacy and how they came to their decisions on their observations and assessments.

5.2 Research questions

The primary research question to this thesis is 'how can health literacy be assessed in a health care environment'? As previously discussed in chapter 1 universal precautions is advocated instead of assessing health literacy due to concerns over upsetting patients by testing their ability in a health care setting. The aim of the heuristic study is to develop an alternative health literacy assessment that does not overtly test the patient's ability. Hence, the heuristic study asks the question 'can health literacy be accurately assessed by heuristics in a community pharmacy?' A quantitative methodology is used for the validation of a heuristic diagnostic instrument to assess health literacy. This allows for statistical analysis of the data which can give an indication of the generalisability of the findings.

Additional questions were developed to answer the aim of the study. These were:

- Will pharmacies be willing to assess health literacy in pharmacies?
- Will patients consent to complete the heuristic assessment?
- Are the indicators correlated to NVS score and levels?
- Can pharmacists accurately assess health literacy using heuristic indicators?
- Which are the best indicators to use to assess health literacy?
- Are the indicators better at identifying limited health literacy than adequate health literacy?

Additional questions were generated to provide a community pharmacy perspective on health literacy research.

- Are age, sex or educational levels confounders of health literacy?
- What is the level of limited health literacy in a community pharmacy setting?

A secondary question within the study was "how do pharmacists assess health literacy heuristically?" A mixed methodology is used to answer this question. A quantitative approach is used to assess the accuracy of the pharmacist's decision making skills and a qualitative approach used to gain an insight into how they made their decisions and on what evidence they based it on.

5.3 Evidence of a diagnostic solution

Section 1.2.6 in Chapter 1 reviewed the existing literature relating to medicine taking and health literacy ability. It demonstrated that limited health literacy impacts on medicine taking behaviour and on the associated knowledge of individuals regarding their medicines. Evidence was provided to indicate that there were a number of indicators or markers of limited health literacy that could be used as either an assessment of health literacy or as part of a suite of markers.

The seven indicators were:

- Poor recall of medication name, purpose, dosage and frequency
- Poor recall of verbal instructions
- Poor recall of written medicine information
- Limited use of medical terminology
- Not seeking new information
- Not asking questions
- Time required to sign their name

Each of these indicators can be potentially assessed in a community pharmacy environment depending on the level of interaction with the patient. There are numerous opportunities within existing pharmacy practice to observe these indicators in a natural way that individuals would not perceive to be any change to existing interactions with the pharmacist. Opportunities include:

- Medicines consultation
- Over the counter prescribing
- Repeat dispensing
- Public health promotion
- Medicines Use Review
- New Medicine Service

5.4 Methods

5.4.1 Pharmacy identification

The pharmacies in this study were in the Clinical Commissioning group that covers North East Essex. A different location was chosen so that different patients and pharmacists were involved. The location was more local to the primary investigator so that it would be easier to provide support to the pharmacies and be able to visit more frequently. As previously described in 4.2.10.4 the relationship of the primary investigator to some of the pharmacists may have influenced their decision to participate.

As in the previously described study NHS choices and the local Pharmaceutical Needs Assessment were used to identify all the pharmacies that were in the CCG area. Distance selling and appliance pharmacies were excluded from the list as they would not be able to use all of the indicators under investigation.

5.4.2 Pharmacy recruitment

All of the non-Boots pharmacies in the CCG area were sent an expression of interest letter. Boots head office was contacted directly and the study submitted to their research group for approval for their branches to participate. Non-Boots pharmacies that completed the expression of interest form (appendix 5.1) were asked to provide information to aid the selection of the pharmacies. The rationale for the request for each of these items of information is described below. It falls into two main categories; to minimise bias in the pharmacy selection and to improve active participation. The information required was:

- How long had the pharmacist been qualified
- How long had the pharmacist worked at that pharmacy
- Pharmacy geographical ward
- Did the pharmacy have a second pharmacist
- Did the pharmacy have at least one full time equivalent (FTE) member of staff or at least two 0.6 FTE
- Participating in Medicine Use Reviews and New Medicine Service services.

The role of intuition in decision making was discussed in chapter 3. This thinking indicates that pharmacists with more experience may have developed a higher level

of intuition and therefore may be more effective in their heuristic decision making. Ensuring that there is a variation in the length of experience of the pharmacists in the study allows the assessment to be tested with pharmacists at different levels of intuition development.

The expectation is that the longer the pharmacist has worked at the pharmacy the greater the likelihood that they know their patients better and the greater the chance that any decision made on health literacy ability on an individual may be based on prior knowledge rather than just the assessment during the study. Whilst knowing this information may not remove this potential source of bias it does allow the pharmacy selection process to choose pharmacies to provide a variation between participating pharmacists' length of time at the pharmacy.

North East Essex is a diverse geographical area that contains the London commuter town of Colchester and the coastal towns of Clacton on Sea, Frinton on Sea and Harwich. The coastal towns have a higher proportion of retired residents compared to the larger town of Colchester which is below the national average for elderly residents. There is also a mixed range of deprivation in the area with Jaywick being one of the most deprived areas in the country and some wards in Colchester some of the most affluent.

Ideally each selected pharmacy should see all health literacy abilities on a regular basis. The concern was that if a chosen pharmacy was in either a very affluent area or a very deprived area that the representativeness heuristic would be used to decide an individual's health literacy ability. The representativeness heuristic described in chapter 3, postulates that decision making is swayed by the ease with which similar characteristics can be recalled from past individuals. Instead of fully evaluating the evidence a cognitive bias and heuristic approach is taken to make the decision which can lead to errors being made. Consequently, the preference would be for pharmacies that are likely to have patients of all health literacy abilities regularly using the pharmacy.

Pharmacies have been historically run by only having one pharmacist present at any time. This practice has started to change in the last decade with busier pharmacies having a second pharmacist on a part-time or full-time basis. A second pharmacist

present may facilitate participation in the research project as work load can be shared between the two pharmacists.

The qualitative work reported in chapter 4 identified the issue of having only part-time staff working in the pharmacy and how this negatively impacted on participating or successful recruitment by the participating pharmacies. Consequently, the expression of interest form asked if the pharmacy if it had any full-time staff working in the pharmacy.

Medicine Use Reviews (MUR) and the New Medicine Service (NMS) are advanced services within the pharmacy contract. They both provide excellent opportunities to assess the heuristic approach to health literacy measurement. Pharmacies that are not providing these services would have fewer opportunities to carry out the required assessment.

5.4.9 Selection criteria

The project research team meet on two occasions to collectively discuss how the selection criteria would be used of to identify the pharmacies to participate in the study. Each criterion was ranked in terms of perceived importance to the study. The agreed prioritisation was:

- Demographic mix
- Non-pharmacist staffing levels
- Length qualified
- Length of time at pharmacy
- NMS and MUR activity
- Second pharmacist

Analysis of ward data from available public health data was deemed the most important factor. Population age profiles and deprivation information were assigned to every pharmacy in North East Essex to create a potential demographic profile based on a projected catchment area for each pharmacy. Pharmacies were annotated as being urban, rural or coastal or a combination of these as this affected the size of the catchment area for the pharmacies.

5.4.10 Number of pharmacies

A pragmatic approach was taken to the number of pharmacies required to participate in the research study. The rationale being two-fold.

Recruitment for the study to assess the NVS in community pharmacies had proven difficult and there had been a disparity in the degree to which pharmacies participated. Limiting the number of pharmacies would simplify the recruitment process and reduce the number of pharmacies that needed further research support (335).

Completing lots of assessments would be time consuming and increase the workload whereas keeping the number low would reduce the time commitment and make the task more manageable. Hence there was a trade-off decision on how to identify an appropriate number per pharmacy. Five pharmacies provide a realistic number to recruit and give each pharmacy enough patients to assess. However, it was accepted that this limited the variation in geographical location and pharmacist experience. As the objective of the study was a preliminary investigation into a heuristic assessment instrument five pharmacies was deemed a pragmatic number to recruit. Limiting to five pharmacies would allow each pharmacy to be given adequate support from the research team and give them sufficient patients to develop an understanding of how to apply the hueristic indicators.

5.4.11 Pharmacy staff training

A training check list was completed at each pharmacy (appendix 5.2) to maintain consistency. Training was provided to the pharmacist and the members of staff that were responsible for participant recruitment and for carrying out the NVS assessment.

5.4.12 Patient identification and recruitment

The process for patient identification and recruitment is described in 4.2.6 apart from one change to the inclusion criteria. As the first study was a feasibility study, severe mental health conditions were excluded. In the heuristic study, the decision was taken to include mental health conditions. The rationale being:

- The validity of the test should be assessed in a 'real world' environment.

- The stress of completion reported in chapter 4, if experienced, was not as great as predicted prior to the start of the feasibility study.

5.4.13 Patient activity

5.4.13.1 NVS assessment

The NVS assessment of the patient was very similar to that described in 4.2.7. There were a few alterations which were a direct consequence of the results reported in chapter 4. The time taken to complete the NVS assessment was not recorded in this study.

Changes added to the NVS script were made for those patients who appeared to be struggling. The changes are shown in table 5.1

Prompt for staff	Question to ask
If the respondent appears to be struggling	Do not worry if you cannot answer all the questions. Some of them are designed to be difficult so not everyone will get them all correct. Please take as much time as you need to answer each question. I can repeat any question you didn't understand.
If the respondent is really struggling	Ok, don't worry if you can't answer this question, some of them are designed to be much harder than others. Let's try the next one.
After completing the last question	Do you want to go back to the questions you passed over?

Table 5.1 changes to the NVS script

These modifications were designed to reduce the likelihood of any individual feeling under pressure to complete the NVS assessment and feeling that they were being tested.

Greater emphasis was added to the study paperwork to ensure that under no circumstances could the NVS assessment be carried out by the pharmacist. The rationale for this is described in chapter 4.3.3.1

On completion of the NVS assessment the completed score sheet was put into a pre-stamped addressed return envelope for posting to the principal researcher. The patient was then handed over to the pharmacist who was given the patient's unique reference number before completing the assessment.

5.4.13.2 Pharmacist assessment

The pharmacist could choose which form of medicine consultation they wanted to use to carry out the heuristic assessment. The pharmacist structured the consultation to trigger participants to demonstrate the potential indicators of health literacy level as identified from the literature. It was the pharmacist's choice on the order to ask the questions within their medicine consultation. For each of the potential indicators the pharmacist evaluated the participant's ability and decide if they demonstrated the characteristic under review. They recorded their assessment for each indicator rating the patient as either poor, fair or good. The pharmacist used the provided question prompt (appendix 5.3 page 272) to ensure that all the health literacy indicators have been assessed during the consultation. After the pharmacist left the consultation the pharmacist wrote down a brief explanation of how they came to their decision on the patient's health literacy level. They were given no guidance on how to do this as the objective was to identify how they made their decision.

They also recorded on a scale of 0 to 10 how easy it was to incorporate into the consultation each indicator and indicated the value of that indicator in reaching their overall assessment of the individual (appendix 5.4 page 274).

The pharmacists' completed assessments were collected from the pharmacy by the principal investigator on a regular basis and matched to the corresponding NVS assessment. The first collection from each pharmacy was soon after the first completed NVS was returned to the researcher so that the paperwork could be checked to ensure the process was being followed correctly and that all the required information was being provided. This was to minimise the amount of missing data within the study which would reduce the statistical power of the sample.

5.5 Quantitative analysis

5.5.1 Descriptive statistics

Data was collected on patient gender, age and education level to ascertain details of the study population. The process used mirrors that used described in 4.2.9 apart from the time taken to complete the NVS assessment for which no data was collected. Spearman's correlation coefficient was used to assess for associations between NVS score and demographic data, except for sex for which Mann-Whitney was used. The kappa score was calculated to investigate the association between pharmacists' estimate of health literacy and NVS health literacy level.

5.5.2 Logistic regression

To address the research question 'can health literacy be accurately assessed by heuristics in a community pharmacy? A logistic regression model was used. The NVS health literacy level was the dependent variable. The outcome is recorded as a dichotomous variable and the data is coded as either true (1) or false (0) health literacy assessment.

5.5.3 Measuring the accuracy of non-test approaches to assessing health literacy

To answer the research question 'can health literacy be accurately assessed by heuristics in a community pharmacy?' It is important to first define accuracy. The diagnostic accuracy, as described by Florkowski (336), is 'the degree of agreement between the index test and the reference standard'. Comparison of these proportions is described below.

5.5.3.1 Sensitivity and Specificity

Sensitivity and specificity were fully described in section 3.2.1.4. Sensitivity is the number of true positive decisions divided by the total number of actual positive cases and therefore is the true accuracy in identifying positive cases. Similarly, specificity is the number of true negative decisions divided by the total number of actual negative cases and is the true accuracy in identifying negative cases.

The collected data was analysed to identify the sensitivity and specificity of each the predictor variables to ascertain their diagnostic accuracy.

5.5.3.2 ROC curves

Receiver Operating Curves show 'all possible combinations of the relative frequencies of the various kinds of correct and incorrect decisions' (306). The area under the ROC curve is known as the AUC or AUROC and is 'interpreted as the average value of sensitivity for all values of specificity' (337). An AUC value of 0.5 or less indicates the null hypothesis and that the performance is no better than chance, whereas a score closer to 1 indicates a high diagnostic performance.

ROC curves were produced to calculate the AUC value for the predictor variables and for the logistic regression model.

5.5.3.4 Negative and Positive Predictive Values

There are two options when creating a diagnostic test. The test can be designed to 'rule out' or to 'rule in' the condition under investigation (336). As described in table 3.1 the negative predictive value (NPV) is the probability of not having the condition for negative results. The positive predictive value (PPV) is the probability of having the condition for positive test results. In the heuristic study the NPV equates to having adequate health literacy and the PPV to limited health literacy. Tests that are designed to 'rule out' require a high negative predictive value (NPV). Whereas tests designed to 'rule in' require a high positive predictive value (PPV).

The NVS scoring classification sub-divides health literacy ability into one of three possible outcomes, limited, marginal or adequate health literacy. Logistic regression uses binary data so consequently the three NVS categories are combined into two. For diagnostic assessment two options exist; combining the marginal with adequate health literacy or combining limited with marginal health literacy. The combination of limited and marginal health literacy combines all those that do not have adequate health literacy and would be a 'rule in' approach (or 'rule out' if the adequate group were used as the primary outcome measure).

The combination of marginal health literacy with adequate health literacy has been frequently used in previous health literacy research (25, 51, 53) but no rationale has been provided. One explanation is to focus on identifying individuals with the greatest health literacy needs. Another possible explanation is that based on the

statistical requirement for the proportions of cases to be in the region of 2:1 to minimise the sample size (see 5.5.4.2).

One cross-sectional study used both combinations to assess doctor's gestalt capabilities to assess health literacy using the NVS (329). The approach used in this study is to also compare both bivariate models and identify if either is more suitable for heuristic assessment of health literacy.

5.5.4 Sample size

Sample size estimation is dependent on the type of statistical analysis that is being carried out and requires decisions on the significance level and power of the test.

A standard accepted practice is:

- To set the type 1 error – alpha, the probability of rejecting the null hypothesis (that there is no real difference) when it is true, to 0.05
- To set the type 2 error – beta, the probability of rejecting the null hypothesis when it is false to 0.20 (80% power)

5.5.4.1 Correlation coefficient

Calculation of the minimum sample size to estimate the correlation coefficient requires the type 1 and type 2 error figures as well as an estimate of the expected correlation coefficient. Using an expected correlation figure of 0.6 (a moderate level of correlation) would require a minimum of 19 cases of both variables being measured (two-tailed) using a type 1 error rate of 0.05 and a power of 0.8. Using a two-tailed measure would allow for a relationship to occur in any direction. A two-tailed approach using Spearman's correlation was used for this study.

5.5.4.2 Area under Receiver Operator Curve (AUROC)

Using the conventional type 1 and 2 error figures and with the accepted null hypothesis value for an area under a ROC curve of 0.5 and a projected area under the ROC curve the sample size can be estimated. The calculation also requires an approximation of the ratio of positive cases to negative cases. A positive case for this study is an individual with limited literacy.

Consequently, using the equation reported by Hajian-Tilaki (338), and a sample size calculator by Medcalc, with the standard type 1 error of 0.05 and type 2 of 0.2 and a

projected area under the curve figure of 0.725 (an acceptable heuristic level) and a ratio of sample sizes of 2 (greater proportion of negative cases) the minimum sample size required would be 57 participants.

5.5.4.3 Logistic regression analysis

A heuristic approach to sample size calculations for logistic regression analysis is to suggest at least ten participants for every predictor (339, 340). Metz (341) suggested that ideally with a minimum sample size should be approximately 100.

5.5.4.4 Selected sample size

At the planning stage of the study no funding stream had been confirmed for the project and the difficulties in recruiting pharmacy participation in the earlier study indicated that getting large numbers of participants through the study would be a costly and slow process. A pragmatic approach was therefore adopted to provide an initial exploration of a new model of assessment. Ninety-five patients were set as the target number with each pharmacy required to collect data from 19 patients. This number meets the sample calculation minimum numbers, described above.

5.5.4.6 Pharmacist accuracy at assessing health literacy

The accuracy of each pharmacist at predicting health literacy were compared to the other pharmacists to assess if there were any differences in their predictive ability.

5.5.4.7 Heuristic assessment

The results obtained from the logistic regression and ROC analysis were used to suggest a heuristic instrument for assessing health literacy that provided the best fit based on the results obtained. Data was analysed using SPSS version 22.

5.6 Qualitative analysis

Each pharmacist had a recording sheet to collect data on their assessment of health literacy for each patient. This recording sheet gave them space to record in their own words how they came to their decision on the health literacy ability of the patient. There was also space to provide additional comments on the process. Previous experience of working with pharmacists indicated that free text feedback was usually of limited value due to an under reporting via this mechanism. This in part may be

explained by the culture within pharmacy of not having to keep full clinical records and not being used to recording observations and experiences.

Semi-structured interviews were arranged with each pharmacist on the completion of their data collection. The interviews were recorded and were held in the consultation room of the pharmacy at a time agreed by the pharmacist.

The key topics within the interviews were:

- How they differentiated between poor, fair and good for each indicator
- Ease of using each indicator within the consultation and how that varied between participants
- Preferred order of using the indicators and which ones they found most useful in the decision process
- How they decided on the overall health literacy ability of each participant
- Over all views on assessing health literacy heuristically
- Barriers and facilitators to assessing health literacy heuristically

All the recordings were transcribed and the methodical approach as described in 4.2.10.5 was used to analyse the transcripts and generate themes for discussion.

5.7 Quantitative results

The primary question was 'can health literacy be accurately assessed by heuristics in a community pharmacy?' This question was supported by the following questions:

- Will pharmacies be willing to assess health literacy in pharmacies?
- Will patients consent to complete the heuristic assessment?
- Are the indicators correlated to NVS score and levels?
- Can pharmacists accurately assess health literacy using heuristic indicators?
- Are age, sex or educational levels confounders of health literacy?
- What is the level of limited health literacy in a community pharmacy setting?

5.7.1 Consent rates

5.7.1.1 Pharmacy consent rates

The figure 5.2 shows both the pharmacy and patient consent rates There were sixty-one community pharmacies in North East Essex CCG, twenty of which were owned

Chapter 5 Heuristic assessment of health literacy

by Boots Chemist Limited. The total number of pharmacies that expressed an interest was seven which was 11.5% of the number of pharmacies within the CCG. Six (14.6%) of the pharmacies not owned by Boots (6/41) replied to the expression of interest letter. Two of these were independent pharmacies and three of the remaining four pharmacies were owned by the same large multiple pharmacy company. Boots agreed to participate in the study and offered one pharmacy.
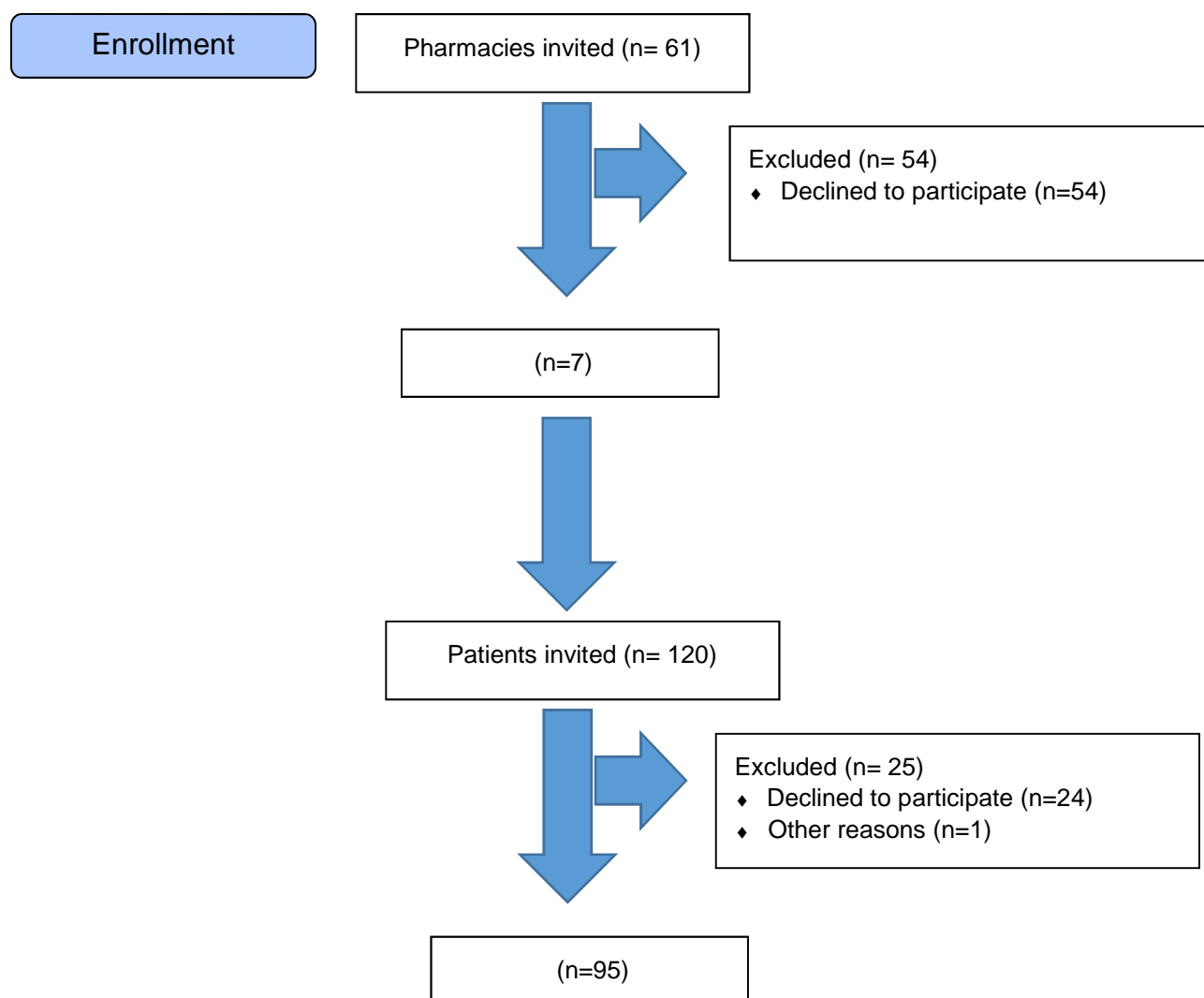
FIGURE 5.2 CONSENT RATE CONSORT DIAGRAM

5.7.1.2 Patient consent rates

From the 120 patients invited to participate, 95 (79.2%) consented. Patient participation rates for each pharmacy were very high and are shown in the bullet point list. The figure in brackets indicates the patient participation rate for the pharmacy. Every pharmacy had 19 patients who completed the assessments.

- Pharmacy 1 invited 21 patients (90.5%)

- Pharmacy 2 invited 20 patients (95.0%)

- Pharmacy 3 invited 27 patients (70.4%)

- Pharmacy 4 invited 30 patients (63.3%)

- Pharmacy 5 invited 22 patients (86.4%)

Only one patient (1%) dropped out during the NVS assessment.

5.7.2 Descriptive statistics

5.7.2.1 Selected pharmacies

Table 5.2 provides information on the pharmacies that expressed an interest in joining the study. All seven pharmacies fulfilled the eligibility criteria of providing MUR and NMS services and having at least one full time or two 0.6 full time equivalents members of staff. The pharmacies that collected data are highlighted in green in table 5.2. Pharmacy six was originally chosen instead of pharmacy four but the company management withdrew permision to participate one month after agreeing. The company changed their policy on allowing individual pharmacies to consent to participation.

All the selected pharmacies had population demographics that encompassed varied levels of deprivation in their catchment areas. The four pharmacies (2,3,4 & 6) that had the lowest percentages of the population under 65 years were in a large town in commuting distance of London whereas the pharmacy with the highest percentage was in a coastal town.

Pharmacy number	% of population over 65	Location	Second pharmacist	Pharmacy ownership
1	38.7	Urban	No	Large multiple
2	12.7	Urban	Yes	Large multiple
3	15.1	Urban	Yes	Large multiple
4	12.7	Urban	No	Large multiple
5	26.8	Rural	Yes	GP owned independent
6	12.7	Urban	No	Large multiple
7	25.1	Urban	No	Independent

Table 5.2 Pharmacy selection data

The characteristics of the selected pharmacists is reported in table 5.3. The pharmacists encompassed a wide range of experience both in terms of length of time at their current pharmacy and length of time practising as a pharmacist. The pharmacist from pharmacy three had also worked at their pharmacy earlier in their career. The pharmacy that dropped out of the study was replaced by another pharmacy where the pharmacist had similar experience and length of time at the pharmacy as the pharmacist originally assigned to the study.

Pharmacy number	Pharmacist gender	Number of years practising	Number of years at current pharmacy
1	Female	30	3.5
2	Male	34	1
3	Male	16	5
4	Male	0.5	1 Month
5	Female	36	11

Table 5.3 Pharmacist characteristics

5.7.2.2 Patient participant characteristics

Table 5.4 shows the variation in patient characteristics at each of the pharmacy study locations. The interquartile range was 62 to 75 years of age. Participants were mainly older people and the widest variation between locations was the percentage of females. Few participants completed higher education.

The age range for leaving education was from 13 to 34. The median age participants left education reflects the current legally permitted school leaving age.

Pharmacy number	Median age	Age range	Median education leaving age	% Female
1	71	46-87	16	26.3
2	72	45-90	16	52.6
3	67	37-81	16	31.6
4	69	44-81	16	47.4
5	67	21-80	16	68.4
Combined	**69**	**21-90**	**16**	**45.0**

Table 5.4 Patient demographics

5.7.3 Health literacy assessment using the NVS

Figure 5.3 reports the percentage of patients that obtained each possible NVS score, where each score indicates the number of questions answered correctly. There was an even distribution between the scores and most of the participants were unable to answer all the questions correctly.
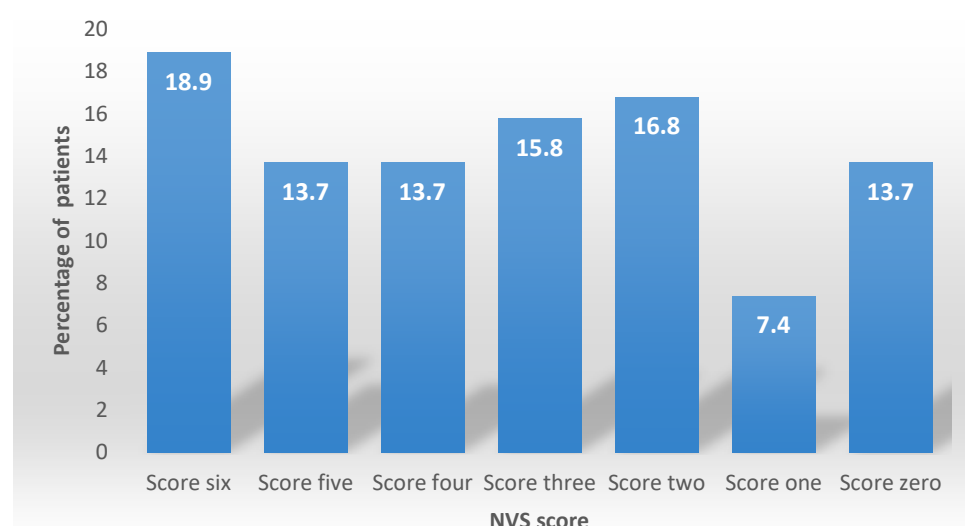
FIGURE 5.3 PERCENTAGE OF PATIENTS OBTAINING EACH NVS SCORE

Table 5.5 compares the obtained NVS level for patients against the number correctly identified by the individual pharmacist's estimation of the patient's health literacy.

Pharmacy	Limited health literacy by NVS	Accurate pharmacist assessment of limited health literacy	Marginal health literacy by NVS	Accurate pharmacist assessment of marginal health literacy	Adequate health literacy by NVS	Accurate pharmacist assessment of adequate health literacy
1	7	1	6	0	6	6
2	0	0	5	2	14	12
3	2	0	10	0	7	6
4	4	1	6	1	9	5
5	7	3	4	1	8	7

Table 5.5 Comparison of accuracy of individual pharmacist's perception of patient's health literacy level.

Table 5.6 reports the combined figures for pharmacists' estimation of the patients' health literacy level. The cells shaded in green indicate the number (%) cases where the pharmacist's judgement matched the NVS level. The pharmacists' assessment of health literacy underestimated the percentage of patients having limited and

marginal health literacy and over-estimated the percentage with adequate health literacy. There was no consistency between the pharmacists' estimate and the obtained NVS level above that expected by chance as shown by the Kappa score of 0.10 which was non-significant (p=0.17).

Pharmacist health literacy assessment	NVS Level			Total
	Limited	Marginal	Adequate	
Limited	5	5	1	11 (11.6%)
Marginal	10	4	7	21 (22.1%)
Adequate	5	22	36	63 (66.3%)
Total	20 (21.1%)	31 (32.6%)	44 (46.3%)	95

Table 5.6 Comparison of pharmacist gestalt with NVS assessment levels

5.7.4 Health literacy levels and confounders

The females in the sample, whilst being in the minority, had more than 50% of the adequate health literacy scores and had just over a third of the limited scores. However, the Mann-Whitney U value of 950.0 was a non-significant result p= 0.18 Similarly, whilst the mean age of patients increased as health literacy level decreased this was not a statistically significant Spearman's rho value. (r= -0.16, p=0.13).

Reflecting the results obtained in chapter 4, a moderate positive correlation was identified between school leaving age and NVS health literacy level (r=0.34, p<0.0001).

Table 5.7 reports health literacy levels for the confounders of age, age left education, sex and prior patient knowledge. Most of the patients were not very well known by the pharmacist. There was no correlation between the NVS level and how well the pharmacist knew the patient (Spearman's r= -0.04, significance p= 0.67) nor between the pharmacist's health literacy assessment and previous knowledge of the patient (Spearman's r=0.12, p= 0.25).

	NVS level		
	Limited	Marginal	Adequate
Female; n (%)	7 (35%)	13 (41.9%)	23 (52.3%)
Age; mean (sd)	71 (9)	68 (11)	64 (14)
Age left school; mean (SD)	16 (3)	16 (3)	18 (4)
New patient	5 (25%)	6 (19.4%)	10 (22.7%)
Know a little	7 (35%)	18 (58.1%)	23 (52.3%)
Know well	5 (25%)	3 (9.7%)	4 (9.1%)
Know Very well	3 (15%)	4 (12.9%)	7 (15.9%)

Table 5.7 Health literacy levels and confounders descriptive statistics

5.7.4.1 Correlation between indicators, NVS level and score

The Spearman correlations between each of the heuristic indicators, the obtained NVS scores and NVS levels are shown in table 5.8. The recall of verbal information, recall of written information and patient's knowledge of their medication were all found to be moderately correlated with the individual's NVS health literacy level. All three were highly significantly correlated.

Use of medical terminology; seeking new information and asking questions were also found to correlated and had slightly lower Spearman correlations.

The correlations with NVS scores provided similar results with slightly stronger correlations for three indicators - recall of verbal and recall of written information and drug knowledge. The seeking new information indicator produced a slightly lower Spearman correlation. Only the time to sign was not associated with the NVS level.

Indicator	NVS score	NVS level
Recall of verbal information	r= 0.47 p<0.0001	r=0.46 p<0.0001
Recall of written information	r= 0.50 p<0.0001	r=0.48 p<0.0001
Drug knowledge	r=0.45 p<0.0001	r=0.45 p<0.0001
Use of medical terminology	r=0.39 p<0.0001	r=0.39 p<0.0001
Seeking new information	r=0.29 p=0.004	r=0.31 p<0.0001
Asking questions	r=0.33 p=0.001	r=0.33 p=0.001
Time to sign	r=-0.03 p=0.81	r=-0.05 p=0.63

Table 5.8 correlations between NVS level and indicators

Figure 5.4 shows the variation in signing time compared with different health literacy levels. The marginal and adequate health literacy level curves have similar trajectories with an initial increase in numbers followed by a decrease in number of patients after two to three seconds have elapsed. All health literacy levels show an initial increase in the number of respondents before declining as time passes. Most patients (94.4%) could complete their signatures within 6 seconds. Of those five patients who took longer than six seconds to sign their name three had limited health literacy and two had adequate health literacy.

Time to sign v health literacy level
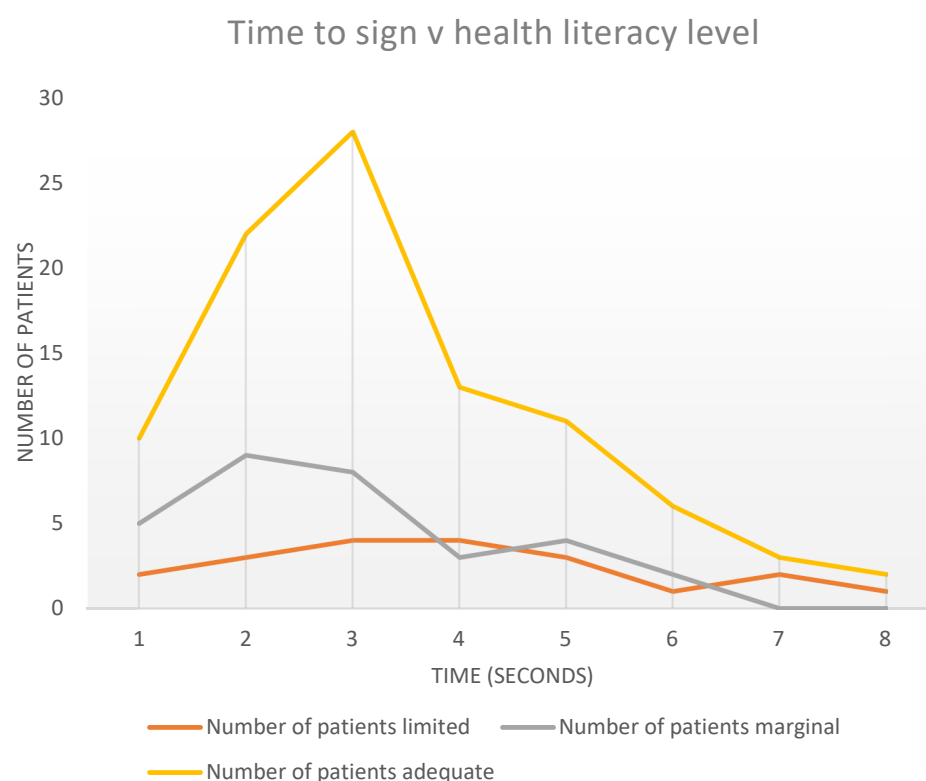
Figure 5.4 Health literacy level compared with the time to sign

5.7.5 Pharmacist accuracy

Three different models were used to report pharmacists' accuracy at predicting limited and adequate health literacy. In each model, the comparison is against each of the six indicators reported in table 5. that were significantly correlated to the NVS.

The first model is the pharmacists' ability to accurately predict limited, marginal or adequate health literacy. The second model reports the pharmacists' predictions when marginal + adequate levels are combined. The final model considers the predictive ability of the pharmacists when limited and marginal health literacy levels are combined.

5.7.5.1 Pharmacist assessment of health literacy level using the indicators

The pharmacists' ability to accurately predict health literacy levels using the indicators is reported in table 5.9. The NVS results for pharmacy 2 indicated that no patients had limited health literacy. Consequently, it was not possible to assess pharmacist's 2 ability to predict true positive or false positive cases. For almost all the indicators the combined results of pharmacists identified a greater percentage of true negative cases rather than true positive cases.

Pharmacist number	Recall of verbal	Recall of written	Drug knowledge	Medical terminology	Seeking new information	Asking questions
1 True positive	1(14.3%)	1(14.3%)	1 (14.3%)	4 (57.1%)	5 (71.4%)	4 (57.1%)
True negative	5 (41.7%)	8(66.7%)	8(66.7%)	6 (50.0%)	8 (66.7%)	8 (66.7%)
2 True positive	No positive cases	No positive cases	No positive cases	No positive cases	No positive cases	No positive cases
True negative	17(89.5%)	13(68.4%)	13 (68.4%)	7 (36.8%)	8 (42.1%)	11 (57.9%)
3 True positive	0 (0%)	0 (0%)	0 (0%)	2 (100%)	0 (0%)	0 (0%)
True negative	8 (47.1%)	8 (47.1%)	7 (41.2%)	6 (35.3%)	6 (35.3%)	6 (35.3%)
4 True positive	1 (25.0%)	2 (50.0%)	1 (25.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)
True negative	6 (40.0%)	8 (53.3%)	10 (66.7%)	6 (40.0%)	6 (40.0%)	6 (40.0%)
5 True positive	3 (42.9%)	3 (42.9%)	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)
True negative	8 (66.7%)	10(83.3%)	9 (75.0%)	8 (66.7%)	10 (83.3%)	8 (66.7%)
Combined True positive	5 (25%)	6 (30%)	5 (25%)	10 (50%)	9 (45%)	8 (40%)
True negative	44 (58.6%)	47 (62.3%)	47 (62.3%)	33 (44%)	38 (50.7%)	39 (52%)

Table 5.9 Pharmacist assessment of limited, marginal or adequate health literacy.

The pharmacists' ability to accurately predict health literacy levels when marginal and adequate assessments are combined is reported in table 5.10

Pharmacist number	Recall of verbal	Recall of written	Drug knowledge	Medical terminology	Seeking new information	Asking questions
1						
True positive	1 (14.3%)	1 (14.3%)	1 (14.3%)	4 (57.1%)	5 (71.4%)	4 (57.1%)
True negative	11 (91.7%)	12 (100%)	11 (91.7%)	11 (91.7%)	10 (83.3%)	11 (91.7%)
2						
True positive	No positive cases	No positive cases	No positive cases	No positive cases	No positive cases	No positive cases
True negative	19 (100%)	19 (100%)	18 (94.7%)	17 (89.5%)	19 (100%)	19 (100%)
3						
True positive	0 (0%)	0 (0%)	0 (0%)	2 (100%)	0 (0%)	0 (0%)
True negative	16 (94.1%)	16 (94.1%)	15 (88.2%)	15 (88.2%)	14 (82.4%)	15 (88.2%)
4						
True positive	1 (25.0%)	2 (50.0%)	1 (25.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)
True negative	12 (80.0%)	13 (86.7%)	13 (86.7%)	9 (60.0%)	10 (66.7%)	10 (66.7%)
5						
True positive	3 (42.9%)	3 (42.9%)	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)
True negative	12 (100%)	12 (100%)	12 (100%)	11 (91.7%)	12 (100%)	12 (100%)
Combined						
True positive	5 (25%)	6 (30%)	5 (25%)	10 (50%)	9 (45%)	8 (40%)
True negative	70 (93.3%)	72 (96%)	69 (92%)	63 (84%)	65 (86.7%)	67 (89.3%)

Table 5.10 Pharmacist assessment when marginal + adequate assessments combined

The combination of marginal health literacy with adequate health literacy improved the predictive ability of the pharmacists to identify true negative cases. Recall of verbal and written information along with drug knowledge were the best indicators for identifying adequate health literacy with an accuracy greater than 90%. Use of medical terminology remained the most accurate indicator for identifying limited health literacy.

The pharmacists' ability to accurately predict health literacy levels using the indicators, when limited and marginal assessments are combined is reported in table 5.11

Pharmacist number	Recall of verbal	Recall of written	Drug knowledge	Medical terminology	Seeking new information	Asking questions
1						
True positive	9 (69.2%)	9 (69.2%)	8 (61.5%)	11 (84.6%)	11 (84.6%)	11 (84.6%)
True negative	6 (100%)	6 (100%)	6 (100%)	4 (66.7%)	5 (83.3%)	6 (100%)
2						
True positive	3 (60.0%)	3 (60.0%)	3 (60.0%)	4 (80.0%)	3 (60.0%)	4 (60.0%)
True negative	14 (100%)	10(71.4%)	11 (78.6%)	4 (28.6%)	5 (35.7%)	6 (42.9%)
3						
True positive	3 (25.0%)	4 (33.3%)	3 (25.0%)	9 (75.0%)	8 (66.7%)	7 (58.3%)
True negative	7 (100%)	7 (100%)	7 (100%)	2 (28.6%)	1 (14.3%)	1 (14.3%)
4						
True positive	7 (70.0%)	7 (70.0%)	8 (80.0%)	9 (90.0%)	8 (80.0%)	8 (80.0%)
True negative	3 (33.3%)	4 (44.4%)	5 (55.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)
5						
True positive	8 (72.7%)	10 (90.9%)	8 (72.7%)	10 (90.9%)	11 (100%)	9 (81.8%)
True negative	5 (62.5%)	5 (62.5%)	6 (75.0%)	5 (62.5%)	5 (62.5%)	5 (62.5%)
Combined						
True positive	30 (58.8%)	33 (64.7%)	30 (58.8%)	43 (84.3%)	41 (80.4%)	39 (76.5%)
True negative	35 (79.5%)	32 (72.7%)	35 (79.5%)	17 (38.6%)	18 (40.9%)	20 (45.5%)

Table 5.11 Pharmacist assessment when limited +marginal assessments combined

Combining marginal health literacy with limited health literacy improved the combined pharmacists' predictive ability to accurately assess true positive cases. Recall of verbal and written information and drug knowledge remained the best indicators to predict adequate health literacy. Using medical terminology, asking

questions and seeking new information were the best indicators for identifying limited health literacy.

5.7.5.2 Correlations between the NVS and pharmacist's indicator assessments

The comparison of Spearman's rho coefficients between the NVS level and each indicator for each pharmacist is reported in table 5.12. The pharmacists made their assessments predicting either limited, marginal or adequate health literacy. The table indicates that there was a wide variation in the ability of the five pharmacists to accurately identify health literacy using each indicator. As reported in tables 5.9 to 5.11 the better performing indicators were the ones that were more effective at identifying true negative cases that is at identifying adequate health literacy.

Pharmacist number	Recall of verbal	Recall of written	Drug knowledge	Medical terminology	Seeking new information	Asking questions
1	r=0.69 p=0.002**	r=0.83 p<.0001**	r=0.56 p=0.01*	r=0.62 p=0.005**	r=0.67 p=0.002**	r=0.75 p=0.0001**
2	r=0.73 p<0.0001**	r=0.29 p=0.23	r=0.40 p=0.09	r=0.15 p=0.53	r=-0.04 p=0.87	r=0.27 p=0.27
3	r=0.39 p=0.10	r=0.56 p=0.01*	r= 0.38 p=0.11	r=0.40 p=0.09	r=-0.19 p=0.43	r=-0.27 p=0.24
4	r= 0.10 p=0.57	r=0.27 p=0.27	r=0.31 p=0.20	r=0.15 p=0.54	r=0.08 p=0.76	r=0.15 p=0.53
5	r=0.54 p=0.018*	r=0.60 p=0.007**	r=0.61 p=0.005**	r=0.62 p=0.05**	r=0.56 p=0.012**	r=0.52 p=0.02*
Combined	r=0.46 p<0.0001	r=0.48 p<0.0001	r=0.45 p<0.0001	r=0.39 p<0.0001	r=0.31 p<0.0001	=0.33 p=0.001
*indicates significance at 0.05 ** indicates significance at 0.01						

Table 5.12 Correlation of NVS level and pharmacist assessment of limited, marginal and adequate health literacy

5.7.5.3 Estimates of model parameters and precision

The earlier section 5.5.3 introduced different approaches to assessing the accuracy of a diagnostic instruments. These included assessing the area under the receiver operator curve; sensitivity and specificity; positive and negative likelihood ratios and negative and positive predictive values. The next section reports the data obtained from the study in the form of two different predictive models; combining marginal and

adequate health literacy levels or combining limited and marginal health literacy levels. The reported data aims to answer the two research questions:

- Which are the best indicators to use to assess health literacy?
- Are the indicators better at predicting limited health literacy than adequate health literacy?'

5.7.5.3.1 Model combining marginal and adequate health literacy levels

The precision of the indicators when marginal and adequate health literacy levels were combined is shown in table 5.13. The generation of ROC curves for each indicator produced moderately strong area under the curve figures (AUC). Using the area under a receiver operator curve as the measure of accuracy indicated that the most influential predictor was the recall of written information. The variation between AUC values for all the indicators was small.

The recall of written information generated the highest R square value. Recall of written information and recall of verbal information were more effective at predicting specificity. The recall of written information had a better recorded sensitivity than recall of verbal information. Similarly, recall of written information and recall of verbal information produced high negative predictive values. The 95% statistical confidence intervals for both negative predictive values indicated that the likely true values were very accurate.

The combination of all indicators into a single model as well as the combination of recall of written and verbal information into a single indictor is reported in table 5.14.

Indicator	ROC (95%CI)	Nagelkerke R square	Specificity (95%CI)	Sensitivity (95%CI)	LR+ (95%CI)	LR- (95%CI)	PPV (95%cl)	NPV (95%cl)
Recall of verbal	0.79 (0.68-0.90)	0.24	85.9 (76.6-92.5)	50.0 (18.7-81.3)	3.54 (1.57-7.98)	0.58 (0.31-1.09)	29.4 (15.6-48.4)	93.6 (88.7-96.5)
Recall of written	0.81 (0.70-0.91)	0.32	87.2 (78.3-93.4)	66.7 (29.9-92.5)	5.21 (2.54-10.70)	0.38 (0.15-0.97)	35.3 (21.0-52.8)	96.2 (90.8-98.4)
Drug Knowledge	0.73 (0.60-0.85)	0.15	82.1 (72.9-89.2)	0.00	0.00	1.22		
Medical terminology	0.73 (0.60-0.85)	0.14	82.1 (72.9-89.2)	0.00	0.00	1.22		
Seeking new information	0.74 (0.58-0.83)	0.10	82.1 (72.9-89.2)	0.00	0.00	1.22		
Asking questions	0.72 (0.60-0.85)	0.16	82.1 (72.9-89.2)	0.00	0.00	1.22		

Table 5.13 Precision measures for indicators when marginal and adequate health literacy levels are combined.

Indicators	ROC (95%CI)	Nagelkerke R square	Specificity (95%CI)	Sensitivity (95%CI)	LR+ (95%CI)	LR- (95%CI)	PPV (95%cl)	NPV (95%cl)
Recall of verbal + Recall of written	0.83 (0.72-0.93)	0.32	87.2 (78.3-93.4)	66.7 (29.9-92.5)	5.21 (2.54-10.70)	0.38 (0.15-0.97)	35.3 (21.0-52.8)	96.2 (90.8-98.4)
Combination of all associated indicators	0.80 (0.68-0.92)	0.38	88.2 (79.4-94.2)	70.0 (34.8-93.3)	5.95 (2.93-12.10)	0.34 (0.13-0.88)	41.2 (25.6-58.7)	96.2 (90.6-98.5)

Table 5.14 Combination of indicators and precision measures when marginal and adequate health literacy levels are combined.

5.7.5.3.2 Model combining limited and marginal health literacy levels

The precision of the indicators when limited and marginal health literacy levels were combined is shown in table 5.15. Combining limited and marginal health literacy levels into a single bivariate category had no impact on the AUC scores. All the Nagel R square values apart from the drug knowledge indicator reduced in the marginal and limited group model. The drug knowledge value changed to become the indicator that influenced the model the most.

In comparison to the previously described model this model improved the sensitivity and positive predictive values but reduced the specificity and negative predictive values. The specificity for the medical terminology indicator which was approximately 20% lower than the preceding model. More sensitivity data was generated with this bivariate combination and the best performing indicator was medical terminology. Medical terminology also produced the highest PPV. Seeking new information also had PPV value greater than 80%.

Indicator	ROC (95%CI)	Nagelkerke R square	Specificity (95%CI)	Sensitivity (95%CI)	LR+ (95%CI)	LR- (95%CI)	PPV (95%cl)	NPV (95%cl)
Recall of verbal	0.79 (0.68-0.90)	0.18	60.7 (46.8-73.5)	74.4 (57.9-87.0)	1.89 (1.30-2.75)	0.42 (0.24-.75)	56.9 (47.6-65.7)	77.3 (65.7-85.8)
Recall of written	0.81 (0.70-0.91)	0.20	64.0 (49.2-77.1)	73.3 (58.1-85.4)	2.04 (1.35-3.07)	0.42 (0.25-0.71)	64.7 (54.9-73.4)	72.7 (61.1 – 81.9)
Drug Knowledge	0.73 (0.60-0.85)	0.22	62.5 (48.6-75.1)	76.9 (60.7-88.9)	2.05 (1.40-3.00)	0.37 (0.20-0.68)	58.8 (49.4-67.6)	79.5 (67.9-87.7)
Medical terminology	0.73 (0.60-0.85)	0.15	66.7 (44.7-84.4)	60.6 (48.3-72.0)	1.82 (1.00-3.30)	0.59 (0.39-0.89)	84.3 (74.8-90.7)	36.4 (27.6-46.1)
Seeking new information	0.74 (0.58-0.83)	0.08	64.3 (44.1-81.4)	61.2 (48.5-72.9)	1.71 (1.01-2.92)	0.60 (0.40-0.91)	80.4 (70.7-87.5)	40.9 (31.5-51.0)
Asking questions	0.72 (0.60-0.85)	0.09	62.5 (43.7-78.9)	61.9 (48.8-73.9)	1.65 (1.01-2.69)	0.61 (0.40-0.92)	76.5 (66.6 – 84.1)	45.5 (35.5 – 55.8)

Table 5.15 Precision measures for indicators when limited and marginal health literacy levels are combined**.**

The combination of all indicators into a single model as well as the combination of recall of written information and drug knowledge into a single indictor is reported in table 5.16.

The Combination of recall of written information with drug knowledge generated a higher Nagel R square value which was greater than that of any of the individual indicators. The model produced a small increase in the specificity compared to the two separate indicators and generated a slightly higher specificity than each indicator. The PPV value increased compared to the two separate indicators but was not as predictive as the asking questions or seeing new information or medical terminology indicators on their own. The increase in PPV created a model that was nearly equally effective at predicting PPV and NPV.

Combining all indicators into a single model improved the specificity and sensitivity as well as increasing the positive predictive value.

Indicators	ROC (95%CI)	Nagelkerke R square	Specificity (95%CI)	Sensitivity (95%CI)	LR+ (95%CI)	LR- (95%CI)	PPV (95%cl)	NPV (95%cl)
Recall of written + Drug Knowledge	0.79 (0.68-0.90)	0.24	70.5 (54.8-83.2)	70.6 (56.2-82.5)	2.39 (1.46-3.90)	0.42 (0.26-0.67)	73.5 (62.9-81.9)	67.4 (56.5-76.7)
Combination of all associated indicators	0.80 (0.69-0.90)	0.25	68.0 (53.3-80.5)	77.8 (62.9-88.8)	2.43 (1.58-3.75)	0.33 (0.18-0.58)	68.6 (58.7-77.1)	77.3 (65.6-85.9)

Table 5.16 Combination of indicators and precision measures when marginal and limited health literacy levels are combined

5.8.1 Qualitative analysis

5.8.1.1 Pharmacist reports

Data collection included comments pharmacists had made to explain how they reached their conclusions. Matching these comments on individual assessments with the patients actual NVS health literacy assessment allowed for comparison within the same health literacy level. Figures 5.5 to 5.7 show for each health literacy level how the comments generally have similar content for that level. Variations in content are shown grouped together at the opposing end of the balance.

Each of the thematic topics discussed below is reported into greater detail during the section 5.8.1.3 of the pharmacists' interviews.

Most of the comments on patients with adequate health literacy indicate that the patient was perceived to have a good understanding of their medication and /or had spent time researching their condition and its treatment. As shown in figure 5.5 there were just a few comments on individuals that demonstrated lack of knowledge and / or interest to finding out more.

The comments on patients with marginal health literacy followed a similar pattern between knowledge and interest and lack of knowledge and disinterest. The results were more mixed between the two extremes and there were examples of patients who had information constantly with them to help them answer pharmaceutical queries.

Individual's with limited health literacy were more likely to have comments reported about them that indicated that the pharmacist perceived they had difficulty understanding the medicines and/ or lacked interest to finding out more about their drugs and their condition. Some of the comments shown on the more knowledgeable end of the spectrum still have some negative elements within the report.

He spoke knowledgeably about the drugs and his condition. He did inform me that he is dyslexic however, he has read about the medication

He told me in detail the action of the drugs and why he was on them. He also informed me that he had read a lot of research papers (he is a retired surgeon)

Pt well informed of his conditions and the necessity of taking the drugs he is on

Very switched on. Knew all about his meds

Patient was a little hesitant about pronouncing his medications, but confident on doses/uses

Patient knew it was for blood pressure, dose, strength etc. and knew a little about how it worked

Has no problem with her medication but was not particularly familiar with her condition (causes, implications of it being untreated)

Very well informed knows what she is talking about. Told me exactly what items were for, when she takes them, pronounced names correctly.

Reasonably well informed about medication, dosages and condition

Very well informed about his medication and condition. Actively seeks information and reads books on a regular basis

Patient seems knowledgeable and compliant

Understood condition and treatment

Didn't understand big words

Understood condition and medication. Knew parameters for blood pressure. Aware of side effects and when to take medication

Patient knowledgeable about own condition

Patient very informed about own conditions and meds. Uses medical terminology frequently. Very well informed and knowledgeable. Uses Internet and other resources to get information

I base this on the patients recall of information and understanding of what and how his medication works.

Had limited understanding of what some meds were for, but knew what he took when

She was knowledgeable about her medicines and medical condition

Patient had good clinical knowledge and fully understood terminology

Knew why he took his medication and working knowledge of long term condition

Patient shows good knowledge of her medications and researches any new medicines

Patient was started on medication a long time ago so was fuzzy about what they had been told initially but had picked up knowledge since

Customer was knowledgeable about his medical condition and was accurate and concise in his understanding and conversation

She could recall names of medications but not strengths or much of what they were for

Doctor hadn't told her anything when first prescribed most of knowledge came from google

Patient only on a couple of medications and has researched them fairly well

Patient had gone to a hospital pharmacist at an information evening and had been taught about his medication and had a good understanding of them

Patient knew what her medications were for and when to take them

He's aware of what his BP needs to be.

Patient had no clue what their medication was for or showed any sign of wanting to know

Patients with adequate health literacy

KEY RED TEXT INDICATES COMMENTS THAT REFLECT LIMITED HEALTH LITERACY, WHITE TEXT ADEQUATE HEALTH LITERACY
FIGURE 5.5 PHARMACIST'S COMMENTS ON PATIENTS WITH ADEQUATE HEALTH LITERACY

KEY RED TEXT INDICATES COMMENTS THAT REFLECT LIMITED HEALTH LITERACY, WHITE TEXT MARGINAL HEALTH LITERACY

FIGURE 5.6 PHARMACIST'S COMMENTS ON PATIENTS WITH MARGINAL HEALTH LITERACY

Got the uses of the meds confused

Had no idea what various of items were for. Consulted his repeat request slip on several occasions but couldn't spot the drugs I was mentioning. Even had what they were for written next to some of them but still didn't know when asked

Pt had no idea of what anything was for. She knew what conditions she had but didn't know which drugs were for what

No idea what most items were for (although he knew what he was suffering from, but not which meds were for what), nor when he took some of them (wife lays them out for him). Refers to 'prostrate'

Wife deals with all his medication. When explaining things to me he couldn't remember all the terminology

Not actively seeking further information

Patient does not remember names and doses but does know what the meds are for when prompted.

Didn't know much about his medication but knew the names and when to take them

Could recall information when prompted otherwise struggled

Patient very reliant on wife to control his health. Relies on her to buy / cook the correct food for his diabetes. Knows value of INR but not really interested in finding out more about it.

Patient didn't seem to care what his medication was or how it worked or showed any wish to learn

Patient is very comfortable with her unusual routine of taking her medications, has a robust routine for not missing any medication but she is not familiar with the possible side-effects of OTC meds can have with her prescription meds.

Hard to know how inclined she was to seek further info

Patient has recently been prescribed 2 new medications to take alongside other medications and wasn't sure what the new ones were.

Patient enthusiastic and knowledgeable

Elderly man who knows what their medication is for and how to take it. Confused about names but once pack is shown is knowledgeable

Knowledgeable about her medication and conditions.

Good knowledge of conditions but seemed to think he needed to request all items each month despite not taking them when he took some of them (wife lays them out for him). Refers to 'prostrate'

Even though the patient was not using medical terminology or asking questions they did have a fair understanding of their medical condition

Patients with limited health literacy

KEY GREEN TEXT INDICATES COMMENTS THAT REFLECT ADEQUATE HEALTH LITERACY, WHITE TEXT LIMITED HEALTH LITERACY

FIGURE 5.7 PHARMACIST'S COMMENTS ON PATIENTS WITH LIMITED HEALTH LITERACY

5.8.1.2 NVS and heuristic assessment

All the five pharmacists were interviewed and the interviews lasted between 25 and 45 minutes. During the interviews the pharmacists discussed testing patients; ease of use of each indicator; heuristic assessment and barriers to implementation. The pharmacists reported their perceptions of feedback from staff on the use of the NVS in the pharmacies. The theme identified, was previously described in the last chapter, that of being tested. Examples of the three sub-themes of examination, performance anxiety and impact on assessors were reported. Two additional themes emerged during the interviews that the pharmacist felt were pertinent to assessing an individual's health literacy ability these were patient knowledge and patient engagement.

As described in table 5.3 Pharmacists P1 and P5 are females and P2 to P4 males.

5.8.1.2.1 Examination, performance anxiety and impact on assessors

Perceived performance anxiety was raised by four of the five pharmacists.

> *'The hardest bit, they found (**staff**) was actually trying to reassure the customer that… because apart from one or two, most of them struggled with it, and I think **name** had it actually sorted out quite nicely where she said, "oh, they're designed to be hard". So, they felt quite reassured at the end of it' (P1).*

Pharmacy 2 reported perceived difficulty for the staff when carrying out the assessments.

> *'Oh, they found it challenging because they said that they are putting the patient on the spot and they were just kind of indirectly challenging their knowledge. So, patients who got confused with some of the questions, they thought that it was just putting them on the spotlight and they just didn't like that, they did not feel comfortable'.*

They were asked:

> '*who didn't feel comfortable, the patients or the staff or both?'*

The reply was:

> *'both. I think the reaction from the patient just affected the staff as well, they didn't know how to deal with that kind of situation'.*

Pharmacist 5 reported the only case of a patient who withdrew during the NVS assessment.

> *'There was, I think, one person who got very frustrated with the questions… about the ice cream, and… they were obviously struggling with it and yeah, got very het up about it, and although she'd originally agreed to take part she then said… she just… I think she threw the bit of card across the table and said no, she couldn't do it!... I then went on to do an MUR with her and she was fine, but… it obviously created a bit of anxiety for her'.*

The member of staff involved with the angry patient asked to speak to the interviewer after the pharmacist interview and stated:

> *'I was glad when the assessments ended I hated the embarrassment of watching patients struggle'.*

Pharmacist 4 recalled that the perceived anxiety of patients carried on into the consultation with the pharmacist.

> *'A couple of people were slightly anxious about the maths side of it. So, you could kind of tell when I first came in they had a slight anxiety because they thought they'd done particularly badly on the maths and even though again it was made clear to them that it doesn't matter if you get the maths questions wrong, it's not about that… a couple of people still feel rather embarrassed that their maths skills aren't particularly good or that it somehow reflects badly on them. Once it was the consultation with me, because it's more of a conversation, it doesn't feel like an exam, they weren't that bad for the rest of it'.*

Pharmacists P5 and P3 also perceived that their assessment was not felt as an examination.

> *'I think the focus was maybe more on us talking about their medication and so on, so I don't think they felt threatened. I don't think they felt as though they were being assessed' (P5).*

Pharmacist 3 stated:

> *'One person said that ''We were careful not to make them sound like guinea pigs of any sort''. One person actually gave us some feedback, one of our customers said, "she wasn't made to feel uncomfortable or anything but it was done in a defined way" … something, I can't remember the exact words she said but it was along those lines' (P3).*

5.8.1.2.2 Ease of use of indicators

There was no consistent approach taken to incorporating the indicators into the medicine consultations. The majority of pharmacists took a structured medicine use review format and introduced the indicators in a regular manner. The other pharmacists allowed the patient to dictate the flow of the discussion.

The numerical assessment of ease of incorporating the indicators into the consultation produced the following ranking (easiest first):

1. Recall of verbal information
2. Time to Sign their name
3. Drug knowledge
4. Use of medical terminology
5. Asking questions
6. Seeking new information
7. Recall of written information.

The interviews provided some insight into the rationale for this ranking outcome.

> *'I thought it was mostly fairly easy, to set it up as a MUR and have them when they came in, I'd say. "Okay, this part is just about you going through what you know about your medication, so can you run through what medication you know you are on, what you remember being told at the time, what things you have learnt since you started" … So, a lot of those ones were easy to fit in. The medical terminology one was more on whether they used it'. (P4)*

This pharmacist described their preference for asking direct questions rather than making observations.

> *'Probably the last ones (**the hardest**) in terms of seeking new information possibly, just because … <pause> it's more of an indirect thing where you*

> *… I mean none of them were overly hard, it's just that some of them were more … you could directly ask as opposed to seeing if they gave a response'.*

Pharmacist 5 shared similar views on incorporating seeking new information.

> *'The seeking medical information or new information I would say was very difficult to assess. Well I suppose you didn't know where they'd got the information from, so you wouldn't always necessarily know whether it was written or verbal… Written information, obviously rather more difficult unless it came up in conversation that they had read things'.*

Other pharmacists also described the difficulty they found in incorporating recall of written information into the medicine consultation.

'How do you ask them recall of written information really? There isn't really anything, whereas recall of verbal information, possibly because the doctors told them something or other. So, the written information I found a bit difficult'. (P1).

'Like I say, the verbal ones were very easy to use, the written ones the harder ones' (P2).

5.8.1.3 Assessing health literacy

Two themes were developed, on decision making strategies, from the pharmacist interviews and from their comments provided on individual assessments. The two themes were patient knowledge and patient engagement.

5.8.1.3.1 Patient knowledge

This was the primary theme that underpinned the whole assessment process. Knowledge was described as having different facets by different pharmacists: the patient's medication; their illness; fluency of communication; use of technical and medical terminology and correct pronunciation.

Pharmacist P1 was asked to give an example of a poor rating for verbal recall of information and said:

> *'the poor people were the ones who really didn't know what their medicine was for. If you asked them how they took their medicines it was like "whatever it says on the label" there wasn't really anything beyond that. And*

> *if you asked them, "what's is your Ramipril for?" "I dunno...I'm sure I knew*
>
> *some time but... I don't know".*

Another pharmacist said:

> '*well poor tended to be they didn't really have an understanding of what*
>
> *their medication was, they couldn't remember even what it was called,*
>
> *even the basics of what it was for in terms of blood pressure'. (P4)*

The pharmacists found it more difficult to describe fair and to distinguish it from good as the pharmacists described different levels of expectation of what they perceived good to be.

> *'Fair was the ones who knew what their medicines were for, they were*
>
> *aware of the side effects that they might expect from them and for the need*
>
> *for having the annual reviews with the doctor even. I think the majority of*
>
> *patients I actually scored as fair, 'cause there's very few that were actually*
>
> *good. And the good ones I would have actually gone for patients who were*
>
> *very knowledgeable, they were probably more knowledgeable than me*
>
> *<laughs> about their condition' (P1).*

In comparison pharmacist P2 said:

> *'if they came back with technical terms which were in the right direction I*
>
> *reckon they had a good understanding of it... those in the middle had some*
>
> *understanding, they could remember the names of the drugs when I asked*
>
> *them to recall them, but they really didn't know which was what'.*

This approach was shared by pharmacist 4 who said:

> *'Fair, they knew what it was called and they roughly knew what it was for,*
>
> *so they knew it was called Ramipril, they knew it was for blood pressure,*
>
> *but they didn't know any more about it. And good was they knew what it*
>
> *was for, more about how it worked... they knew it was an ACE inhibitor...*
>
> *and they knew roughly what those things did'.*

Pharmacist P5 described good as:

> '*showing an overall good knowledge and appreciation of their condition and*

their medication'.

This was smilar to pharmacist 3 who said:

> 'if they were also confident talking about their medical condition and how they manage it then I would normally rate them as adequate'.

5.8.1.3.2 Patient engagement

The second theme developed was the perceived level of interest of patients to learn new information. The desire (or lack of) to find out more information was often mentioned when describing how they differentiated between poor, fair and good for each indicator in the assessment (figures 5.5 to 5.7). Pharmacist P2 said;

> *'some people have obviously read the patient information leaflet in detail and they knew everything that's on there and they could probably tell you more about them than I can tell; others hadn't got a clue, they hadn't even opened the boxes'.*

Pharmacist P4 reported asking patients what they had learnt about their medication since their initial consultation with the GP.

> 'if they said, "I Googled a lot of stuff when I got home" or anything like that I'd use that'.

One of this pharmacist's reports stated:

> '*patient didn't seem to care what his medication was or how it worked or showed any interest to learn'.*

The pharmacist perceived that the lack of interest of patients was linked to their willingness to accept the GP or pharmacist's analysis.

> *'In talking to them they were very confident people but they didn't really have any knowledge about their medication. They weren't that fussed about finding out new information, mainly because they said, "oh well, you know what you're talking about". So, I wonder how much there's a problem with if they trust the doctors and they trust us that we know what's best for them, they don't actually look into their medication'.*

5.8.1.4 Heuristic assessment

When it came to making an overall decision on health literacy the numerical assessment of importance of the indicators produced the following ranking:

Chapter 5 Heuristic assessment of health literacy

1. Drug Knowledge
2. Recall of verbal information
3. Use of medical terminology
4. Time to sign their name
5. Asking questions
6. Recall of written information
7. Seeking new information

The pharmacists in the interviews were openly sceptical of the indicator of the patient signing their name. This is incongruent to the score ranking for this indicator.

Pharmacist P4 reported:

'So, I had one old man who really (sic) good knowledge about all his medication, he'd been on them for a long time, he'd done a lot of research on them, very clever man, and he had a hugely elaborate signature which took him about three or four seconds to do, and then I've done a couple of other people whose signatures pretty much an X but have no idea what they were coming at'.

This reflects the views of other pharmacists such as P5 who said:

'obviously, there are some people who do really struggle to write but I didn't really come across that particularly. People who maybe took longer to sign, it was only because maybe they had a longer name or something'.

Another pharmacist was more reflective quoting past observations.

'*From experience, we've observed customers signing their names, often the people who would take longer to sign their name would be maybe elderly patients who would take time to form each of the letters and everything and that gave us a preconceived idea that perhaps they're not that good with health literacy but then I think in the end, that could be wrong, it could be wrong to just use that on its own' (P3).*

5.8.1.4.1 Approaches to deciding on health literacy ability

One pharmacist described a numerical approach to deciding the health literacy of the patient.

> 'you'd scored them 0 to 10, and in the end, to stop yourself making a subjective judgement, which you could do really…. In the end I was scoring them, so anything 6 and above I was giving a particular score… If say the majority of the scores were 6 and above, I would give them a fair rating, where if I found that the majority of them was five or below I would give them a poor rating' (P1).

The remaining pharmacists chose a different process to make their health literacy assessment which was to give a higher weighting to the patient's drug knowledge and or use of medical terminology. Pharmacist P5 said:

> '*well it was probably more a general assessment of how our conversation had gone but incorporating into that the competencies, but I think that for me, what I consider perhaps erroneously, to be of the greatest or most important markers I suppose, was the correct use of medical terminology and understanding of their condition and their medication, what they took it for and when they took it'.*

Pharmacist 4 stated:

> '*mainly based on the recollection of what it was for, how it worked, if they had any medical terminology or not'. They later added 'I tended to weight it more in terms of if they knew what it was for and they had recollection of that'.*

Pharmacist 3 also identified the importance of assessing the patient's drug knowledge and use of medical terminology.

> '*Generally, I would have looked at how fluent the patient was when they were speaking and also, I was looking at the bigger picture really, I was breaking it down into those six different criteria, so you can often judge or gauge how knowledgeable a patient is by how fluent they are and their use of medical terminology'.*

5.8.1.4.2 Barriers to accurate assessment - managing conflicts

Another theme that was developed from the interviews was that of managing conflicts during decision making. The theme can be divided into three sub-themes, existing patient knowledge; consultation limitations and coping strategies.

5.8.1.4.2.1 Patients existing knowledge

The indicator of seeking new information caused doubts for some of the pharmacists particularly for individuals that had been on their medication for many years.

> *'but when that person's been on medication for 26 years they don't ask questions. So just trying to prompt them to ask questions or even…I think some of them, the feeling was that they were doing you a favour, doing the study or... <laughs> Yeah, I don't know really… it's a difficult one' (P1).*

> *'in some cases, I thought they probably hadn't asked questions perhaps because they felt that they did know sufficiently anyhow, so I suppose to some extent that was quite a tricky one' (P5).*

Pharmacist P3 recalled patient's comments:

> *'I've taken such and thing for a number of years and I know exactly…' 'I've been on this medication for 10, 15 years and I've always taken them in the morning or at this time.'*

5.8.1.4.2.2 Consultation limitations

Concerns and doubts were raised by the pharmacists over the limitation of completing a health literacy assessment during a brief consultation.

> '*Because an MUR is so closed, you're looking at five medicines the patient is taking, and either they know about them or they don't know about it, but to me health literacy is a broader thing, isn't it? And I don't think that the ones I spoke to, apart from maybe a couple, actually knew anything much beyond their medication. So how does that test their health literacy really?'* (P1)

The pharmacist went on to describe perceived problems of assessing regular patients.

> '*It was very hard to do it on customers you know, because you know them, don't you? I think I was giving them the benefit… I was giving them a better score because I knew them. Because you know them, you know that... this 20-minute session isn't going to be their health literacy, if you see what I*

mean. Because you've interacted with them before. Maybe they were just having a bad day or something'.

They also said;

'If I was to do the study again, I probably wouldn't be so lenient. I probably erred on the side of being… it's very hard, in our area, 'cause it's an elderly population and you don't really know whether it's because they don't understand or whether it's because their memory's failing. Whereas if you are dealing with younger -… I might have been harsher if I was dealing with a younger population'.

Pharmacist P4 referred to their difficulty in deciding during the consultation the difference between lack of interest and inability to learn new information.

*'I think a lot of the time they would (sic understand) but they're not that fussed. Which was the only one (**indicator**) that made it harder to really judge those people, just because you'd feel like they would understand it and when… at the end of the sessions I'd say, "do you want me to go over this and teach you what it is?" They were perfectly capable of learning that, it's just that they hadn't bothered to up until that point'.*

5.8.1.4.2.3 Coping strategies

One pharmacist highlighted an issue of patients having a coping strategy for their medicines.

'I would say out of the 19, I probably had about 5 who actually had a crib sheet with them. And there wasn't an appointment we'd made for them; they were customers who'd just come in'… 'It was quite difficult because some of them literally carry <chuckles> a sheet of paper in their pocket with all their medicines, what they're for, written out. So effectively every time you ask a question this sheet came out and they were just sort of… so that makes it quite hard, doesn't it, because it's all written… either another healthcare professional has done it or their children have done it for them, and that was a bit difficult. So, I think then you tried to ask them questions which weren't related to their medicines… so you just have to step outside the crib sheet to see if you could find something' (P1).

5.8.1.5 Future use

The pharmacists reported their perceptions of how the assessment process could be improved.

> *'I some-times need to be spoon-fed, so maybe a bit more information on what would be regarded as easy, what would be regarded as not so easy. Because I think sometimes you felt as if you were working blind'.* They also added: *'you're sometimes clutching at straws, aren't you, to make a judgement?' (P1).*

Pharmacist 2 built on the concept of identifying criteria for health literacy assessment and linked this best practice in supporting individuals with limited health literacy.

> *'I think it's really working out from the start what your expectations of the patients are… I've always been in the mind not to bombard them with too much information and hopefully whenever I give a prescription out or ever have a review I may come out with up to three key points, anything more than that I think we're pushing our luck really'.*

Pharmacists P4 and P5 also highlighted the need for greater guidance on the process.

> *'Nothing I can really think of other than if you had more of a set script… Other than that, we've already got it set out where you've got to ask these questions and it has phrasing for you… no, 'cause really it did feel like it did suit the MUR style' (P4).*

> *'Yes, how to assess it yes (**guidance),** definitely, would be more helpful. So, you had specific guidance and yeah, you would be then specifically looking out for that in the patients you were talking to' (P5).*

Barriers to future adoption were reported by the pharmacists; the most frequently cited issue was finding the time to carry out the assessments. Two pharmacists highlighted the time issue from the pharmacist's perspective.

> *'Only time… it was perhaps slightly bad time 'cause we were really busy leading up to Christmas' (P5).*

> '*It was mostly not having the time to recruit patients when we first started doing it, so for example, around November, December time we were doing 'flu jabs and then we went straight into the Christmas period' (P3).*

Both pharmacists suggested that the number of indicators should be less.

> *'Off the top of my head maybe narrowing it down to three or four of the criteria, I suppose, or…?' (P3).*

> *'Just reduce how you are going to grade people. That would make it far easier.' (P5).*

Another pharmacist raised the issue of time from the patient's perspective.

> '*I guess time is their only barrier, you know, oh wife's outside in the car or left the dog tied up outside or I've got to get the bus in two minute's time 'cause I've got to meet the kids from school. Those are the time barriers. And because we… obviously, we don't make appointments for people usually, they come in on spec … I think you're always going to get some that can't really… if I knew I was going to be this long I would've made an appointment and come back and seen you later. That's occasional, the comments you get' (P2).*

One pharmacist raised the issue of getting pharmacists to incorporate something new into their existing practice.

> *'Initially it would be perhaps introducing that into your thinking, maybe it would be similar to changing habits, you have to do something maybe half a dozen times, 10 times before it becomes second nature or I think it's maybe 20 times before it becomes second nature, so I think it would have to be… make ourselves conscious to try and work out a different format to take into consideration the findings of the study'. (P3)*

5.9 Quantitative discussion

5.9.1 Pharmacy and patient consent rates

It is difficult to directly compare the pharmacy consent rate with other studies for two reasons. The pharmacy recruitment strategy for this study only involved one expression of interest letter being sent to non-Boots pharmacies. Other studies

have indicated that having multiple requests to pharmacies improves the study uptake rate (342, 343).

The 2015 systematic review of pharmacies willingness to participate in research (307) reported five UK based pharmacy studies all which were carried out before 2001. Pharmacy ownership has changed significantly since then with a fifty percent increase in company ownership over the period 1997 to 2007 (344). Change of corporate policy has resulted in Boots adopting a centralised approach to consenting to research making direct comparison of response rates difficult. During the study period Lloyds also changed their policy on allowing individual pharmacies to consent to participation. This change in policy resulted in the change of pharmacy 4 within the study.

The pharmacy that had the highest patient acceptance rate allocated the task of recruiting patients to one individual, the pre-registration pharmacist working in the branch who asked patients whilst they were waiting for their prescriptions to be dispensed. The pharmacy reported during the interview that they believed linking the recruitment with the patient's availability improved uptake of study participation. For the other pharmacies, the ranking of acceptance rates was comparable to the length of time the pharmacist had work at the pharmacy. Generally, the longer they had been there the higher was their acceptance rate. The feasibility study described in chapter 5 highlighted the willingness of patients to support they local pharmacist with whom they had built up a professional relationship. Whilst the patients in this study were not asked why they were willing to participate it may well be for similar reasons.

5.9.2 Descriptive statistics

5.9.2.1 Pharmacists

Three of the five pharmacists had been practising for 30 years or more, indicating that the selected pharmacies are not fully representative of the wider community pharmacy sector. A General Pharaceutical Council review of pharmacy registrants indicated that the average age of practising pharmacists was 39.9 years of age with just under a third of registrants in the 30 to 39 year age bracket (345). However, with such a small sample this was never the aim and the sample does contain a wide variation in experience from novice to highly experienced pharmacists.

Four of the pharmacists had been working at their current pharmacy for one year or more which creates the environment where patient-pharmacist relationships can be developed, which was important to the focus group participants of the previous study. The fifth pharmacist was new in post so this provides additional variation between the pharmacies in the study.

5.9.2.2 Patients: Age, gender and education level

The results obtained for age and age leaving education were similar to the previous study reported in chapter 4. There was a slight increase in median age of patients and extended age range but neither was statistically significant. It might have been expected to see a different profile as the pharmacies were selected for this study to provide a demographic mix. Three of the pharmacies were in wards where the percentage of the population over 60 years old were low yet there was no appreciable difference in the age of the recruited patients. This supports the previous discussion in chapter 4 that pharmacy users tend to be older than the average for that of the local community due to increasing need of prescribed medication.

The percentage of female patients in the sample was lower than the previous study and in contrast to the Tully analysis of pharmacy users (313). Tully conducted face to face interviews of 1882 people to ascertain their useage of community pharmacies. Gender was identified as the most important predictor of visiting a pharmacy with females being the most frequent users. The lower percentage of females in the thesis study may be due to the maths content within study which was mentioned in the patient information leaflet. Previous work has indicated that males are more interested and perform better in mathematical tests than females (346, 347).

5.9.3 Health literacy levels

The estimation of adequate health literacy in this sample was more consistent with the findings of Protheroe et al. (331) and generated a similar proportion of patients in the adequate health literacy grouping. The major variation between the two studies was the greater proportion of patients with marginal health literacy in the thesis study.

5.9.4 Health literacy levels and confounders

In comparison to the feasibility study there was no correlation found between patient age and NVS level. It is possible that the heuristic study population was not reflective on the wider population and that a larger sample size may have found a negative correlation as described in the feasibility study and by other NVS studies (172) (331). The median age and Interquartile range within the heuristic study was much higher than other studies using the NVS where the median age reported has been in the early forties (90, 328, 348, 349).

Like the first study using the NVS in community pharmacies no correlation was found between the patients gender and their health literacy level. Most studies involving the NVS, including the instrument validation papers, do not report a correlation of gender with the NVS (90, 172, 190, 349). However, Shah's study did report a correlation (328). A possible explanation for the general lack of evidence for a correlation between gender and NVS health literacy may be due to the mathematical element within the NVS compared with other health literacy instruments. As previously mentioned males perform better at numerical tests whereas females have been reported as having better health literacy than males (318, 350). These two conflicting performance traits may counterbalance each other making the findings non-significant.

The identification of a moderate correlation between health literacy and educational level is consistent with the body of evidence that indicates a relationship exists (350, 351).

5.9.4.1 Correlation between indicators and NVS level

The time to sign indicator was the only indicator used to heuristically assess health literacy that did not generate a statistically significant correlation and provide data to support the original research. The study by Sharp et al. (76) indicated the time sign a prescription was a potential predictor of limited health literacy. It involved a sample population of a similar size to the heuristic study (98 patients). It differed in that it used REALM to identify health literacy ability rather than the NVS. The range of time taken to sign their names in the Sharp study was very different to the findings reported earlier. The range varied from 1 second to 23 and the mean time was ten seconds whereas no individuals in the heuristic study took longer than eight seconds to sign their name. Consequently, the recommended cut off point

identified by Sharp of six seconds incorporates most of the patients in the heuristic study and therefore has little direct comparison of pre-and post-six second's data.

5.9.5 Pharmacist accuracy

The gestalt ability of pharmacists to identify health literacy was consistent with other studies that found healthcare professionals over estimate adequate health literacy (282, 329, 352-354).

The pharmacists in the heuristic study showed a wide variation in their individual ability to effectively use the heuristic indicators to make judgements on health literacy ability. The variation could be explained in terms of the number of years practising as a pharmacist, however, this was not formally tested for as it was not one of the research questions. The study by Carpenter was the only previous study that used practitioners with different levels of experience, hospital residents and treating physicians. The studies by Bass, Rogers and Lindau only used hospital resident doctors whereas Kelly used more experienced primary care physicians that averaged 15 years of practice.

There is evidence in other professional groups of practitioners being able to accurately use heuristic assessments for other purposes. A Study of the heuristic assessment skills of nurses (246) found that greater years of critical care nursing increased the likelihood of consistent decision making. Similarly, a study of nurse practitioners' decision making abilities indicated that more experienced nurses were better at making accurate intuitive decisions (355).

A study by Frederick indicated that females were more likely than males to trust their intuitive decisions and were less likely to reanalyse their initial decision and therefore were better at heuristic judgements (346). Further investigation of what makes some pharmacists more accurate at predicting adequate health literacy would enable other pharmacists to better understand how to make more effective assessments using the indicators and thereby improve the overall diagnostic ability.

In general, all the pharmacists were more accurate at assessing negative predictive values than positive predictive values. An explanation of this difference could be down to the predictive properties of the NVS instrument rather than the heuristic indicators. The validation of the NVS by Weiss et al. (90) and the subsequent further validation by Osborne (326) demonstrated that the NVS

strength is its ability to accurately assess adequate health literacy due to its very high specificity for this cut off point. Whereas the specificity and sensitivity were reduced to 72% and 87 % for the limited health literacy group (90). Hence the early language used when reporting limited health literacy with the NVS was to use adequate health literacy and the terminology of likely limited literacy.

5.9.6 Estimates of model parameters and precision

The combination of adequate and marginal health literacy levels into a binary logistic regression model provided a comparison of indicator performance against NVS attainment. Not all measures could be calculated due to the relatively small number of limited health literacy cases within the sample size and the unequal distribution within the pharmacies. The consequence of this small number of cases was to generate wide 95% confidence intervals for the sensitivity, positive likelihood ratios and positive predictive values where they could be calculated.

The data on the indicator recall of written information is comparable to the results obtained by Chew (356) when advocating the use of a single question 'confident with forms'. Chew used two health literacy instruments to compare her heuristic approach, S-TOFHLA and REALM. The S-TOFHLA evaluation produced an AUROC value of 0.74 (95%Cl 0.69-0.79) and the REALM 0.84 (95%Cl 0.79-0.89). The answer of 'a little bit' to how confident with forms generated a LR+ of 5.15 (3.17-8.38) and an LR- of 0.72 (0.58-0.89) against S-TOFHLA. The REALM based values were LR+ 6.5 (4.18-10.1) and LR- 0.61 (0.45-0.83). The S-TOFHLA is probably a better comparator to the NVS due to the inclusion of a numerical component to the instrument.

An alternative Single Item Literacy Screener (SILS) question was evaluated by Goodman et al. (357). She evaluated a question regarding difficulty in understanding written information. Both sets of results are very similar but with the heuristic study obtaining slightly higher values for each of the measures. The Goodman study reported the difficulty in understanding written information question had a sensitivity of 62%, specificity 81% and LR+ of 3.26 and an LR- of 0.47.

Combining two indicators recall of verbal information and recall of written information did generate the highest ROC value of any combination or single

indicator but added nothing more to the results obtained by the recall of written information indicator.

Combining all the six indicators that had a correlation to NVS levels did not improve the overall ROC value compared with the recall of written information indicator alone. It did however create a small improvement in all the other measures bar the negative predictive value. Potentially the combination could be explored further, however it would be a more complicated model to use in practice and takes longer to complete the assessment. Based on the data obtained so far it is not clear that the extra increase in sensitivity and positive predictive value is sufficient to make this worthwhile. The heuristic assessment within this model combination is much better at assessing negative predictive capability. That is, its ability to identify adequate health literacy. Consequently, adding all the indicators together does not improve the negative predictive value compared to the single indicator of recall of written information.

The Combination of limited health literacy with marginal health literacy improves the positive predictive capabilities of the model. The predictive values were approximately double that achieved with the marginal and adequate bivariate model. The increase in positive predictive values was partially compensated by the decrease in negative predictive values. The use of medical terminology and seeking new information indicators were stronger indicators for predicting positive values than recall of verbal information. The current thinking on health literacy assessment recommends the use of the universal precaution approach (9, 329). The universal precaution assumption is to treat all individuals as potentially having limited health literacy. In effect this approach has 100% sensitivity and low specificity. In comparison, the heuristic model under discussion, results in a less accurate assessment of limited health literacy. The bivariate model of combining limited and marginal health literacy therefore appears to be less useful model when compared with universal precautions. Whereas, the marginal and adequate health literacy grouping is better at predicting adequate health literacy which is ignored in the universal precautions approach.

5.10 Discussion

NVS assessment

The pharmacists' comments reported in this study are consistent on the theme of being tested in the pharmacy to that described in chapter 5. The continuing sub-theme of performance anxiety of patients and its impact on the assessor is of note. The previous chapter highlighted the problems associated with the pharmacist carrying out the NVS assessment. This study adds to the previous findings the reported perceived perspective of non-pharmacist staff carrying out the assessments. It is perhaps, not surprising that they also reported discomfort at watching patients struggle to complete the assessment and were unsure how to react to the new experience within the pharmacy. It is a very different to existing practice that is designed to put the patient at ease and provide support and assistance as opposed to expecting individuals to struggle unaided (358, 359).

5.10.1 Heuristic assessment of health literacy

The themes developed from the interview transcripts (appendices 6.1 to 6.5) indicate that the pharmacists were cognisant of a broader definition of health literacy that went beyond the capacity to understand information and encompassed seeking and applying information. However, when they came to make a heuristic assessment of health literacy most reverted to assessing medicine knowledge and ignored the attitudinal component.

The pharmacists' assessment of individuals' health literacy ability was consistent to previous research (282, 329, 352, 353) with an overestimate of adequate health literacy. All the studies that have considered the professional's ability to judge health literacy have used different health literacy instruments as a comparator. The study by Carpenter used S-TOFHLA as the primary reference instrument but also used the NVS as a comparator. Despite the overestimate the paper argued that the gestalt result obtained, for sensitivity and specificity, was 'as accurate as any currently validated health literacy tests and does not require additional time for testing' (329). However, the authors believed that as it could not accurately exclude adequate health literacy it should not be used and that universal precautions were preferable.

None of the previous studies provided any evidence for the professionals' decision making processes. This study is the first to capture insights into why the clinicians

over estimate health literacy. Comparison of pharmacists' reflection on individual consultations and the obtained health literacy level for those individuals generates some interesting observations. The themes of knowledge and patient engagement are clearly visible within each health literacy level. The variation between each level suggests a pattern of increasing knowledge and engagement with higher health literacy levels. The observed pattern is keeping with previous research that indicates that those with limited health literacy and are less likely to access information and lack health knowledge (33, 35, 42, 43). The pattern reflects the definition of health literacy, the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health. For each health literacy level, there were exceptions that contradicted the expected pattern. If the pattern was being used to inform the health literacy assessment it is not surprising that the pharmacists reached the wrong conclusion on the individual's health literacy level. It is not known if these variations are an indication that the health literacy level obtained was a false positive or false negative result or whether the individuals were atypical.

Pharmacist 5 who was the most accurate at using the indicators referred frequently during her interview and in her reflection of patient assessments the importance of the individual's ability to correctly pronounce medical terms and conditions. The pharmacist was therefore using a heuristic version of the REALM instrument as part of her decision making. It is unclear to what extent this heuristic version of REALM influenced her final decisions. It does raise the possibility that future research could explore the use of a heuristic use of REALM as an alternative mechanism to assess health literacy.

Pharmacists reported being conflicted on decision making when faced with patients who had been on their medication for many years as they appeared to not require further knowledge and were aware of their medication. Previous studies have looked at the impact of educational training has on health literacy ability. A longitudinal qualitative study (360) indicated that patients that had a long-term condition could develop health literacy skills overtime. However, this was a study of 18 patients whose health literacy level was not assessed. The demographics of educational level obtained and professions of the individual's participating indicates that most would be likely to have adequate health literacy. Whereas, a

cross sectional study (361) reported that all individuals benefited from an educational intervention but that the patients with inadequate health literacy learned significantly less than those with adequate health literacy.

It is unclear whether the patient coping strategy identified by one pharmacist is a potential indicator of limited health literacy and is an aid to managing limited literacy or whether it is a recognition of reduced cognitive function. However, either way it may still be an indicator of limited health literacy as a previous study has indicated that older patients screening positive for cognitive dysfunction compared with older patients that screened negative had significantly lower health literacy (317). As these patients were not identifiable from within the data set. Further research would be required to further investigate if there is any association between the use of crib sheets and limited health literacy ability.

In contrast to the quantitative findings the pharmacists perceived using the recall of written information the hardest indicator to incorporate into a consultation, which raises the question of future implementation of the indicator as a health literacy assessment process. However, any future heuristic health literacy assessment would require further research which would have to include guidance on how to use the indicator in a consistent way. This guidance could therefore address these initial concerns and lead to a fully validated heuristic assessment observation or direct question.

5.11 Summary

The feasibility study indicates that a hueristic health litreacy instrument has the potential for use in a routine clinical environment. Chapter 6 concludes the thesis by discussing the weakness and limitations of the conducted studies and suggests further research to develop a heurisitic health literacy instrument.

Chapter 6

Discussion

6. Discussion

Limited health literacy has a major impact on health outcomes and is largely overlooked by UK healthcare professionals. The adoption of universal precautions is currently advocated as the best practice for heathcare professionals to use to compensate for limited health literacy. However, universal precautions does not support patient-centred care where the emphasis is on the needs of the individual rather than taking a standarised approach. Universal precautions has not been widely adopted by healthcare professionals, consequently patients with limited health literacy do not get the additional support they require to succesfully navigate the healthcare system and manage their own health.

Chapter 2 reported the findings of the systematic review of health literacy instruments to assess their potential for use in a routine clincal environment. Sixty-four instruments were identified and evaluated. The large number of health literacy instruments found demonstrates the divided opinion on how health literacy needs to be assessed. The systematic review adds to the existing body of knowledge by identifying the optimum health literacy instrument to use in a clinical environment and provides a detailed rationale for the selection on the Newest Vital Sign.

The feasibility study provides some initial evaluation of the use of the NVS in community pharmacies in the UK and provides an analysis of health literacy ability of pharmacy users. It expands the existing research literature on the question of how long the NVS takes in practice to complete and provides some patient and pharmacist insight into the acceptability of the assessment in a community pharmacy environment.

The NVS was chosen as the health literacy instrument to assess in community pharmacies based on the systematic review in chapter 2 which had a completion time of five minutes or less as a selection criterion. This study's results show that the median completion time was within this parameter but not all were able to complete within the projected time. Worryingly, some required double this to complete, however it is unclear whether the time taken to complete was influenced by the pharmacists who admitted to trying to support the patient through the process.

Chapter 6 Discussion

The qualitative analysis provides some new insights into both pharmacists and patients perspectives of assessing and being assessed with the NVS. The value associated with the ongoing patient-pharmacist relationship is worthy of future research to see how widely this phenomenon exists and to explore how it can be used to improve patient outcomes, particularly in relation to supporting individuals with limited health literacy.

There are several limitations and weaknesses to the NVS feasibilty study. The numbers participating are small and there were small focus group numbers per health literacy ability level. This may impact on the breadth of perspectives observed and may not be a true reflection of the variation in perspectives between health literacy levels which may impact on the transferability of the insights gained.

Participation in the study was strongly affected by the existing relationships with the pharmacy staff and the willingness of patients to 'help' their pharmacist. It is unclear if other pharmacy users would have very different perspectives on completing the assessment, particularly, individuals that do not have a regular pharmacy they use or individuals that frequent pharmacies that operate by using locums. No focus group data was collected from participants unwilling to participate to see if they had different perspectives.

The study was designed to gauge the initial impressions of patients to completing the NVS and therefore the concept of testing patients was not overtly promoted in order not to scare individuals with limited health literacy from participating. There was no explicit conversation over assessing health literacy with the patients before starting the assessment. Different perspectives could have been captured if they were implicitly aware that they were being tested.

The findings indicate that the pharmacist involvement in NVS assessments may have facilitated the patients' completion of the NVS and this may have over inflated the individuals obtained NVS score. This may have resulted in higher levels of health literacy being recorded for these individuals and over-estimated the time required to complete the assessment. Over estimating health literacy ability may then have resulted in focus group members not being in their correct health literacy ability group, which may impact on the recorded perspectives of that group and the collected views may not reflect the true views of individuals of that health literacy ability level.

It was never the studies intention to have the pharmacists complete the assessment and further studies should be aware of the potential impact of the study protocol being overridden.

The systematic review identified the NVS as the 'gold standard' or optimal measurement instrument. The feasibility study indicated that patients would complete it for research purposes so it could be used for further research in clinical environments. The results are less convincing for its use a practice based assessment instrument. The longer time to complete than the reported 2-3 minutes and the introduction of a formal test into existing practice identify huge challenges that require large changes to culture and practice, both for patients and pharmacy staff.

Another area of concern for the implementation of the NVS into standard practice is the issue of funding. It was reported earlier in this thesis that the study was unable to recruit pharmacies to participate without adding a payment for assessment. This might be due many factors such as, the pharmacies not prioritising research, or not finding the research topic of interest or relevance to them or might be down to adding new activities to the workload that are not remunerated at the expense of activities that are. It is not foreseeable with limited NHS financial resources that payments would be made available to pay pharmacies to complete the assessment as this study did.

In the existing pharmacy environment, where practice still focuses on prescription numbers and time is an ever-increasing limited resource, and with no funding for assessment, the likelihood of the successful introduction of this assessment instrument is highly unlikely.

6.1 Heuristic assessment

The study provides an additional evaluation of the use of the NVS in community pharmacies. It reinforces the findings within chapter 4 that it is not a suitable instrument for use within community pharmacy practice as standard practice.

The qualitative analysis of pharmacist's perceptions of using heuristic judgement provides a useful insight to gestalt judgements and generates some new understanding of assessing health literacy in a community pharmacy. It also gives

a greater depth of interpretation to the quantitative assessment generating richer understanding of the data.

The findings from the study indicate that a heuristic assessment of health literacy could be developed via further research for use in community pharmacies. The Medical Research Council guidance on developing and evaulating complex interventions recommends that after completing feasibility studies and evaluation that implementation studies are carried out to assess the behavioural change and dissemination requirements for future implementation.

6.1.1 Weaknesses and limitations of the heuristic study

The small number of pharmacists in this study may not reflect the wider population of UK pharmacists and therefore the results may not be replicable with a different cohort. The small number effects both the qualitative and quantitative analysis. The pharmacists were predominately selected from a small group of pharmacists who were keen to engage in research and this may have introduced bias into the study. The pharmacists also differed from the wider pharmacist population in that they on average were highly experienced pharmacists who were working consistently in just one pharmacy. As indicated by the findings this influenced the outcomes. Further work would be required with randomly selected pharmacists to assess if similar outcomes could be achieved in a profession that uses locum pharmacists on a regular basis.

The population sample with the study was not a true reflection of the wider population due to the proportion of males and the higher mean age of the sample. Further investigation would be required to see if the results were replicable with a different sample group.

The completion of the NVS prior to having the pharmacist assess the patient may have introduced bias into the study as reports were obtained of patients wanting to talk about the assessment with the pharmacist. A future solution would be to have the pharmacist assessment first consequently removing this potential bias.

6.2 Summary

The initial investigation of a heuristic assessment of health literacy was positive demonstrating the ability of pharmacists to be able to identify health literacy during a medicine consultation using a few different indicators. Further research is

required to ascertain if a heuristic assessment of assessing patients recall of written information can be used to accurately identify individuals that have adequate health literacy. Further exploration of the role of experience within heuristic assessment could potentially identify which characteristics the experienced pharmacists base their judgement. The use of this knowledge could then inform the appropriate use of a heuristic indicator. Thereby identifying those patients that lack adequate health literacy and consequently require different interventions to support.

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Appendices

Appendix 2.1 Systematic review search strategy

Appendices

Appendices

Appendix 4.1 Prepared script to invite patients to join the study to

assess health literacy in a community pharmacy using the

NVS

Script for requesting patient participation

- This pharmacy is participating in a University of East Anglia research project to understand how easily facts about health can be understood by patients.
- We are asking patients that are collecting a prescription for their blood pressure tablets if they would like to be involved in the study.
- If you agree to take part it would require you to answer a few questions in the consultation room and would take about 5-10 minutes of your time.
- For most patients that would be the end of the study.
- A small number of patients might be contacted again and asked to join a small discussion group.
- You will be given a £5 voucher as a thank you for participating

Give the patient the Patient Information Leaflet and consent form.

- The leaflet gives you more information on the study.
- We suggest you take the information away and think about if you want to take part.
- Please return the consent form to this pharmacy if you want to take part.

Appendix 4.2 Prepared script to assess patients using the NVS

Script for carrying out a NVS assessment

- Thank you for agreeing to take part.
- Please take a seat.
- I am going to explain what is going to happen and you can ask any questions.
- I will ask you in a moment to confirm a few details about yourself.
- I will then give you a short information leaflet about the contents of an ice cream tub.
- If you prefer I can read the information leaflet to you.
- I will then ask you to answer up to six questions about the leaflet.
- I will time how long it takes to answer the questions.
- Do you understand and are you okay with the process?
- Do you have any questions?
- Would you like to read the leaflet yourself or would you prefer me to read it to you?
- You can stop at any time you wish without giving a reason.
- If for any reason you are upset with any aspect of the study you can contact the project supervisor whose details are on the Patient Information Leaflet.
- Okay we will start now.
- Please confirm your age
- At what age did you leave full time education?
- Are you prepared to take part in the discussion groups?
  If so
- Are you happy for your contact details to be passed on to the researcher?

The staff member would record the answers along with the participant's gender. The participant would then be given the Newest Vital Sign information leaflet and be asked to read it. The time would be recorded. When the participant was ready the staff member would read the questions, and record the answers provided and record the time when the last question was answered.

- Thank you for taking part

- Just to remind you that (if agreed to group work) that they might be contacted to take part in the small group discussions.

Appendix 4.3 Patient Information Leaflet for the study to assess the NVS

in community pharmacies

Version 14 14/9/15

What happens if I agree to take part?

You will be asked to read (or be read to) an ice cream container information sheet before being asked up to six questions on the information. Some of the questions involve simple sums. You will be asked your age, gender and educational status. We will let you know by letter whether we would like you to attend the focus group. If we do not contact you, there is nothing further for you to do. If we do invite you to attend a discussion, you will be sent a choice of dates, times and locations and we will ask you to let us know which ones are okay for you. After the focus group, there is nothing further that you will need to do.

What about confidentiality?

We will keep all your personal information safe and not share it with others. The groups will set ground rules so everyone agrees to respect views and maintain privacy. Nothing that can identify you will be published.

What if I want to take part?

Please complete the enclosed consent form and return it in the pre-paid envelope provided. If you change your mind, you are free to withdraw from the study at any time without providing a reason.

What happens when the project ends?

The results of the study will be published. This would not have any of your personal details in it.

Who is doing this research?

This research is being carried out Paul Duell who is a researcher at University of East Anglia. The research will lead to a higher educational qualification

What if there is a problem or I want more information?

Please phone or e-mail Debi Bhattacharya who is the person in charge of this study on 01603 593391 or D.Bhattacharya@uea.ac.uk or for independent information go to http://www.nihr.ac.uk/get-involved/research-matters.htm

How you understand the side effects of your tablets

UEA
University of East Anglia

An invitation to take part in a research project

Patient version 14
September 2015

What is the study about?

We are interested in finding out how easily facts about health can be understood by patients. We want to know what patients think about having their health knowledge measured.

We also want to find out whether patients think that help from a pharmacist might be useful to better understand the risk of side effects from taking medicines for blood pressure.

How can I help?

We want to know your views on getting advice about the side effects of your blood pressure medication. We also want to find out how to improve the information you receive. In order to design a study that is appropriate to patients we want to make sure that we measure all of the things that are important. We intend to do this by obtaining the thoughts of a wide range of patients before designing the study. We will do this through listening to the discussion when people get together in a focus group.

What is a focus group?

A focus group is where a small number of people (about 6- 8) meet to share views on a topic. Groups are supported by researchers who help to look after the group and set off conversations relating to the study topic.

The focus group will last up to 90 minutes and will be sound recorded.

It will take place at a location near to where you live. There will be refreshments provided.

During the focus group the researcher will ask the group to discuss topics related to the study which included your views on:

- being asked health questions in a pharmacy
- the amount of information about your blood pressure medicine you received from your pharmacy or doctor's surgery
- getting advice from a pharmacist about side effects of blood pressure tablets
- the type of information you require

Why have I been chosen?

Your pharmacy has agreed to be involved in the study. You have been selected because you have been prescribed treatment for blood pressure.

How will my opinion be heard?

Researchers will support the group discussion and ensure that everyone is able to speak freely and comfortably.

Will I be able to see the results?

Yes you can ask for a copy of the results.

Are there any disadvantages to taking part?

We do not think that there are disadvantages to taking part. We would only ask you to give up some time to take part in the project.

Expenses and payments

You will be given a gift voucher worth £5 for completing the questions.

You will be paid all expenses including travel costs and will be given a gift voucher worth £20 after attending the focus group

2

3

4

Appendix 4.4 Patient consent form for the study to assess the NVS

in community pharmacies

Appendices

How you understand the side effects of your tablets
Patient Consent Form

UEA
University of East Anglia

If you wish to be involved, please initial each box and complete the details at the bottom of the form. Once completed, please return in the envelope provided.

1. I confirm that I have read and understand the information sheet dated September 2015 Version 14 for the above study. I have had the opportunity to ask questions which have been answered to my satisfaction.

2. I am willing to allow the discussion within the focus group to be audio-taped for the purposes of analysing the conversations that take place.

3. I understand that I may be contacted by the research team with further information about the location and time of the focus group using the information that I provide below.

4. I agree to take part in the study.

Family name	_____	First name	_____
Signature	_____	Date	_____
	_____		
Address	_____		
	_____		
Telephone number	_____	E-mail address	_____

Patient consent form version 6 September 2015

Appendices

Appendix 4.5 Semi-structured questions for focus groups

Appendices

Patient topic guide – using the NVS in community pharmacies and how patients use the pharmacy to manage side effects of tablets.

<u>Introduction</u>

Thank you for agreeing to come to this focus group meeting today. It is a chance for you to share your views on taking part in this study and tell us about how you deal with worries over side effects of your medication.

<u>Information on how the focus group will be run</u>

- The views of everyone are important so please let others have time to speak and please feel free to join in the conversation
- Do not worry that the conversations are being taped it is only to ensure that we capture all the comments and no one will be identified in the final write up
- This is one of a number of focus groups and a single report will be written
- The meeting should last no longer than 90 minutes and at the end we will ask you to sign a form so that we can give you some M&S vouchers as a thank you for your time today
- At the end, we will ask you if you wish to receive a summary of the final report of the focus group work
- Are there any questions before we start?

So we can get to know each other a little better I am going to ask each one of you to tell us your first name and to tell the group what your favourite TV programme is.

Tell us why you agreed to take part in this study?

<u>Prompts</u>

- What would make taking part in pharmacy research more appealing / interesting to you?
- What was the most important reason to take part?
- What things would make you not want to join in?

- What is the biggest barrier to taking part?

We are going to give you three coloured cards green, yellow and red. In this situation red means did not like; yellow neither liked or not liked and green means liked.

Using the coloured cards, how would you rate the experience of answering the nutritional questions on an ice cream container in a pharmacy?

<u>Prompts</u>

- Why do you feel this way?
- What if anything would make it a better experience?
- Would you complete this again if asked in the future?

How often do you use the same pharmacy?

Using the coloured cards how important do you think it is to know the pharmacist within the pharmacy? (use cards red=low; yellow = medium; green = high)

<u>Prompts</u>

- Why did you use the red/ yellow/ green Card?

What is your experience of receiving information from a pharmacist on your blood pressure medication? Use the coloured cards (red = bad; yellow ok; green= good)

<u>Prompts</u>

- What information is important to you?
- How easy or difficult was it to get the amount of information you wanted?
- To what extent did the pharmacist describe the benefits and risks associated with your medication?
- Was there anything you wanted to know that they did not discuss with you?
- Did you feel you had the opportunity to ask questions? Why was this?

What information do you need to help you decide whether to take the medication?

<u>Prompts</u>
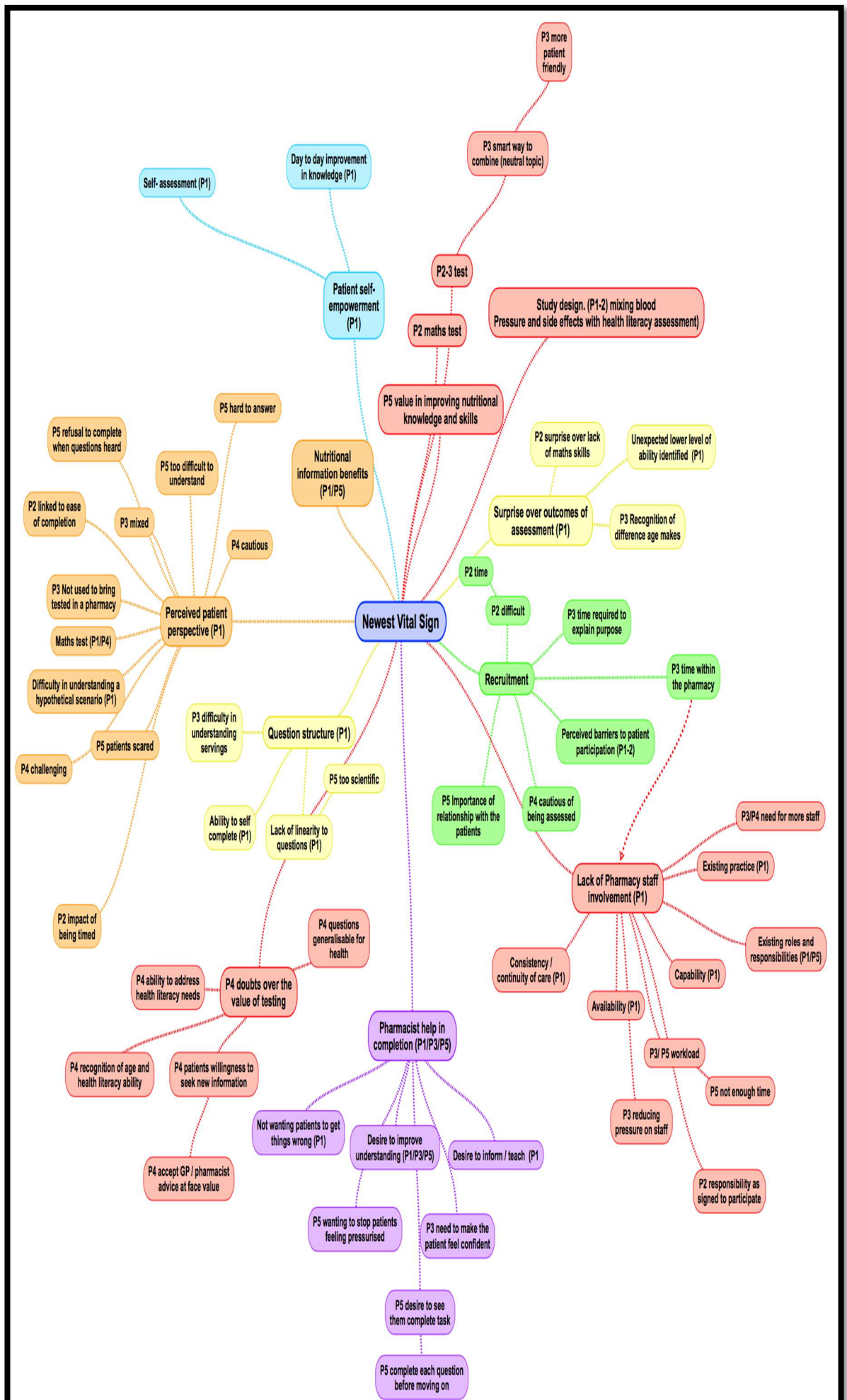
- How helpful or not are the written information leaflets in the medicine packets?
- How easy or difficult is it to understand written numerical information regarding risk?
- What are your thoughts on the role of the pharmacist in providing medicine side effect advice?

Thank you for your time today. Would you like a copy of the summary of the final report?
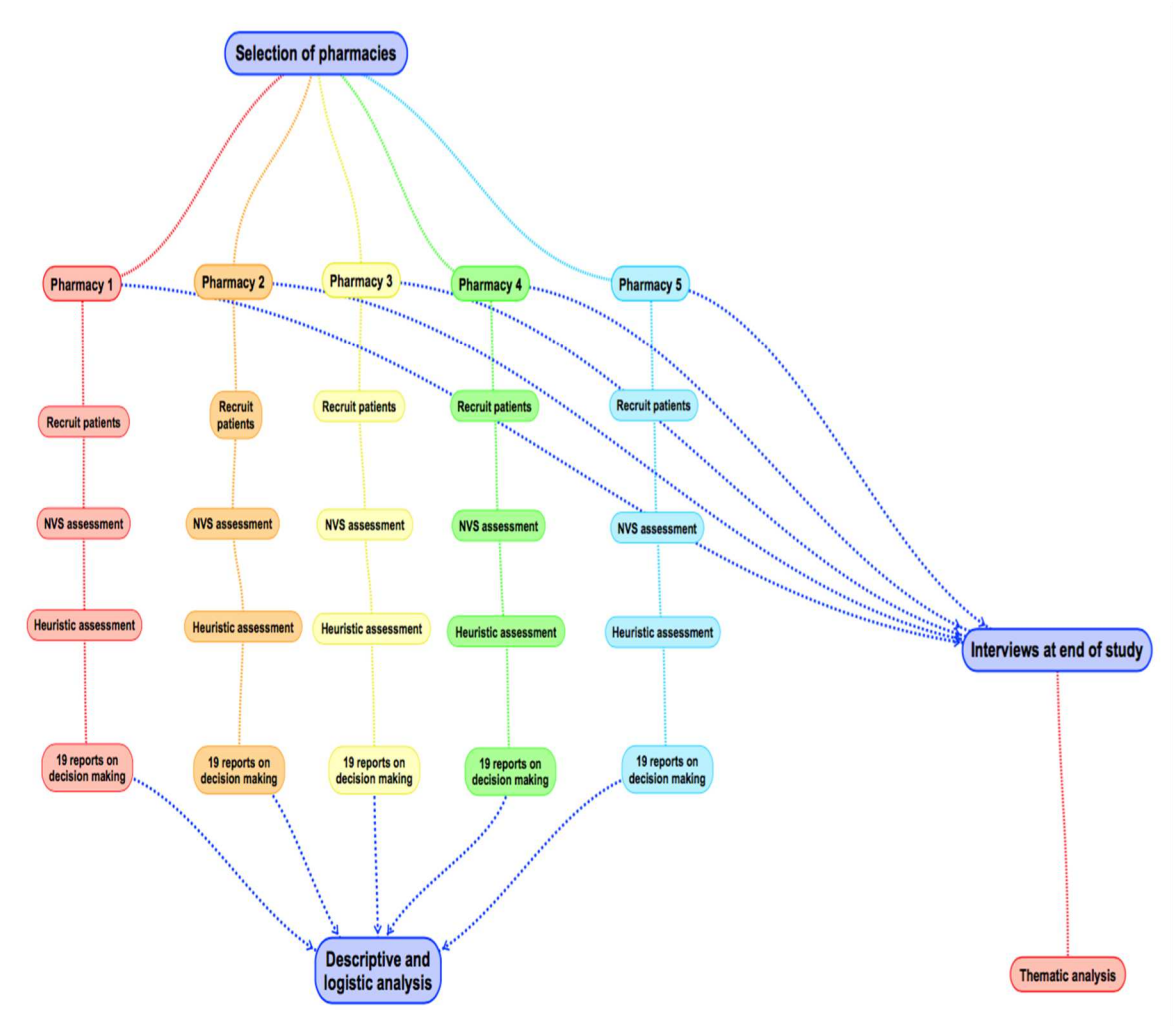
Appendices

Appendix 4.6 Mind map

Appendices

Newest Vital Sign

Patient self-empowerment (P1)
- Self- assessment (P1)
- Day to day improvement in knowledge (P1)

Nutritional information benefits (P1/P5)
- P5 value in improving nutritional knowledge and skills

P2-3 test
- P3 more patient friendly
- P3 smart way to combine (neutral topic)
- P2 maths test
- Study design. (P1-2) mixing blood Pressure and side effects with health literacy assessment)

Perceived patient perspective (P1)
- P5 refusal to complete when questions heard
- P5 hard to answer
- P5 too difficult to understand
- P2 linked to ease of completion
- P3 mixed
- P4 cautious
- P3 Not used to bring tested in a pharmacy
- Maths test (P1/P4)
- Difficulty in understanding a hypothetical scenario (P1)
- P5 patients scared
- P4 challenging
- P2 impact of being timed

Surprise over outcomes of assessment (P1)
- P2 surprise over lack of maths skills
- Unexpected lower level of ability identified (P1)
- P3 Recognition of difference age makes

Recruitment
- P2 time
- P2 difficult
- P3 time required to explain purpose
- P3 time within the pharmacy
- Perceived barriers to patient participation (P1-2)
- P4 cautious of being assessed
- P5 Importance of relationship with the patients

Question structure (P1)
- P3 difficulty in understanding servings
- P5 too scientific
- Ability to self complete (P1)
- Lack of linearity to questions (P1)

P4 doubts over the value of testing
- P4 questions generalisable for health
- P4 ability to address health literacy needs
- P4 recognition of age and health literacy ability
- P4 patients willingness to seek new information
- P4 accept GP / pharmacist advice at face value

Pharmacist help in completion (P1/P3/P5)
- Not wanting patients to get things wrong (P1)
- Desire to improve understanding (P1/P3/P5)
- Desire to inform / teach (P1
- P5 wanting to stop patients feeling pressurised
- P3 need to make the patient feel confident
- P5 desire to see them complete task
- P5 complete each question before moving on

Lack of Pharmacy staff involvement (P1)
- P3/P4 need for more staff
- Existing practice (P1)
- Existing roles and responsibilities (P1/P5)
- Consistency / continuity of care (P1)
- Capability (P1)
- Availability (P1)
- P3/ P5 workload
- P3 reducing pressure on staff
- P5 not enough time
- P2 responsibility as signed to participate

Appendices

Appendix 4.7 Study flow diagram

Appendices

Appendix 5.1 Expression of interest form

Pharmacist decision making during a medicine consultation

Health Care Professional

Expression of interest Form

If you wish to be involved, please initial the box and complete the details on the form. Once completed, please return in the envelope provided.

1. I confirm that I have read and understand the information sheet dated 16th June 2016 Version 4 for the above study. I am interested in participating in the study.

   Number of years practising as a pharmacist _____
   Number of years at current pharmacy   _____
   Does the pharmacy have a second pharmacist? _____
   Does the pharmacy have at least one full time or two 0.6fte members of staff?   _____
   Does the pharmacy complete MURs each month? _____
   Does the pharmacy complete NMSs each month? _____
   Geographical ward name_____

Family name _____	First name _____
Signature _____	Date _____
Pharmacy _____	
Address _____	
& _____	
postcode _____	
Telephone number _____	E-mail address _____

HCP Expression of interest form v4   16/6/16

Appendices

Appendix 5.2 Training check list

Appendices

Summary of training

Staff

- Explanation of participating script
- Use of stickers
- Show consent form
- Explain study count form
- Run through SOP
- Get consent form signed
- **Explain script for NVS assessment stress importance of what to do if struggling to answer and stating some questions are designed to be harder than others**
- Explain reference numbering system
- Explain the recording of NVS scores and **adding patient number, age, gender and age left education on form**
- **Must not tell any member of staff, including the pharmacist of any patient NVS score.**
- **Explain return of NVS score process**
- **Make sure that patient identification number is given to the pharmacist before their assessment of the patient**

Pharmacist

- Run through SOP
- Explain HRA statement of activities
- Get consent form signed
- Explain voucher claim form and **the need to state amount paid (£15) patient name and date and signature only after completion of pharmacist assessment**
- **Explain the timing mechanism for signing their name (for vouchers) – practice with a stop watch at estimating seconds**
- **Must not under any circumstance carry out the NVS assessment**
- **Importance of keeping the vouchers safe**
- Sign for vouchers
- Choice of Medicines consultation or MUR (except Boots). **Need to be explicit that patient payment is not for NHS service if MUR provided.**
- Explain factors to be assessed and use of pharmacist judgement
- Run through assessment questions

Appendices

Appendix 5.3 Reminder card for including indicators into medicine consultations

Indicators

Recall of verbal information	Poor	Fair	Good
Recall of written information	Poor	Fair	Good
Recall of medication name, dosage, medicine frequency and medication purpose?	Poor	Fair	Good
Use of medical terminology	Poor	Fair	Good
Seeking new information	Poor	Fair	Good
Asking questions	Poor	Fair	Good

Appendix 5.4 Pharmacist record sheet

Appendices

Pharmacist assessment of health literacy

Pharmacy Name …………………………………………………………

Health Literacy is defined as the ability to access, understand and utilise health information to manage their health.

Participant identification number xx

1. How well do you know this patient? Tick the relevant box

Very well - Speak to them on a regular basis

Well – have spoken on a number of occasions

Know a little – speak occasionally

New – one of the first occasions that we have spoken

2. On completion of the consultation circle your chosen answer for each of the sections in the table

Recall of verbal information	Poor	Fair	Good
Recall of written information	Poor	Fair	Good
Recall of medication name, dosage, medicine frequency and medication purpose?	Poor	Fair	Good
Use of medical terminology	Poor	Fair	Good
Seeking new information	Poor	Fair	Good
Asking questions	Poor	Fair	Good

3. Time taken to sign their name (in seconds)

| |
| |

4. How easy on a score of 0 -10 (higher score indicates easier to incorporate) was it to assess each of the indicators?

Recall of verbal information	
Recall of written information?	
Recall of medication name, dosage, medicine frequency and medication purpose?	
Use of medical terminology	
Seeking new information	
Asking questions	
Signing their name	
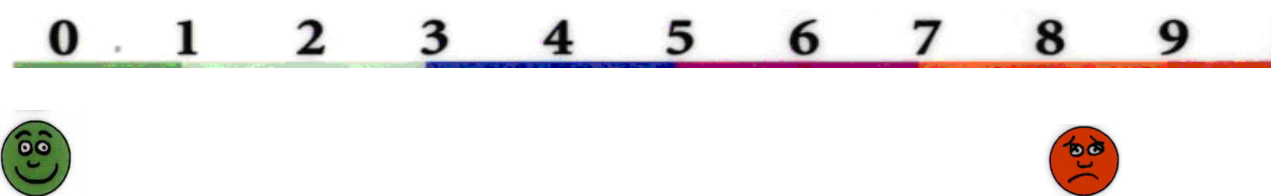
5. What is your final assessment of the health literacy for this patient?

Circle you chosen answer.

Limited   **marginal**   **adequate**

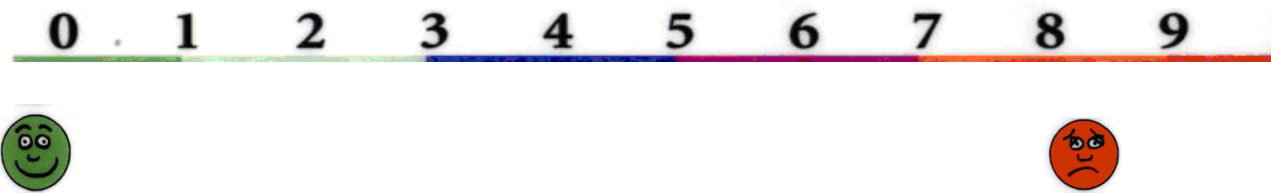6. Explain in your own words how you came to this decision.

7. Which of the indicators did you find the most helpful to make your decision?

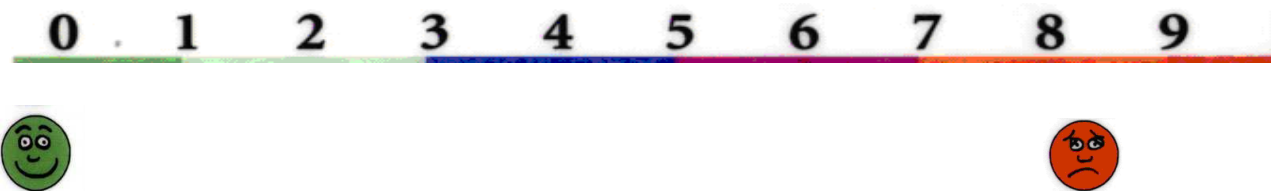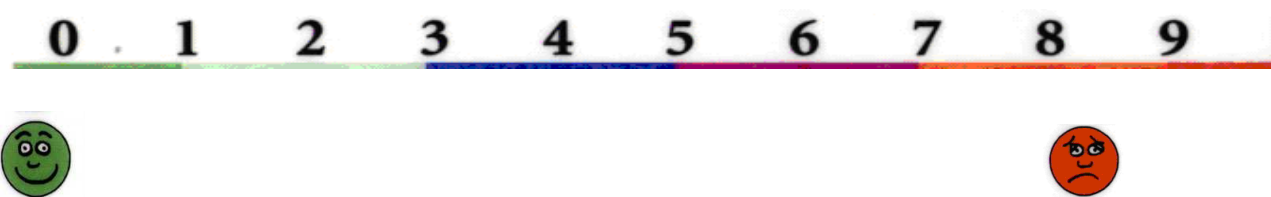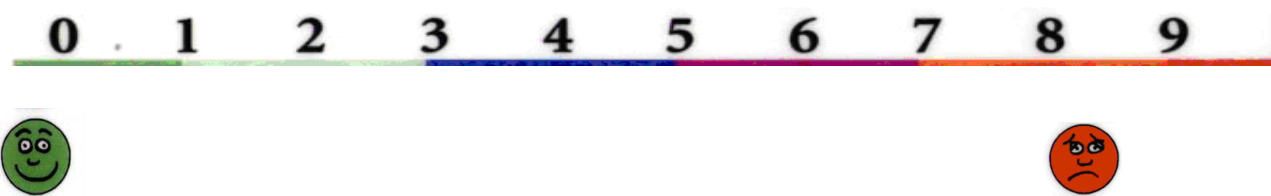   Rank each with a score of 0-10 where 10 indicates the least helpful.

Recall of verbal information

0 . 1　2　3　4　5　6　7　8　9

Recall of written information

0 . 1　2　3　4　5　6　7　8　9

Recall of medication name, dosage, medicine frequency and medication purpose?

0 . 1　2　3　4　5　6　7　8　9

Use of medical terminology

0 . 1 2 3 4 5 6 7 8 9

Seeking new information

0 . 1 2 3 4 5 6 7 8 9

Asking questions

0 . 1 2 3 4 5 6 7 8 9

Signing their name

0 . 1 2 3 4 5 6 7 8 9

8. How would you describe the level of detail you used in the consultation? Please put a cross against your choice.

   The same as speaking to another health care professional

   The same as speaking to a non-health care professional

   The same as speaking to a layman

   Limited basic information

9. Additional comments

Please double check that all questions have been answered.