

**DEVELOPMENT AND VALIDATION OF A HEALTH
LITERACY MEASURE FOR LIMITED LITERACY PUBLIC
SECTOR PATIENTS IN SOUTH AFRICA**

A thesis submitted to Rhodes University in fulfilment of the requirements for
the degree of

Doctor of Philosophy (Pharmacy)

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January 2018

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Grahamstown

South Africa

ABSTRACT

The growing complexity of healthcare demands greater patient involvement and skills to navigate this complex system. It has therefore become increasingly important to identify individuals with inadequate health literacy, by using efficient, short and reliable measures for doing so. Most research on the development and validation of health literacy tests has been conducted in high-income countries, with very little reported from low-and middle-income countries (LMICs). Existing health literacy measures have come under scrutiny for their lack of cultural sensitivity, bias towards certain population groups and failure to acknowledge health literacy as a multidimensional concept. These measures usually have limited application in LMICs due to the significantly different structuring of healthcare systems, they overlook the extreme discrepancies in educational levels, and rely too heavily on the ability to read health information. No health literacy data for South Africa are available, and only a few health literacy-based research papers have been published in this country.

The aim of the study was to develop and validate a health literacy measure that is contextually and culturally appropriate to measure health literacy in limited literacy public sector patients in South Africa.

An Item Bank of 30 questions was developed with the input of a diverse expert consultant panel, and included skills-based and self-reported questions which ensured cultural, contextual and educational level appropriateness. The Information and Support for Health Actions Questionnaire (ISHA-Q) is a health literacy measure developed to assess health literacy for LMICs which includes 14 core scales. These were useful in ensuring coverage of a range of health literacy constructs within the Item Bank. The 30 questions were then allocated to one of three health literacy domains: Procedural knowledge, Factual knowledge and Access to healthcare, health services and social support.

Ethical approval for the study was obtained. The questions were translated into isiXhosa and underwent pilot testing. Following pilot testing, 120 isiXhosa first-language speakers, at least 18 years old, who attended public sector facilities and had a maximum 12 years of education were recruited from a primary healthcare clinic in Grahamstown. An interpreter was trained and he participated in all interviews. A questionnaire was used to collect data on the 30-

question Item Bank. The Multidimensional Screener of Functional Health Literacy (MSFHL) was used as the primary comparator.

The second phase of the study involved the refinement of the 30 questions in the Item Bank, which involved a multi-stage process. Data were analysed statistically using t-test, correlations, chi-square and ANOVA tests at a 5% level of significance, in order to identify problematic questions. Item Response Theory was used to ascertain difficulty and discriminatory ability of the questions. Each question was further subjected to in-depth interrogation by a panel of healthcare professionals to ensure that questions were supported by the conceptual framework and the definitions of health literacy adopted for this study. The number of questions was reduced from 30 to 12, and formed the new Health Literacy Test – Limited Literacy (HELT-LL). To validate the HELT-LL, 210 patients with the same inclusion criteria as previously noted, were recruited from four primary healthcare clinics in the Eastern Cape Province. Individual interviews were conducted with the assistance of the interpreter to collect sociodemographic data as well as data from the HELT-LL, the primary comparator (MSFHL), and a secondary comparator which was a South African modified version of the Newest Vital Sign (NVS-SA). The HELT-LL was re-administered to 40 patients in a follow-up interview two weeks later.

The HELT-LL categorised only 17.6% of the patients as having adequate health literacy, just over a third with inadequate health literacy, and the majority with marginal health literacy. Questions in the cognitively demanding Procedural knowledge domain were the most poorly answered, with a mean score of $48.6 \pm 24.9\%$. Patients had great difficulty performing the basic numeric tasks in this domain. The overall mean score for the HELT-LL was $52.8 \pm 18.4\%$, compared with the more cognitively demanding NVS-SA with a mean of $28.6 \pm 21.1\%$, and clearly illustrated the impact of the strategy to include in the HELT-LL a variety of questions with differing cognitive load. The MSFHL, which is based on demographic characteristics and perceived difficulties with reading and writing, had an overall mean score of $44.4 \pm 26.2\%$. Demographic characteristics including age, education and English literacy, were found to be good predictors of limited health literacy, with significant correlations being found between these variables and the mean HELT-LL score. An acceptable value for Cronbach's alpha, excellent test-retest reliability and excellent concurrent validity show that the HELT-LL is a valid and reliable measure of health literacy in our target population.

As there is a paucity of health literacy research emanating from developing countries, this study presents a significant contribution to literature. It is the first study to report the development and validation of a health literacy measure to address the dearth of available health literacy measures applicable for South Africa. If implemented for use in clinical settings and for research purposes, it could provide valuable South African health literacy data which could inform the development of interventions focusing on improving health literacy and health outcomes.

DEDICATIONS

“I can do all things through Christ who strengthens me.”

Philippians 4vs13

This thesis is dedicated to my beloved sister

Dr. Miriam Marimwe

ACKNOWLEDGEMENTS

For their financial support in the form of the Henderson Scholarship, I would like to thank Rhodes University.

I am sincerely grateful to the following people for their contribution to this study:

First and foremost, I would like to thank the Lord Almighty for guiding me throughout my research, His ever flowing blessings and wisdom.

My supervisor, Professor Ros Dowse, for her constant support, encouragement, guidance, and constructive criticism. Most of all, I am grateful for being there for me whenever I needed her throughout my research and writing the thesis.

The district pharmacist, Mr Mohamed Docrat and the sisters in charge at the local clinics in Grahamstown and Port Alfred.

The Faculty of Pharmacy Ethics Committee and Eastern Cape Department of Health for granting me permission to carry out this study.

The nurses, pharmacist and doctors who made up my team of consultants, for all their opinions and views, as well as their commitment and assistance throughout my research

Dr Maseko for the translation of the information materials.

Mr. Xolani Nobebe for his assistance in interpretation.

Mr Collin Ntoyi and Thando Fleck for their assistance with organising transportation to the study sites.

Dr Sirion Robertson for his kind assistance with proofreading my thesis.

My parents, Mr Wilfred Marimwe and Mrs Nyadzi Marimwe and my sisters, Miriam, Tendai and Rumbidzai for all their unending support and prayers over the years.

To my dear friends Diana, Fadzai, Ida, Mehrusha, Tendai, Tinatsei, and Rufaro for their support and encouragement. A special note to Farai Nduma and Mellisa Chikukwa, for your support through all the late nights, you were always there with a word of encouragement and a listening ear.

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LIST OF ACRONYMS

ANOVA	Analysis of Variance
BEHKA-HIV	Brief Estimate of Health Knowledge and Action
BHLS	Brief Health Literacy Screener
HLS-EU	European Health Literacy Survey
GHNT	General Health Numeracy Test
HCPs	Healthcare Professionals
HELT-LL	Health Literacy Test for Limited Literacy
HICs	High Income Countries
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HLQ	Health Literacy Questionnaire
HLSI	Health Literacy Skills Instrument
HLSI-SF	Health Literacy Skills Instrument-Short Form
IRT	Item Response Theory
IOM	Institute of Medicine
LMICs	Low- and Middle-Income Countries
MAHL	Multidimensional Measure of Adolescent Health Literacy
MART	Medical Achievement Reading Test
METER	Medical Term Recognition Test
MLT	Medicines Literacy Test
MSFHL	Multidimensional Screener for Health Literacy
MUSE	Medication Understanding and Use Self-Efficacy
NAAL	National Assessment of Adult Literacy
NUMI	Numeracy Understanding in Medicine Instrument
NVS	Newest Vital Sign
NVS-SA	Newest Vital Signs South Africa
PHCs	Primary Healthcare Clinics
REALM	Rapid Estimate of Adult Literacy in Medicine
REALM-R	The Rapid Estimate of Adult Literacy in Medicine-Revised
SAHL-E	Short Assessment of Health Literacy -English
SILS	Single Item Literacy Screen
STOFHLA	Short Test of Functional Health Literacy in Adults

TB	Tuberculosis
TILS	Two Item Literacy Screener
TOFHLA	Test of Functional Health Literacy Adults
TTS	Time to Sign
UIS	UNESCO Institute for Statistics
UK	United Kingdom
UNESCO	United Nations Educational Scientific and Cultural Organisation
USA	United States of America
WHO	World Health Organisation

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CHAPTER 1

INTRODUCTION

1.1 Background

Health literacy has been commonly defined as ‘the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions’ (1). Over several decades there has been an increase in literature addressing health literacy, reflecting its importance in social, economic and health development (2). Mounting evidence suggests that limited health literacy has been associated with lower use of preventative services (3,4), poor adherence to medical instructions, poor understanding of medical conditions, increased hospitalisation rates and use of healthcare services (4,5), increased mortality (6) and poor self-management of chronic diseases (7,8).

Individuals at risk of limited health literacy are often those with low educational levels, low income and constitute the ethnic majority (9), characteristics of many patients served by the South African public healthcare sector. Limited health literacy is a factor which will continue to compound the vast health inequalities in South Africa, therefore identifying individuals with inadequate health literacy would be the first step in mitigating these disparities. Information such as educational attainment is often used as a surrogate measure to estimate an individual’s health literacy but it is not always an accurate representation (10). Subjective assessment offers an alternative method to identify individuals with limited health literacy, but it depends on the experience and competence of the healthcare professional (11). Many patients do not reveal their literacy problems to healthcare providers (HCPs) due to embarrassment, thereby exacerbating the problem of effective transfer of health information (12), and HCPs tend to overestimate the literacy levels of their patients (13), making it difficult to identify those patients at risk of limited health literacy.

A more appropriate assessment method would be the use of a validated health literacy measure. Although numerous measures have been developed, there is no universal ‘gold standard’ for assessing health literacy. Some are mainly used for screening purposes, while others are used for a more comprehensive assessment. The most widely used of these measures include the Test of Functional Health Literacy in Adults (TOFHLA), which assesses reading comprehension and numeracy (14), the Rapid Estimate of Adult Literacy in

Medicine (REALM), which tests word recognition and pronunciation of medical terms (15), and the Newest Vital Sign (NVS), which assesses reading comprehension and numeracy using an ice cream label (16). These widely used measures have many strengths, but have come under scrutiny as they lack cultural sensitivity and are often biased towards certain population groups (17).

1.2 Significance of research

Since its inception in 1974, growth in the field of health literacy has been rapid and researchers have sought a greater understanding of the concept. Much health literacy research, editorials and commentaries have been published; however, the majority emanates from high income countries (HICs). Health literacy remains a relatively under-researched concept in low and middle-income countries (LMICs), particularly so in South Africa, despite the greater prevalence of limited health literacy in these populations (18). This has been further highlighted by Pleasant (19) who conducted a literature search of peer-reviewed publications in efforts to ascertain the prevalence of the concept of health literacy research worldwide. In a discussion with a panel of experts from South Africa, it was reported that the term health literacy is not commonly used in the country and has not been formally defined as a public policy issue. Compounding that, there are no health literacy measures appropriate for use in South Africa (19). These responses not only offer an explanation for the relatively restricted research around health literacy in South Africa; it also becomes apparent that there is room for further research in and around the field of improving health literacy in South Africa.

Furthermore, many of the reference measures were developed in HICs, and adapting them for use in LMICs is challenging due to difficulties in reconciling differences in language, culture, education and healthcare systems. Countries with their own unique features will need to develop and validate their own health literacy tools (20).

This study therefore intends to address the lack of a health literacy measure applicable for use in South Africa. It was anticipated that the resultant measure would be culturally, contextually and educationally appropriate for our diverse population, as well as address the concept of health literacy as a multidimensional concept. The measure is intended to be useful in both clinical practice, to identify individuals with limited health literacy, and for

further research purposes in the field. The study should make a significant contribution to knowledge associated with the assessment of health literacy in diverse settings.

1.3 Study aim and objectives

The aim of the study is to develop and validate a health literacy measure that is contextually and culturally appropriate to measure health literacy in limited literacy patients in South Africa.

The associated objectives are:

- To develop an Item Bank of questions that are multidimensional and address a range of health domains
- To critically evaluate Item Bank questions for content validity and face validity
- To evaluate the psychometric properties of Item Bank questions in order to truncate the Item Bank
- To propose the structure and content of a health literacy measure named the Health literacy Test for Limited Literacy (HELT-LL)
- To validate the HELT-LL in limited literacy public sector patients.

1.4 Conceptual framework

A conceptual framework is the foundation for developing a valid and reliable measure of health literacy (21). Just as there are numerous health literacy definitions, similarly there are a number of health literacy frameworks, and there is no widely agreed upon framework (22).

The definitions of health literacy that under-pinned the development of the framework were informed by two definitions; the first was proposed by the USA Institute of Medicine (IOM) (22):

‘...the degree to which individuals can obtain, process and understand the basic health information and services they need to make appropriate health decisions’.

The second was from the World Health Organisation (WHO)(23):

‘...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’. Further explanation is offered, that ‘...health literacy implies the achievement of a level of knowledge, personal skills and confidence to take action to improve personal and community health by changing lifestyle and living conditions’.

The conceptual framework for this study was developed by drawing upon two health literacy models: the health literacy framework by the IOM (22) and the health literacy skills framework by Squires *et al* (24). This framework explains the factors influencing the acquisition of health literacy, those factors associated with the application of health literacy, and the resulting health outcomes. The framework is divided into three components illustrated in Figure 1.1: mediators, moderators and outcomes.

Mediators

These are factors influencing the development of health literacy (24). This framework begins by looking at the foundational component to health literacy, i.e. literacy *per se*, which is defined as ‘a set of reading, writing, basic mathematics, speech, and speech comprehension skills’ (25). Literacy provides the skills needed to understand and effectively communicate health information and concerns. In the IOM framework (22), health literacy is depicted as the active mediator between individuals and health contexts. The individual characteristics, which include cognitive skills (brain-based skills we need to carry out simple and complex tasks) and social skills (skills used to communicate and interact with other individuals) are identified as factors which determine health literacy.

Moderators

In addition to the individual characteristics, we draw inferences from the health literacy skills framework which posits that numerous agents influence the relationship between health literacy and health outcomes. These include both system level and societal influences. Societal influences refer to culture, community and family, whereas system level influences involve the healthcare system and healthcare professionals (24).

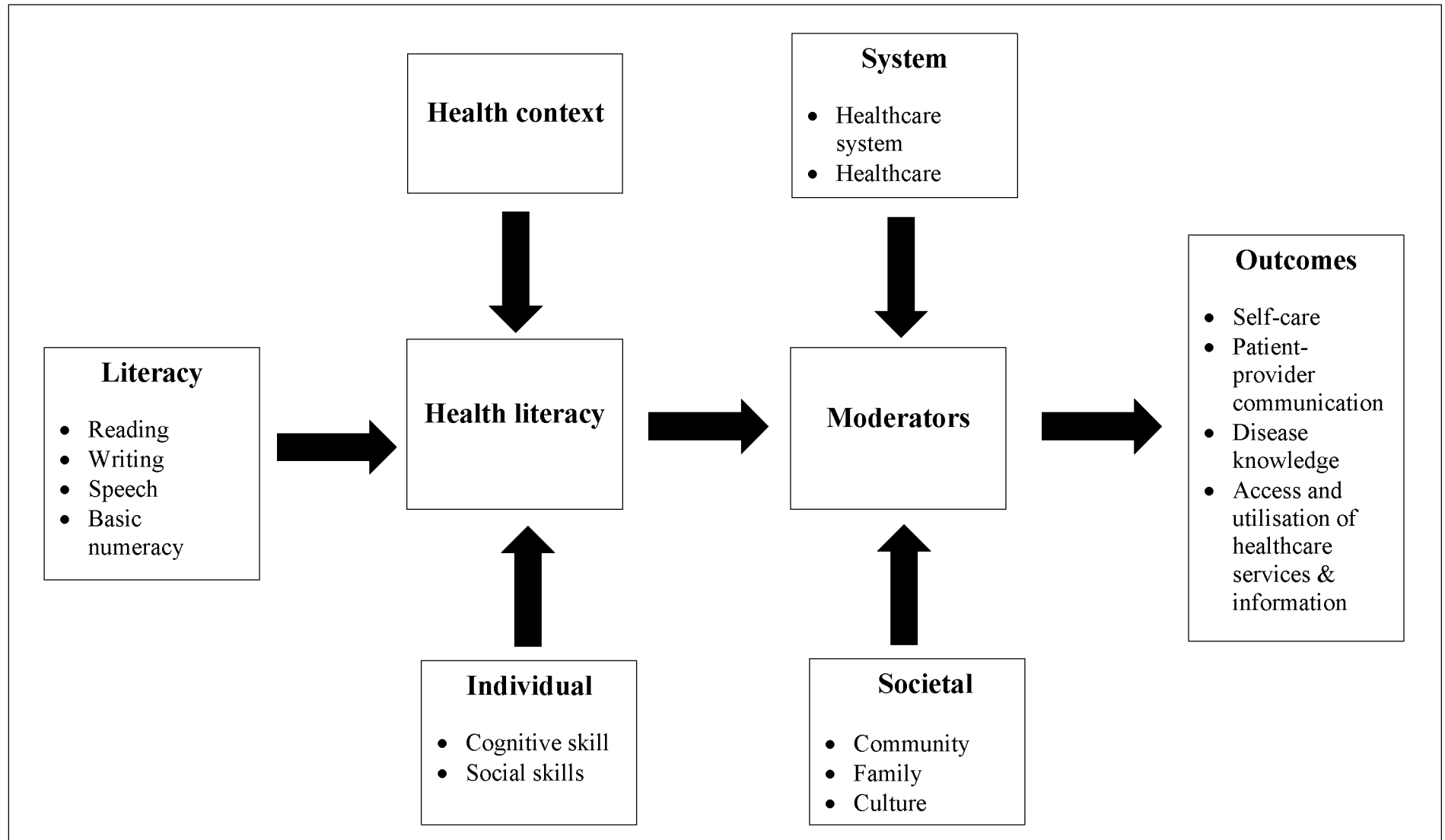


Figure 1.1 Health literacy conceptual framework

Societal influences are clearly important to include within the framework, given that in developing countries, dyads, families, and communities play a prominent role in health information acquisition, comprehension, and decision-making (26). Culture also contributes to how individuals perceive health, beliefs around health and illness, the ability to retain, comprehend and act on instruction from HCPs, in ways that are intimately connected with literacy levels (27). System influences are equally important as they impact how accessible healthcare is and how effectively healthcare information is communicated to patients (22).

Outcomes

The framework concludes by depicting the influence of health literacy on health outcomes. The ultimate goal of health literacy is to improve health-related outcomes, and much has been documented on how different levels of health literacy influence various health outcomes. This framework proffers that individuals with high health literacy levels will have better health outcomes regarding self-care, patient–provider interaction, disease knowledge, access to and utilisation of healthcare services and information.

1.5 Dissertation Outline

Background

Chapter 2 presents a review of the literature on health literacy, beginning with the broader concept which links literacy and health literacy. The numerous definitions of health literacy are reviewed and the available conceptual models derived from some of these definitions are discussed. The effects of health literacy on health outcomes, its role in bridging health disparities, and its positive role on empowerment are discussed. In the chapter, I also look at ways in which to measure health literacy and the tools which are available nationally and internationally. To conclude, the review includes a summary of strategies which can be used to improve health literacy.

Part 1 (Chapters 3 – 5)

The focus of Chapter 3 is the development of the Item Bank of health literacy questions. It provides comprehensive details relating to the progression of modifications of successive versions of the Item Bank in order to produce the final version of 30 questions. Justifications for the changes are presented along with the modifications. It also outlines the steps taken to ensure content and face validity of the Item Bank of questions.

The methodology (Chapter 4) commences with a detailed description of the questionnaire used to collect data. The pilot study and results obtained are presented. Consequent changes made to the research instrument, based on feedback from the pilot study, are outlined. Finally, the main study in the target population is described.

Chapter 5 reports the quantitative results associated with the performance of individual questions of the Item Bank, as well as associations between selected demographic and socioeconomic variables. The chapter concludes with a brief discussion of the results and contextualises them within the literature.

Part 2 (Chapters 6 – 9)

Chapter 6 outlines the refinement of the Item Bank. Evaluation of the psychometric properties of Item Bank questions obtained in Chapter 5 as well as the item response theory (IRT) software-jMetrik and SPSS software are applied to inform decision-making related to elimination of individual questions to propose the structure and content of a health literacy measure. In addition to psychometric analysis, selection of questions is also guided by opinions from an expert panel.

Chapter 7 gives details of the psychometric validation of the HELT-LL, through the evaluation of internal consistency, test-retest reliability, criterion validity and construct validity. It concludes with the results obtained from validation of the HELT-LL.

Chapter 8 presents a general discussion of the results obtained during validation within the broader context of the international literature, and integrates all research findings of this project.

The conclusion, Chapter 9, speaks to the study objectives, integrating the findings of the research study and offering practical implications of the research and suggestions for future research.

CHAPTER 2

LITERATURE REVIEW

2.1 Literacy

Literacy is central to and closely related to the development of health literacy. To better understand health literacy, it is necessary to understand the underlying construct of literacy (28) while at the same time acknowledging that literacy and health literacy describe different skills and are not necessarily interchangeable (29,30).

Literacy, in its simplest definition, is ‘an individual’s ability to read and write, listen comprehend and speak a language’ (31,32). It has advanced from a one-dimensional view and now encompasses a variety of skills, not only the ability of a person to read and write. This wide array of skills includes basic numeracy, speech, comprehension and developing critical judgement at a certain level which allows a person to function in society (22,31,33,34). The United Nations Educational Scientific and Cultural Organisation (UNESCO) broadly defines literacy as the ‘ability to identify, understand, interpret, create, communicate, compute and use printed and written materials associated with varying contexts. It involves a continuum of learning in enabling individuals to achieve their goals, develop their knowledge and potential and to participate fully in their community and wider society’ (35).

According to UNESCO, three general literacy categories have been identified (35):

- Illiterate: the inability to read or write in any language.
- Semi-literate: the limited ability to read and write, where these skills have not been permanently acquired and may easily regress to being illiterate.
- Literate: the permanent acquisition of reading and writing skills.

Among people who are literate, the following broad levels of literacy proficiency can be identified (35):

- Pre-literacy: this is the first level of progress on the path of literacy where an individual starts to acquire the knowledge of basic language and the arithmetic skills

that are needed to master literacy. An individual at this level is not permanently literate and may easily relapse into illiteracy.

- Basic literacy: at this level, one can permanently read and write short simple communications that relate to everyday life.
- Functional literacy: this may be linked to either a specific work environment, a service or a community and describes the ability to read, understand and interpret what has been read and to then use it accordingly to cope adequately in a complex, demanding society.

Basic literacy skills are needed to enable individuals to develop their knowledge, improve their personal health and participate fully in society. For these reasons literacy levels in a country are an important measure of social as well as economic development (36).

According to 2014 figures from the UNESCO Institute for Statistics (UIS), an estimated 781 million people worldwide were illiterate (37), meaning they are unable to read, write or use numbers effectively to function in society (34). The global literacy rate is estimated at 84.1%, and almost two thirds (63.8%) of that population is made up of women who lack the most basic literacy skills (32). Nearly the entire adult illiterate population can be found in developing countries. Sub-Saharan Africa has been identified as one of three regions with the lowest literacy rate, with 24% of all illiterate people living in this region. According to the 2015 South African General Household Survey, 16.2% of the adult population is regarded as functionally illiterate (have received no schooling or have not completed grade 7), therefore the functional literacy rate among the adult population can be estimated at 83.8% (38)

2.2 Defining health literacy

The term health literacy first emerged in 1974 in relation to health education as a policy issue affecting health systems (31,32). It was not until the mid-1990s that interest in the topic began to peak due to the rising concern of healthcare providers about the number of patients who did not possess adequate literacy skills to maintain a healthy lifestyle (32,39). Since its introduction, researchers have continued to engage in attempts to operationalize and identify constituent dimensions of health literacy and this has seen a proliferation of health literacy definitions (40).

The earliest definitions of health literacy were limited in scope and complexity, mainly making reference to applying literacy skills (reading, writing and numeracy) to health-related material (14,41). Possession of high literacy skills does not necessarily imply the ability to apply these skills, suggesting that the most important aspect is what people are able to do with those skills (29) .

Accordingly, over the years, there has been a shift from the earlier, more restricted definitions of health literacy to an increasingly broader focus that encompasses higher order abilities; accessing and using health information from multiple resources, understanding and applying health instructions and health information, navigating healthcare services and communicating with healthcare providers (42,43) (Table 2.1). The wide range of health literacy definitions reinforces the multidimensional nature of the concept.

Table 2.1 Outline of the evolution of health literacy definitions.

Definition	Origin
Ability to apply literacy skills to health-related materials such as prescriptions, appointment cards, medicine labels, and directions for home healthcare.	Parker <i>et al</i> , 1995 (14)
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.	WHO 1998 (23)
A constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment, such as the ability to read and comprehend prescription bottles, appointment slips, and other essential health-related materials.	AMA Ad Hoc Committee on Health Literacy, 1999 (41)
The cognitive and social skills that determine the motivation and ability of individuals to gain access to, understand, and use information in ways that promote and maintain good health.	Nutbeam, 2000 (39)
The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.	Nielsen-Bohlman <i>et al</i> , 2004 (22) Selden <i>et al</i> , 2000 (42)
The wide range of skills and competencies that people develop to seek out, comprehend, evaluate, and use health information and concepts to make informed choices, reduce health risks, and increase quality of life.	Zarcadoolas <i>et al</i> , 2006 (44)
Personal, cognitive, and social skills that determine the ability of individuals to gain access to, understand, and use information to promote and maintain good health. These include such outcomes as improved knowledge and understanding of health determinants, and	Nutbeam, 2006 (45)

changed attitudes and motivations in relation to health behaviour, as well as improved self-efficacy in relation to defined tasks.

The ability to function in the healthcare environment and depends on characteristics of both the individual and the health care system. An individual's health literacy is context specific (dynamic) and may vary depending upon the medical problem being treated, the health care provider, and the system providing care.	Baker, 2006 (1)
The ability to make sound health decisions in the context of everyday life - at home, in the community, at the workplace, the health care system, the market place and the political arena.	Kickbusch & Maag, 2008 (46)
Public health literacy is the degree to which individuals and groups can obtain process, understand, evaluate, and act upon information needed to make public health decisions that benefit the community.	Freedman <i>et al</i> , 2009 (47)
Health literacy is the degree to which individuals have the capacity to read and comprehend health related print material, identify and interpret information presented in graphical format (charts, graphs, tables), and perform arithmetic operations in order to make appropriate health and care decisions.	Yost <i>et al</i> , 2009 (48)
The knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life throughout the course of life.	Sorensen, 2013 (40)

There also seems to be relative agreement among most of the health literacy definitions that skills such as accessing, understanding, evaluating and applying health information form the core of the construct of health literacy (30,49), thereby placing the onus of responsibility of health literacy on the patient. Although the importance of these skills is acknowledged in order to participate fully in society, health literacy, as for so many 'literacies', is not only individually developed, but is also shaped by social factors and structures (22,47) which broader definitions acknowledge. Few definitions have made an attempt to emphasise these domains of health literacy (23,46,47).

2.2.1 Relationship between health literacy measure and definitions

Explicit and clear definitions of health literacy play an integral part in measuring health literacy, as they form the basis of the development of measures (50,51). However, despite the numerous definitions available, there is a disconnect between the measures and the definition of health literacy (40,52,53). Health literacy measures often claim to be underpinned by one

of numerous definitions of health literacy, but the specific constructs embodied in the definitions are seldom incorporated into and examined by the measures (29).

The popularly known tools Rapid Estimate of Adult Literacy In Medicine (REALM) (15) and the Test of Functional Health Literacy Adults (TOFHLA) (14), are a classic example of tools which align superficially with definitions of health literacy. In the development of the REALM, there was no definition upon which the instrument was developed (15). However, as a word pronunciation test, it aligns itself with a restricted definition of health literacy which barely begins to address the complexity of the concept. The TOFHLA takes a broader view of health literacy, with a definition of functional literacy being provided, but not of functional health literacy or health literacy (29,53).

This disconnect in the evolution of health literacy measurement may be reducing. The Health Literacy Questionnaire (HLQ) (54) and the European Health Literacy Survey Questionnaire (HLS-EU-Q) (55) are examples of newer tests where specific constructs within the definition of health literacy that are proposed have been built into and tested with the measure.

2.3 Conceptual models of health literacy

In an attempt to conceptualise health literacy, various models of this construct have been developed over the years. The conceptual models posit health literacy within a larger context which is associated with different components and is influenced by a variety of individual and system level factors.

One of the earliest and most cited health literacy models was proposed by Nutbeam (39). He emphasised that health literacy consists of the most basic skills, such as reading and writing, and progresses to those skills which require higher cognitive functions. He identified three levels of health literacy: level one - functional health literacy, level two - interactive health literacy and level three - critical health literacy (39).

Functional health literacy is the ability to apply basic literacy skills in reading and writing to essential health-related tasks to be able to function effectively in everyday situations. The greatest obstacle for many patients is accessing health information resources about their conditions as well as ways to use the health system to manage the condition (39). The

drawback with functional health literacy is that it does not focus on improving knowledge pertaining to health risks, services and adherence to prescribed actions. Interactive health literacy focuses on the development of personal skills which aim to improve motivation and self-confidence to act on advice received from healthcare providers. Critical health literacy relates to superior cognitive skills which, in combination with social skills, can be employed to critically examine information and use it to exert greater control over life situations (39).

The categorisation of health literacy into these distinct levels highlights how individuals can advance from the most basic level of being able to read and write, to one which requires greater cognitive abilities, allowing for greater autonomy and empowerment (39). It further reiterates that health literacy is a dynamic process which continually changes over time. It is important to note that the progression from one level to the next does not rely solely on an increase in cognitive abilities; but also on exposure to a range of health information, communication with HCPs, and how individuals respond to this information they receive (39).

The Institute of Medicine (IOM) used a different model to define health literacy that includes components relating to the broader concept of literacy (Figure 2.1): 1) cultural and conceptual knowledge, 2) oral literacy which includes listening and speaking, 3) print literacy, including writing and reading skills, and 4) numeracy (22).

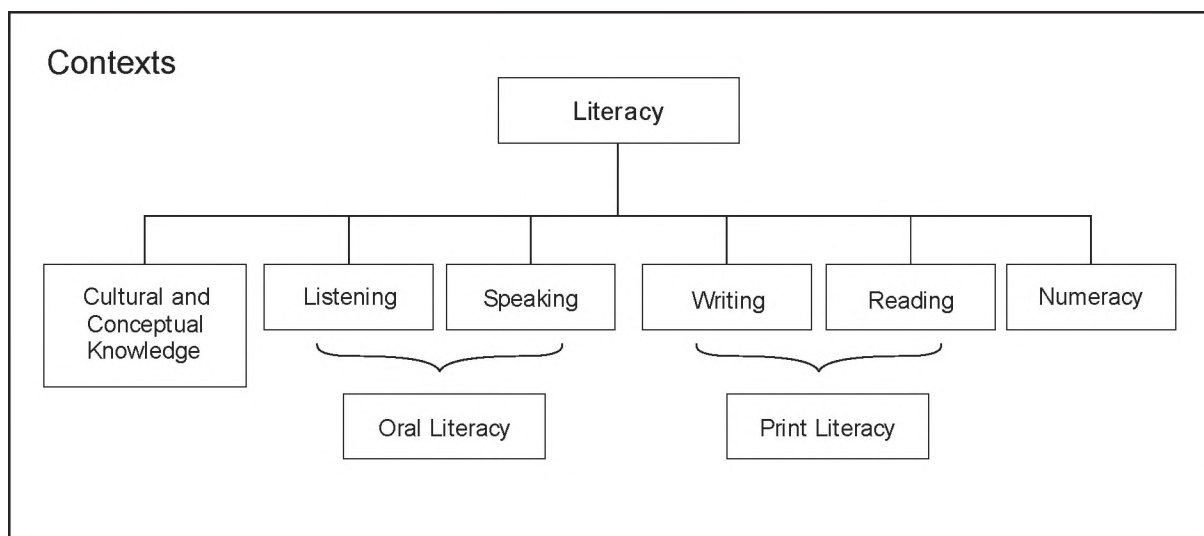


Figure 2.1 Model from the IOM relating health literacy to literacy and its components (22)

Cultural and conceptual health literacy is characterised by the individual's understanding of health and illness, and conceptualisation of risks and benefits (22). Oral exchange, the term used to refer to speaking and listening activities involved in communication, is a pivotal aspect of patient-provider interaction in order to achieve positive health outcomes (56). It has been shown to influence patient health, knowledge, decision-making, engagement and empowerment (57–61). Furthermore, obtaining the appropriate diagnosis, treatment and management of diseases strongly relies on effective oral communication between patients and healthcare providers (60,61).

Print literacy has been the most rigorously investigated component of literacy. It refers to the ability to read, write and understand written language with which one is familiar or of which one has requisite background knowledge (62). Numeracy skills are required for numerous health-related tasks such as calculating dosages and timing of medications, calculating nutrients on food labels or assessing health risks (22).

In a later model, Speros (63) acknowledges the skills included by the IOM (reading and arithmetic) as important components of health literacy, but goes further to incorporate the ability to comprehend and use health information to make informed decisions and to function successfully in the healthcare environment. These are also included as fundamental components of health literacy. Comprehension is the ability to use prior knowledge to aid in the reading process and make sense of what is read. Apart from the ability to read health information, being able to understand the information in order to act on it is a critical aspect of health literacy (64). Using health information to make informed decisions has long been a goal of health education and is an essential attribute of those with adequate health literacy (63). Numerous reviews include some mention of successfully functioning as a health care consumer; this enables individuals to solve problems and apply new information to varying circumstances in order to navigate the health care system (65,66).

In an attempt to link health literacy, health status and the utilisation of health services, Lee *et al* (67) have created a model which incorporates four interrelated factors: disease and self-care knowledge, health risk behaviour, preventive care and physician visits and compliance with medication (Figure 2.2). This model suggests that individuals with limited health literacy are less likely to use preventative care, have fewer physician visits, poor medical

knowledge and poor medication adherence. Consequently, these lead to undesirable health outcomes (67).

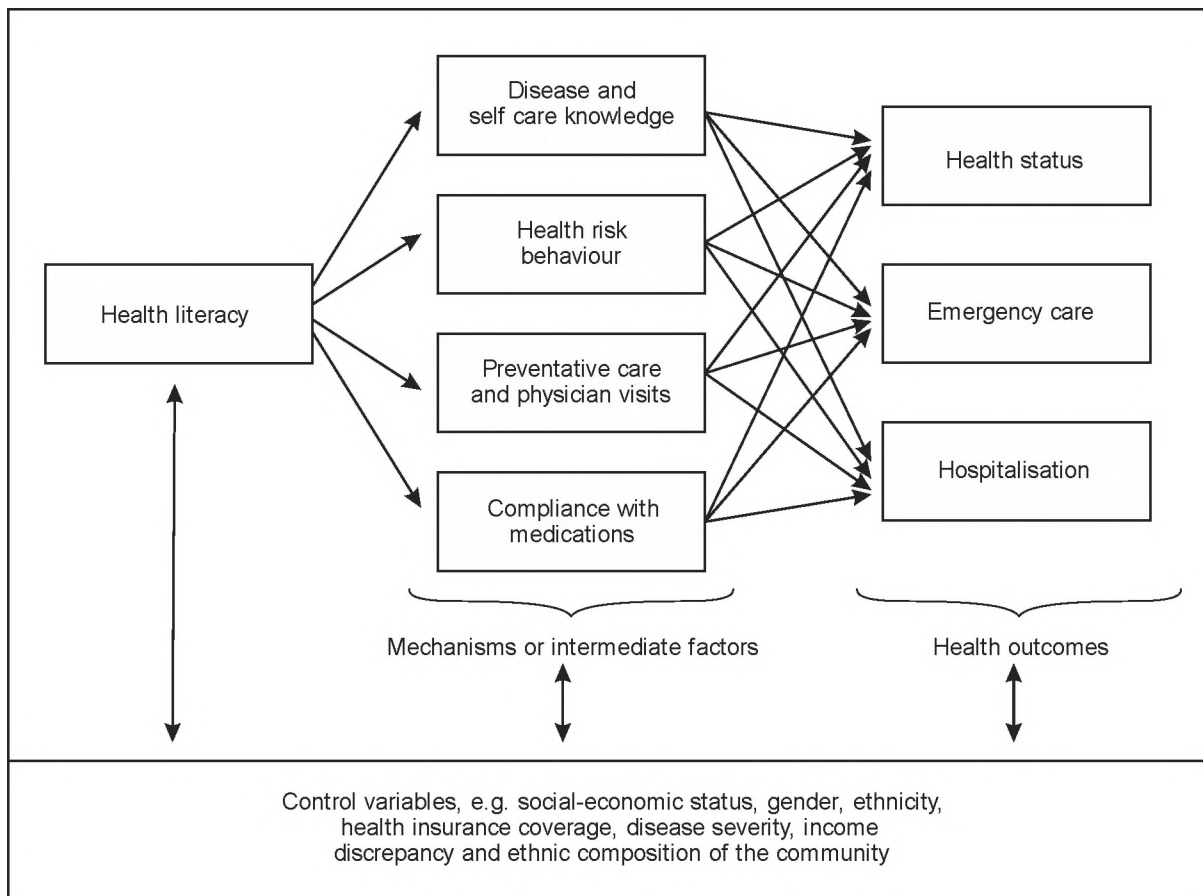


Figure 2.2 Model from Lee *et al* linking health literacy to health outcomes (67)

Health literacy models often primarily assess individuals, and fail to highlight the influence of health literacy within the context of families, communities and population groups (68). McCormack *et al* (69) developed a framework which outlines how health literacy functions at an individual level, while acknowledging that other external factors including family, community, setting, culture and media influence all components outlined in the model (Figure 2.3).

The framework consists of four elements: health related stimulus, factors influencing the development and use of health literacy skills (socio-demographic characteristics, resources, prior knowledge and capabilities), health literacy skills needed to comprehend the stimulus and act on the information (print literacy, numeracy, communication and information seeking), and mediators between health literacy and health outcomes (69).

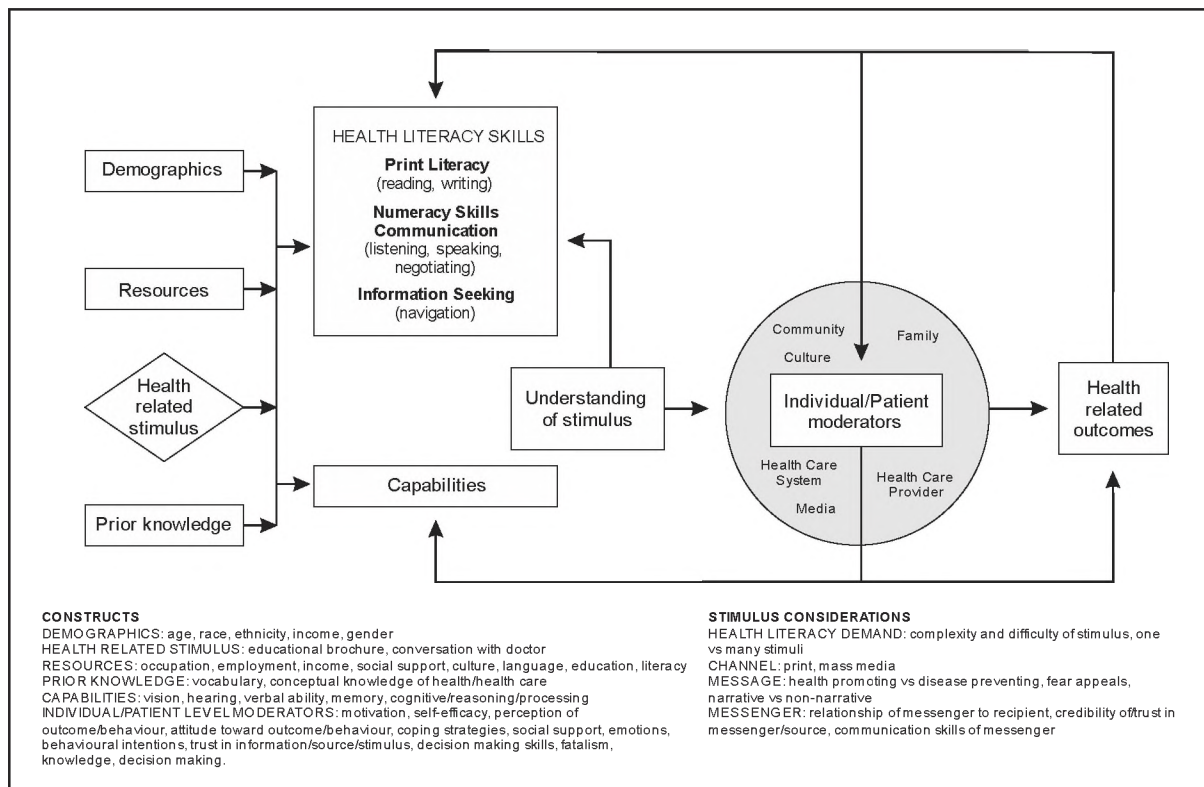


Figure 2.3 Conceptual framework for individual health literacy from McCormack *et al* (69)

Although there is an apparent wide variation between factors regarded as key components of health literacy, they all address cognitive abilities, skills, behaviours and mediators which are necessary for an individual to function within the healthcare system (40).

Moving beyond identifying factors which affect health literacy, the health literacy skills framework proposed by Squires *et al* (24) covers a continuum, from the development and moderators of health literacy skills, to the application of the skills as well as looking at the outcomes associated with these health literacy skills. This framework comprises four components (24).

Factors that influence the development of health literacy skills

The authors acknowledge demographics, individual resources, capabilities and prior knowledge of health and healthcare as major factors which influence how an individual develops and uses health literacy skills (24).

Health-related stimulus

The framework addresses health related information materials individuals come across in a healthcare setting such as brochures and prescription labels as well as encounters with HCPs which they experience. The authors posit that how individuals interact with this material and respond to these interactions will be largely dependent on the health literacy skills an individual possesses (24).

Health literacy skills required to understand and perform the task

Reading, writing, numeracy, communication (listening and speaking) and information-seeking skills are identified in this framework as the key health literacy skills required to obtain, process and understand health information (24).

Mediators between health literacy and health outcomes

Mediating factors affect how individuals retain and use information which they obtain from various stimuli in order to make appropriate health decisions. Squires *et al* acknowledge the relationship between health literacy skills and health outcomes; however, they also identify numerous factors which they define as ecological factors, comprising culture, family, social support, media, access to health resources and HCPs which affect health-related outcomes (morbidity/mortality, disease state, utilization of healthcare services, self-efficacy and health) (24).

2.4 Health literacy around the world

In 2002 the USA was the first to pioneer a nationwide assessment of health literacy with the National Assessment of Adult Literacy (NAAL). The NAAL was administered to 18,000 participants nationwide. The survey evaluated basic reading skills in three domains: document, prose and quantitative. Twenty-eight items selected from these three domains comprised the NAAL health literacy component, the main purpose of which was to describe the status of health literacy among the nation's adults. It was also a means to improve understanding of the numerous factors associated with health literacy (70).

Although health literacy has become an international phenomenon since its inception, the United States of America (USA) still dominates health literacy research (71). A 2013 review of a total of 569 peer-reviewed publications identified the first author of the majority of the

publications as originating from the USA, Australia, the United Kingdom (UK) and Canada (Table 2.2).

Table 2.2 Peer-reviewed publications on health literacy by nation of first author (adapted from Pleasant) (19)

Country	Frequency	Country	Frequency
United States	360	Israel	3
Australia	48	New Zealand	3
United Kingdom	37	Nigeria	3
Canada	25	Taiwan	3
Netherlands	14	Argentina	2
Germany	12	Belgium	2
Japan	7	India	2
Spain	6	Malaysia	2
South Africa	4	Norway	2
Sweden	4	Singapore	2
Brazil	3	Switzerland	2
China	3	Thailand	2
Iran	3		

Despite the domination of the USA in the research field, this review shows that there is growing internationalisation of health literacy (19). Beyond peer-reviewed publications, numerous multinational programs and other research efforts have emerged from Europe (72). In developing countries, successful health literacy programs have been developed at a community level as well (73). All these efforts help strengthen international collaboration essential for success in the field of health literacy (74).

2.5 Health literacy and health outcomes

With the ever-growing complexity of the healthcare system, limited health literacy has been shown to significantly influence health outcomes and patient health (34,75). Research studies have identified key relationships between health literacy and health outcomes.

Use of preventative services:

Individuals with limited health literacy tend to skip preventative measures such as mammograms, pap smears and flu shots, and generally tend to visit the healthcare system when their health has significantly deteriorated (3,75–77).

Knowledge of medical conditions and treatments:

Individuals with inadequate health literacy are more likely to have chronic diseases and are less likely to manage them appropriately as they often engage in risky health choices such as smoking, alcohol abuse, poor dietary habits and lack of physical activity. These are the four major risk factors implicated in the rise of non-communicable diseases such as diabetes and hypertension (34,78,79). Similarly, these individuals with chronic illnesses are more likely to lack basic knowledge about their illness and its management e.g. the normal range for blood glucose in diabetes (5,12,62,80–85).

Nonadherence:

Adherence has been defined by the World Health Organisation (WHO) as the ‘extent to which a person’s behaviour - taking medication, following a diet, and/or executing lifestyle changes corresponds with agreed recommendations from a healthcare provider’ (85). Medications are central to the treatment and management of numerous conditions, notably chronic illnesses. Limited health literacy has been strongly correlated with poor adherence (82). People with low health literacy are twice as likely to misinterpret prescription label warnings (63). Instructions, such as ‘take on an empty stomach,’ ‘take one pill every 12 hours by mouth with a meal,’ ‘do not chew or crush; swallow whole,’ ‘take with food,’ ‘avoid prolonged or excessive exposure to direct sunlight while taking this medication,’ and ‘medication should be taken with plenty of water’ are often misunderstood (83).

Hospitalisation and use of health services:

Inadequate health literacy is associated with high hospitalisation rates (5,84) and an inability to use health services effectively (34).

Increased healthcare costs:

Limited health literacy tends to result in a lower usage of services that are intended to prevent complications (3), leading to more frequent use of healthcare services designed to treat complications of diseases. The economic consequence of this silent epidemic on countries is staggering, particularly in countries with a higher burden of low literacy rates (31).

Stigma and shame:

Individuals with inadequate health literacy often report feeling ashamed about their skill level and are often uncomfortable with their inability to read or write well. As a result they develop strategies to compensate, and consequently these individuals who so desperately need help when it comes to obtaining best health outcomes, often go unnoticed (12).

2.6 Health literacy and health disparities

In addition to limited health literacy being linked to poor health outcomes, it is also prevalent among certain populations. The USA State Department of Health and Human Services reports that cultural and linguistic differences among patients directly impact their health literacy levels, which, in turn, contributes to an increased prevalence of health disparities (86). There is a dearth of research which explains the role health literacy plays in creating health disparities, as well as how it can help to eliminate these disparities (87).

Health disparities have been defined as ‘differences in health that occur by particular categories: gender, race or ethnicity, income and education, disability, living in rural locality or sexual orientation’ (88). Studies have shown that ethnic minorities, individuals with low education or income and the elderly are associated with lower levels of health literacy (5,74,89). These individuals are most likely to fall victim to greater health disparities, which consequently leads to worse health outcomes.

Research regarding health disparities has evolved in a similar manner to that of health literacy; the problem has been identified in different populations and then advanced into understanding the mechanism of the problems, with current research aimed at designing interventions and evaluating outcomes to minimise health literacy (90). Health literacy is potentially modifiable, thus researchers have begun to investigate it as a point of intervention at which health disparities can be minimised (91,92).

Paasche-Orslove and Wolf (87) presented preliminary recommendations for how health literacy can help to eliminate health disparities and consequently promote healthcare equality. Their first recommendation is to measure health literacy, as without having knowledge of the health literacy of populations who are at risk of health disparities, it is hard to decipher the relevance of health literacy in reducing these disparities. It would also be difficult to design

interventions which address relevant factors. Other recommendations included improving patient education, using health information technology to allow for greater outreach, and standardising the manner in which information is communicated between individuals (87). As general literacy contributes to the development of health literacy, targeting the education systems can be a long-term goal in decreasing disparities (87). Finally, they suggested simplifying the healthcare system through improving three key factors: access and utilisation, education and training of healthcare professionals (HCPs), and promoting patient self-care (87).

2.7 Determinants of health literacy

Low health literacy has been found to be predicted by age, low educational level, ethnicity, and pre-existing chronic illness (93,94).

Age:

Increasing age is negatively related to health literacy (95) with older populations shown to have lower levels of health literacy. Although the reasons for this are not clear, some researchers attribute it to a number of factors including a decrease in mental processing skills due to advanced age, having more long term health conditions (96), and having less formal education than subsequent generations (97).

Low educational attainment:

Health literacy is influenced by low levels of education. Individuals with low educational attainment are less likely to have the skills required to access, process and understand health information necessary to achieve desired health outcomes. Education is often used as a proxy for health literacy, assuming that higher educational attainment will result in higher health literacy levels. Although the connection is present, it is not definitive (7).

Ethnic minority:

Evidence shows that ethnic minorities, often in HICs, have limited health literacy and poorer health outcomes than the general population (98). It is thought to be influenced by greater difficulties in obtaining and acting on health information as a result of language barriers.

Pre-existing chronic illness:

The management of chronic diseases often requires individuals to modify health behaviours and partake in self-management strategies using information and support obtained from various health resources (99). To do this, health literacy skills which include accessing, comprehending and evaluating information relating to health are used, resulting in improved health and well-being (100).

2.8 Measuring health literacy

Measuring health literacy is important as it provides a population profile which can be useful in developing policies and can offer some insight into trends to see whether health literacy is decreasing, increasing or remaining unchanged. It also allows for interventions to be identified which can be targeted at improving health literacy and improving healthcare (30,101). One of the most important aims of measuring health literacy is for research, which enables greater expansion of knowledge and understanding of health literacy (30).

2.8.1 Identifying individuals with limited health literacy

As the term health literacy includes the word literacy, an assumption is often made that it is a concern only for those who cannot read or write. Inadequate health literacy is non-discriminatory and is found in all segments of society. However, certain population groups are at a greater risk of having inadequate health literacy. These include the elderly, people with limited education, ethnic minorities, those who speak English as a second language in an English-speaking country, people who have a low income and those with chronic illnesses (9,102).

It is often impossible to predict whether a person has limited health literacy by simple observation. However, HCPs can pay attention to certain behaviours exhibited by patients with inadequate health literacy (47,103). These include submitting incomplete or inaccurately completed forms, frequently missing appointments and not adhering to their medication regimens. There is also a lack of follow through with medications, interventions or referrals and these individuals often ask very few questions during a consultation (102).

Patients often avoid reading written information during consultations and offer the following excuses: 'I forgot my glasses', 'I'll read this when I get home', 'I forgot my glasses, can you read this for me' and 'let me bring this home so I can discuss it with my children'. They are often unable to name their medications, explain what they are used for, and how and when to administer them (102), and are unable to play a successful role in self-care (103). Patients with limited health literacy may not exhibit all the behaviours mentioned above. If highly articulate, they tend to be proficient at successfully disguising their literacy issues (15).

People may have several years of education and high functional literacy (reading, writing and numeracy skills), but their health literacy skills can still be limited (7). In contrast, individuals with low literacy who may have had exposure to certain circumstances such as personal chronic illness or caring for a person who is unwell, become familiar with selected aspects of disease and health information. Health literacy challenges arise when individuals are not familiar with medical terms, how their bodies function, their illnesses, medicines, equipment they may need for managing their conditions and when they have health conditions which require complicated self-care (104).

2.8.2 Screening vs measurement of health literacy

Some tests measure, whereas others screen health literacy. In a clinical context, a screening tool is intended to be short, quick and easy to use (105). Screening categorises people as either healthy or sick and provides no further explanation as to what is wrong with the person. This all stems from the fact that the tool is used in a clinical setting. Measurement goes a step further and explores the structure and function of objects of interest. Its purpose is to advance health knowledge, explore and explain structure and function, monitor effectiveness and equity of interventions, indicate major problems confronting society and contribute to setting policy goals (105). The approach adopted in health literacy would depend on the setting and the desired outcome of the process of either screening or measuring health literacy.

2.8.3 Measurement of health literacy in clinical practice

As health literacy is a strong predictor of health and health outcomes, routine assessment for compromised health literacy should be standard practice in a clinical setting. Numerous

health literacy tools have been developed and validated over the decades in order to make a measure available for healthcare professionals (HCPs) to use in everyday practice, and to enable use of these measures across a range of different populations (14,15). Despite their availability, HCPs do not routinely screen for limited health literacy as several factors preclude this: multi-item tests such as the TOFHLA are long and time-consuming to administer; tests can be potentially embarrassing to the patient and stigmatize those with poor health literacy; if testing becomes routine in clinical settings, individuals who fear their inability to read being exposed may look for medical services elsewhere; and finally it is costly, as it requires extensive training of HCPs to administer most of the tests appropriately (106–109).

There is a need to identify a tool that is brief yet comprehensive, and is able to identify in a non-threatening manner those patients at risk for limited health literacy (107).

2.8.4 Health literacy tools

The number of health literacy measures has proliferated over the years, with over 100 instruments having been developed (110,111). This implies little consensus on which measure to use, how to measure health literacy, and the lack of a ‘universal or gold standard’ measure of health literacy which can be used in a range of diverse populations (52,112).

Table 2.3 Measures used to assess health literacy

Measurement approach	Year	Author	Test
Objective	2012	Osborn <i>et al</i> (113)	General Health Numeracy Test (GHNT)
	2010	Rawson <i>et al</i> (114)	Medical Term Recognition Test (METER)
	2010	Lee <i>et al</i> (115)	Short Assessment of Health Literacy-English (SAHL-E)
	2008	Osborn <i>et al</i> (116)	Brief Estimate of Health Knowledge and Action - HIV version (BEHKA-HIV)
	2005	Weiss <i>et al</i> (16)	Newest Vital Sign (NVS)
	1999	Baker <i>et al</i> (81)	Short Test of Functional Health Literacy in Adults (STOFHLA)
	1997	Hanson-Divers (117)	Medical Achievement Reading Test (MART)
	1995	Baker <i>et al</i> (14)	Test of Functional Health Literacy in Adults (TOFHLA)
	1993	Davis <i>et al</i> (15)	Rapid Estimate of Adult Literacy in

Subjective	2013	Apolinario <i>et al</i> (118)	Medicine (REALM) Multidimensional Screener for Health Literacy (MSFHL)
	2013	Massey <i>et al</i> (119)	The Multidimensional Measure of Adolescent Health Literacy (MAHL)
	2013	Brice <i>et al</i> (120)	Two Item Literacy Screener (TILS)
	2012	Sharp <i>et al</i> (121)	Time to Sign (TTS)
	2011	Cameron <i>et al</i> (122)	Medication Understanding and Use Self-Efficacy (MUSE)
	2009	Jeppesen <i>et al</i> (123)	Screening questions (SOS Mnemonic)
	2007	Chew <i>et al</i> (106)	Brief Health Literacy Screener (BHLS)
	2006	Morris <i>et al</i> (124)	Single Item Literacy Screen (SILS)
Mixed	2012	Bann <i>et al</i> (125)	Health Literacy Skills Instrument-Short Form (HLSI-SF)
	2012	HLS-EU Consortium (55)	European Health Literacy Survey Questionnaire (HLS-EU-Q)
	2010	McCormack <i>et al</i> (126)	Health literacy Skills Instrument (HLSI)

A major challenge to healthcare providers is identifying patients with inadequate health literacy. Simply relying on observing patient behaviours and patients to report difficulty comprehending medical information is not practical and often leads to missed opportunities in providing medicines information resources (127,128). Therefore a brief, reliable and efficient way of assessing health literacy is essential when used in a clinical setting. For research purposes, the measures tend to be longer, may include a number of testing strategies and may include the use of supplementary materials or props such as audio, text passages and pictures. Measures for assessing health literacy can be categorised according to measurement approach: either objective, subjective or a mixture of both (Table 2.3) (129).

2.8.4.1 Objective health literacy measures

With the objective measurement approach, the assessment measures involve direct testing of skills related to the health literacy construct (129).

Rapid Estimate of Adult Literacy in Medicine (REALM):

This assesses the ability to pronounce medical terms. It consists of 66 increasingly difficult medical terms, with the number of correctly pronounced words related to the

approximate grade level of reading. The REALM is administered in two to three minutes (15,107). One of the most evident shortfalls of the REALM is that the results of the test do not imply comprehension or interpretation, only agreement on the pronunciation of the word (57). The Rapid Estimate of Adult Literacy in Medicine-Revised (REALM-R) is the truncated version of the original REALM consisting of 11 items with an average administration time of two minutes (130).

Medical Achievement Reading Test (MART):

The test presents 200 words in order of ascending difficulty. The words are grouped into 20 word sets that give an approximate grade level of reading. The MART takes 5-10 minutes to complete (117).

Medical Term Recognition Test (METER):

This test includes 40 medical and 40 non-medical words. It is aimed at assessing the ability of patients to identify the medical words. This test takes approximately two minutes to administer (114).

The Short Assessment of Health Literacy - English (SAHL-E):

This consists of 18 test items. It uses the word recognition approach and combines it with comprehension of the medical terms. To guarantee word recognition as well as understanding, the participants read the words aloud and associate the term with another word of similar meaning (115,131).

Newest Vital Sign (NVS):

The NVS consists of a nutrition label for ice-cream accompanied by six questions. It takes approximately three minutes to administer and assesses comprehension and numeracy (132). Patients are categorised as having either low (0–4 correct) or adequate health literacy (5-6 correct). A limitation of this test is its inability to differentiate between adequate and marginal health literacy, leading to a possible overestimation of patients with low literacy due to its specificity (16,36).

Test of Functional Health Literacy in Adults (TOFHLA):

The test consists of two parts: reading comprehension and numeracy. It measures the ability to read and understand three passages: preparation of an upper gastrointestinal tract

radiograph series, the patient's rights and responsibilities section of a Medicaid application form, and a hospital informed consent form. The test takes approximately 22 minutes to administer and is based on the Cloze method, where participants fill in the blank spaces using words selected from a multiple choice list (14). The S-TOFHLA is the shortened version reduced to two reading comprehension passages. The first passage is at a 4th grade reading level, the other at a 10th grade reading level. The average administration time for this test is 8-12 minutes (81).

General Health Numeracy Test (GHNT):

The 6-item numeracy test assesses a wide range of numerical skills such as understanding number hierarchy, performing calculations and estimating probability pertaining to health outcomes. The test takes approximately 5-8 minutes to administer (113).

Brief Estimate of Health Knowledge and Action-HIV (BEHKA-HIV):

The test assesses HIV knowledge and treatment action using a total of eight items. The knowledge subscale measures the ability to understand health information, while the action subscale measures the ability to make the decision to obtain health information (116).

2.8.4.2 Subjective health literacy measures

Self-report measures emerged recently as a means of evaluating health literacy. This approach is characterized by reporting perceived abilities in multiple domains. Chew (133) identified various characteristics of an ideal self-report measure and suggests it should quickly identify patients with limited health literacy and do so as accurately as possible, be easy to administer, therefore making it possible to be used in a busy setting, and it should not cause shame or embarrassment to the patient.

Pleasant (29) reported that some researchers are apprehensive about the use of this method as they report that it assesses self-efficacy rather than health literacy. They also raised concerns that the issue of shame may play a significant role in results from self-report measures of health literacy (29). However, he notes the importance of such measures, and comments that, although this method may not be entirely reliable, it may provide a means of validating the underlying theoretical constructs of health literacy.

The following are various examples of subjective (self-report) measures currently being used.

Single Item Literacy Screener (SILS):

This consists of a single question which is intended to identify patients who need help with printed health material (124).

The Multidimensional Measure of Adolescent Health Literacy (MAHL):

This test assesses health literacy by addressing several health literacy domains: patient-provider communication, interaction with the healthcare system, health information and adolescent rights and responsibilities (119).

Multidimensional Screener for Health Literacy (MSFHL):

This is a 6-item Brazilian screening tool based on three demographic characteristics and three questions related to frequency of use of computers and difficulty with reading and writing print materials (118).

Time to sign (TTS)

This consisted of the Time to Sign test which measures the time taken to write a full signature, and assesses the relationship between time taken and health literacy (121). Adequate health literacy was displayed by individuals who completed their signature in six seconds or less. No modifications were required for this measure (121).

Medication Understanding and Use Self-Efficacy (MUSE)

The measure consists of eight questions, under two subscales. It assesses the ability to understand medication instructions, medication use and medication self-efficacy (122).

Brief Health Literacy Screener (BHLS)

The measure assesses confidence in filling out forms, problems with learning and difficulty reading, using a total of three items (106).

2.8.4.3 Mixed health literacy measurement

This measurement approach is a combination of a direct testing and a self-report of health literacy skills (129)

Health Literacy Skills Instrument (HLSI and HLSI-SF)

The HLSI is a 25-item tool which was designed to measure print, oral and numeracy skills as well as internet-based information-seeking skills. The instrument takes approximately 5-10 minutes to administer (126). The shortened form, HLSI-SF contains 10 items which were developed from data collected for the development of the longer version (125).

European Health Literacy Survey (HLS-EU)

This is a self-report survey with 47 items. It defines health literacy in three domains (health care, disease prevention, health promotion) and four modes (access, understand, evaluate and apply health information (55).

2.8.5 Criticism of current health literacy tests and guidelines for developing new tests

Criticism of existing tests has been widely expressed in the literature. Critical observations of some of the existing measures of health literacy are that they:

- are not based on the underpinning concept of health literacy
- lack cultural sensitivity and are biased towards certain population groups
- do not evaluate oral communication skills
- have not been used in a consistent way
- have not undergone extensive psychometric analysis
- place a problematic burden and label on patients
- do not focus on the multiple dimensions upon which health literacy has been built
- do not distinguish between people with very low and very high levels of health literacy
- are limited in their approach to evaluating skills (1,17,44,134–137).

Most of the work in the development of health literacy measures has been conducted in high income countries (HICs) (137,138). As a result most of these measures make reference to the language, culture, education and healthcare systems of those respective countries. It becomes very hard to consolidate these differences when adopting measures for other countries which have their own distinct characteristics (139). Researchers have warned against assuming universal applicability of health literacy measures, but rather to take into account the local language, culture and healthcare setting prior to use of the instruments in practice (18,140).

While there has been an increase in addressing issues of health literacy among individuals with limited English literacy, it is often difficult to find a valid measure to assess health literacy. The REALM have been used in different populations and have been found to be inappropriate for second language English speakers (141,142). The TOFHLA is another standardised test available in both English and Spanish, however it heavily references the United States' healthcare system and is inapplicable in other settings (11). Because of this deeply rooted use of the English language and strong reference to the United States' healthcare system, simply translating these instruments will lead to limited application in other countries (143–145).

Cultural differences have been established as a factor contributing to poor health literacy, as it influences how individuals interact with HCPs, use information provided by HCPs and how they perceive health and illness (27). Neglecting to recognise the influential role cultural differences have in health literacy is likely to exclude the needs of the populations which suffer from higher levels of inadequate health literacy (27).

The average educational level in HICs is often relatively high in comparison to LMICs. As health literacy has been found to correlate with literacy, it is essential to tailor health literacy measures to make provision for those with limited literacy. Dowse (18) suggests accounting for low literate individuals by developing measures which do not rely solely on cognitive abilities such as reading and numeracy, adopting test formats which do not require self-completion and adopting response formats which are simple for individuals to comprehend.

Countries with unique educational, cultural and healthcare system differences are encouraged to develop their own health literacy measures which will be able to generate valid and meaningful health literacy data (139). The lack of valid health literacy tools has meant that in most LMICs there are no national data available, which precludes any assessment of the prevalence of limited health literacy in these countries.

Pleasant *et al* (146) propose the following eight principles to consider when developing a comprehensive health literacy measure:

- It must be built explicitly on a testable theory or conceptual framework.

- The framework needs to be based on multiple conceptual domains and multiple skills and abilities (finding, evaluating, understanding, and navigating).
- Several methods must be used, as different skills and abilities are needed in the numerous proposed concepts of health literacy.
- Communication and health literacy need to be clearly distinguished from one another.
- The comprehensive measures of health literacy should contain items which sample from all domains outlined by the framework or underlying theory.
- It must honour the principle of compatibility i.e. a measure which focuses only on the clinical setting is not suitable when researching public behaviours and outcomes.
- It must allow good comparisons across all contexts, cultures and population groups.
- It must prioritise social research and public health application versus clinical use.

2.9 Strategies to improve health literacy

The most important step in improving health literacy is to identify patients who are at risk of not being able to access, understand and use health information (103). Communicating clearly with patients can improve health literacy (103). This involves the use of plain language in both written and verbal health information and is achieved by limiting the use of medical jargon and replacing it with words that can be understood by a lay person. When using plain language, cultural sensitivity must be considered particularly in a culturally diverse population. Information that is often clear in plain language to one culture may not be to another (103).

Advancing from the traditional verbal and written teaching methods, alternative teaching methods can also be employed to educate patients on numerous health issues. The use of materials such as videos, audiotapes, pictograms and models can be essential in improving health literacy among those individuals who are visual or auditory learners (103). Patients often get overwhelmed with information they receive from HCPs, particularly those patients with low health literacy. It is recommended that the information provided to such patients be succinct, limiting it to only two or three key points. Repetition should also be used to further enforce all the information provided (103).

Once health information has been given to the intended recipient, there is still a risk that it is not processed or understood (103). This is often the case in the clinic setting when patients feel pressure to agree that they have understood information when they do not. When talking directly with patients, using methods such as the teach-back method can be an effective strategy to facilitate understanding. In this method patients repeat back to the provider the information they believe they have just heard. (103).

Although individuals are increasingly required to take an active role in improving their health literacy, key role players such as organizations, HCPs and policymakers can collaboratively play a vital role to improve health literacy (147). They must aim to improve communication between individuals and facilitate understanding of health materials by simplifying them in order to alleviate the demands it places on patients. However, individuals need to recognize their roles and responsibilities to be informed and to be vigilant in protecting their health (148).

CHAPTER 3

DEVELOPMENT OF RESEARCH TOOL

3.1 Introduction

More than 100 health literacy measures have been developed worldwide (111). The lack of an all-encompassing definition of health literacy has meant that there is no health literacy measure which can be used as a ‘gold standard’ in diverse populations (20). The majority of the tests which are widely available emanate almost exclusively from HICs (18,140,143,144). The most commonly used tests include the Test of Functional Health Literacy in Adults (TOFHLA) (14) and its shortened version, the S-TOFHLA (81), the Rapid Estimate of Adult Literacy in Medicine (REALM) (15) and the Newest Vital Sign (NVS) (16). Minimal health literacy research from sub-Saharan Africa has been reported, nor are there any health literacy tests that have been validated for use in South Africa. This chapter details stages in the development and modification of an Item Bank of health literacy questions which lay the groundwork for the development a health literacy measure for South Africa, and potentially, for other general limited literacy populations.

3.2 South African healthcare system

Healthcare in South Africa is delivered by two distinct systems: the private sector and the public sector. Although the private sector offers a highly efficient service, it is inaccessible to most of the population and services only 16% of the population (149). The public sector caters for 84% of the population (149). Most individuals utilising public healthcare facilities are from the lower socio-economic bracket who tend to be unemployed, and are children or pensioners (150).

The Alma-Ata Declaration in 1978 strongly reaffirmed health as a human right and the need for PHC services to provide the first level of contact for health care to communities (151). Following the Alma-Ata recommendations, South Africa adopted the PHC concept in 1994. There are currently 3477 public health facilities in South Africa (152). Grahamstown, the main site of this research study, is served by six PHCs (Raglan Road, Virginia Shumane Clinic, Extension 7 Clinic, Town Clinic, Middle Terrace Clinic, and Settler’s Day Hospital) and three hospitals (Settlers Hospital, Fort England Hospital and Temba TB Hospital).

Services provided by PHCs include mother and child care, immunisation, family planning, treatment for sexually transmitted infection, minor trauma, and care for those with chronic illnesses (eg. diabetes, hypertension). These services are primarily provided by nurses, although doctors also consult at the clinics on a rota basis (153).

3.3 Language use in South Africa and the Eastern Cape

South Africa has a diverse cultural and ethnic population. Of the 55.9 million South Africans, 80.7% are black, 8.8% are coloured, 8.1% are white and 2.5% are Indian (154) . There are eleven official languages in South Africa; Zulu (22.7%), Xhosa (16%), Afrikaans (13.5%), English (9.6%), Sepedi (9.1%), Tswana (8%), Sotho (7.6%), Tsonga (4.5%), SiSwati (2.5%), Venda (2.4%) and Ndebele (2.1%) (155)

Although English only ranks fourth, it has been adopted as the language of use in, business, politics and media. However, all 11 languages are mandated to have equal emphasis and importance in use. The languages most frequently spoken in South Africa will depend on where in the country you are. South Africa has nine provinces, each with a predominant language which is spoken. IsiXhosa is South Africa's second most commonly spoken language. Over a third of the speakers live in the Eastern Cape, where it is the language of 77.6% of the provincial population (155).

3.4 Objectives

The objectives of this phase of the study were:

- To develop an Item Bank of questions that are multidimensional and address a range of health domains
- To critically evaluate individual questions for content validity and face validity
- To organise Item Bank questions into health literacy domains

A flow diagram detailing the steps in the development of the Item Bank is shown in Figure 3.1.

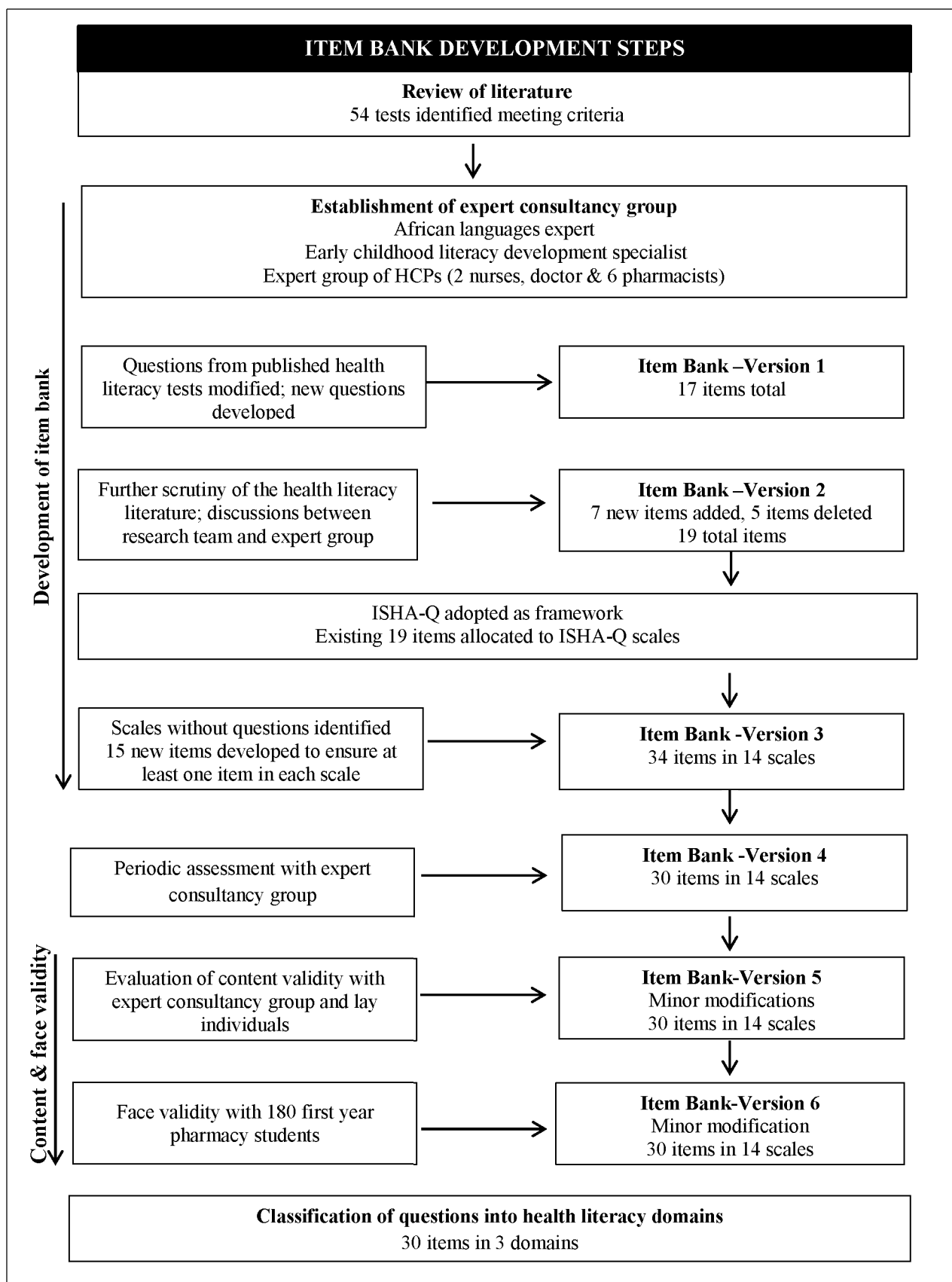


Figure 3.1 Steps in the development of the Item Bank

3.5 Structure and content considerations in developing the Item Bank of health literacy questions

3.5.1 Structure

Test formats and their associated response formats may be familiar to certain populations. For example, multiple choice questions have been widely used in the USA, however the assumption of familiarity within other different populations cannot be made (156). The use of Likert-type responses can present challenges to low literate, non-English speakers and ethnic minorities (157–159). Having more than four points on a Likert scale (158) has been found to be confusing for respondents, and one approach has been to reduce the number of points in the scale in order to improve understanding and facilitate appropriate responses (158,160). Culture can also influence patterns of response to Likert items, with certain cultures being less willing to select extreme responses. Other cultures may not be familiar with measuring constructs on a continuum, resulting in scores from Likert scales being less reliable (161). Different test formats and their associated issues can be a source of invalidity of test results. A recommended approach is to combine different formats to counteract sources of invalidity during the assessment process (156).

The mode of administration of a health literacy measure plays an important role in its use and applicability. They can either be self-administered (indirect administration), administered face-to-face, or it can be a single measure that is administered directly and indirectly (162). Newly-developed health literacy measures tend to favour self-administration methods as these do not require an assistant or an HCP to administer (162,163). However, the validity of the information provided with the indirect self-administration method may be questionable, particularly in limited literacy respondents (164), as researchers have found that they are likely to select answers on the measure without understanding them (165). Such measures may therefore not be suitable for these individuals with limited reading ability. In such cases, face-to-face administration methods are preferred.

3.5.2 Content

When developing health literacy measures, it is important for the content to depict the culture, lifestyle, and disease burden of that population, as well as the characteristics of the healthcare system (18). When issues regarding the content are not addressed, it makes it difficult to obtain meaningful and accurate data from the measure. This is often evident when tests developed in one country are applied in another, either in its original or modified form (142).

A study in the Netherlands translated the NVS to Dutch. Results reported difficulties in cross-cultural applicability as a result of the ice-cream food label. The differences in layout and content of the label rendered it unfamiliar to the participants who found it difficult to interpret. Compounding this lack of familiarity was the much lower consumption of ice-cream in the Netherlands as compared to the USA. The participants also had difficulties in calculating in portions instead of grams (140). The TOFHLA, another common health literacy measure has been identified in other studies to be strongly rooted in the USA healthcare system (143,144). The same issue was echoed in a study conducted in South Africa where the REALM was found to have a cultural bias and ultimately disadvantage the local population, as it was generated in a health setting different from that experienced by South African public sector patients (142).

3.6 Validating the final research instrument

The process of validation requires gathering and evaluating a comprehensive body of evidence for a measure in order to understand and support the properties of an instrument (166). Reliability and validity are crucial components in determining the quality of research instruments (167).

3.6.1 Reliability

As the term implies, a reliable measure is one which performs in a consistent and predictable manner (168). Reliability demonstrates consistency of measured items (166,169), therefore multiple items attempting to measure the same construct should be correlated (166). The most commonly used methods for reliability testing are test-retest and internal consistency (166).

3.6.1.1 Test-retest

The purpose of the test-retest method is to evaluate consistency over time, and it relies on achieving the same results on different occasions (168,170). It is carried out by administering the same test to the same group of people on two different occasions in order to minimize the chances of deterioration or improvement in the individual's scores. If the scores from the two administrations are correlated, the test is deemed consistent (171).

3.6.1.2 Internal consistency

The most widely used method of measuring internal consistency is Cronbach's alpha, which makes the assumption that items measuring the same construct should correlate (168,170,172).

3.6.2 Validity

Validity of the measure is the extent to which an instrument measures what it purports to measure (167,168,170,173), and is dependent on the reliability (173,174). Numerous methods of validity testing have been suggested in the literature. These include content and face validity, criterion validity and construct validity (166–168,170) (Table 3.1). Assessment of validity with all the methods mentioned above is not necessary, as they apply differently in different contexts. However, it is recommended to assess content and face validity with at least one other kind of validity (168).

3.6.2.1 Content and face validity

This type of validity must ideally be established during the initial development of the measurement (168) (addressed in Sections 3.9.1-2). Content validity is assessed through inspection by experts in the field and the researchers involved in the development of the instrument (170). It is concerned with how comprehensively the items represent the construct being measured (166,168,170). Face validity is a component of content validity and it assesses whether the scale is appropriate (170). In contrast to content validity, the individuals involved in the assessment of face validity must be drawn from the target population to which the measure will be administered (168).

Table 3.1 Methods of validity testing (adapted from Moerdyk 2009) (170)

Type	Purpose	Form	Question asked
Content	Does the measure accurately reflect the content of the domain being assessed?	Content validity	Are the items representative of the domain under investigation?
		Face validity	Do the items appear to be appropriate for the test purpose?
Criterion related	Does the test correlate with external criteria?	Concurrent validity	Does the test result correctly identify groups that are known to differ on the characteristic being assessed?

3.6.2.2 Criterion validity

Criterion validity relates to the performance of a measure, with some external criterion (168,170). Concurrent validity is an index of criterion validity (167,168,170) used to compare the performance of a new measure with that of an existing one that is known to measure that same construct (167,168,170). The two measures must be completed concurrently by the same subjects (168). A significant association between the two measures will indicate good concurrent validity (168).

3.7 Review of items in current health literacy tests

An initial search of the literature revealed a dearth of research on health literacy tools prior to 1993. This date was identified as being suitable for a review of health literacy tests as it encompasses the date of the first widely used health literacy measure, the REALM (15). Inclusion and exclusion criteria for selection of literature describing health literacy tests were developed and are outlined in Table 3.2.

Table 3.2 Inclusion and exclusion criteria for literature selection

Criteria	Inclusion	Exclusion
Time frame	January 1993- September 2015	Any study outside this time frame
Language	English	Non-English
Type of article	Research article published in a peer-reviewed journal	Not a peer-reviewed journal article and/or unpublished
Focus	Development and /or validation of health literacy instrument providing detailed description of the questions	Health literacy instrument with no detail of questions

The selected databases used for the search were PubMed and Health Literacy Tool Shed, manual searches using Google search engine and reference lists in published papers were used as additional sources. The following terms/phrases were used: ‘health literacy’, ‘tests’, ‘tools’, ‘measurements’, ‘development’ and ‘validation’. Based on these search terms, 54 published studies meeting the inclusion criteria relating to the development and/or validation of health literacy tests were identified (Figure 3.2).

3.8 Establishment of an expert team for consultation

The initial members of this group were an African languages expert and an early childhood literacy development expert. They were consulted for their expert input in guiding the development of the early versions of the Item Bank, in order to address cultural appropriateness, as well as the literacy and cognitive demands of the Item Bank questions.

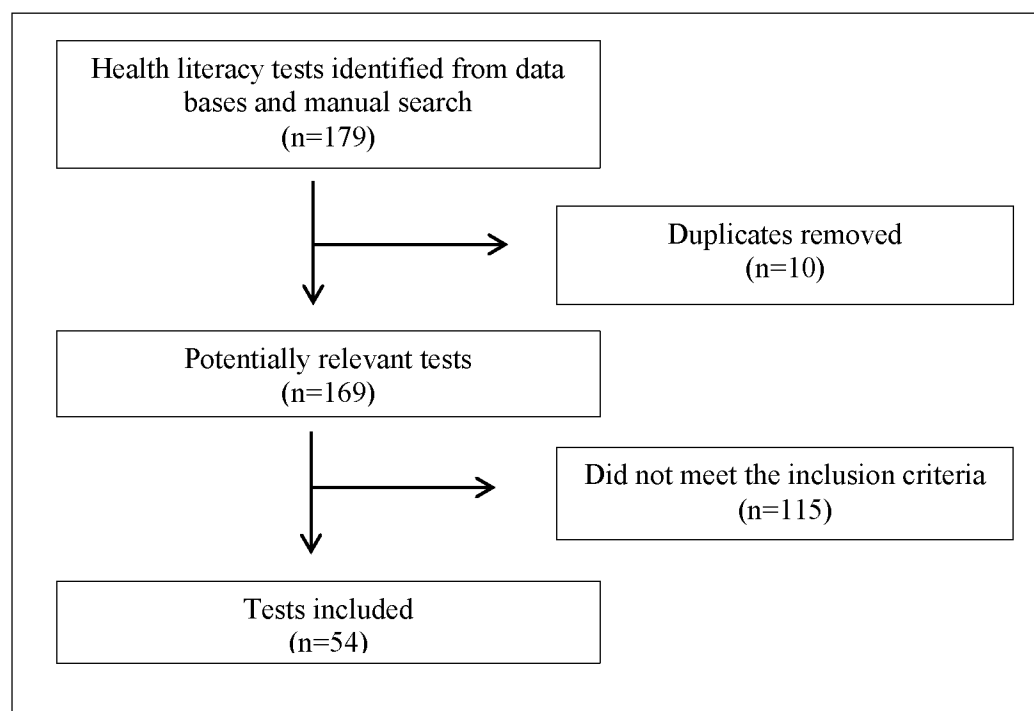


Figure 3.2 Literature search for health literacy tests

Dr Maseko, the African Languages expert from the Division of African Languages at Rhodes University, was consulted for translation of the questions into isiXhosa, as well as any associated linguistic issues. The chief concern related to appropriate translation from English to isiXhosa was that many English words, concepts and phrases have no direct equivalent in

the isiXhosa language. For example, questions beginning with the phrase ‘how often’ are challenging to translate, as in isiXhosa the concept of time is abstract and does not lend itself to direct translation. Using the more direct, numerically based phrase ‘how many times’ was considered to be more acceptable. However, no changes were made to the original English version of these questions beginning with the phrase ‘how often’ as the phrase automatically translates to ‘how many times’ in isiXhosa.

Dr Maseko cautioned that although the questions were written in simple English and were easy to read, there is a chance that the questions can lose this characteristic once translated into isiXhosa. Consultation with back-translators would therefore be essential. Other recommendations were to review the questions and attempt to conceive them in the destination language (isiXhosa); this could help in ensuring that the meanings of the questions are maintained.

A nationally recognised literacy expert and specialist in early childhood literacy development, Ms Sarah Murray from the Faculty of Education at Rhodes University, was also consulted at this early stage. The main issue identified was that many of the available tests focus mainly on reading and writing skills and fail to assess other fundamental health literacy skills such as accessing, understanding and applying health information to daily situations. Despite availability of health information from various sources, basic reading and writing skills are often inadequate when individuals have to comprehend and utilise this information.

The expert group was expanded to include a team of healthcare professionals comprising two nurses, a doctor with extensive experience in working with public sector patients and six pharmacists; three were practising pharmacists based at a local PHC in Grahamstown, and the remaining three were from within the Faculty of Pharmacy. These individuals were consulted in order to establish content validity of the later versions of the Item Bank.

3.9 Development and modification of initial health literacy questions: Item Bank-Version 1 and Item Bank-Version 2

When developing a health literacy measure, a constellation of health literacy skills are considered including accessing healthcare services, communicating with healthcare

providers, locating health information, evaluating information for usefulness and quality, interpreting test results, calculating dosages, and analysing relative risks and benefits. These health literacy skills are the cornerstone to improving health outcomes (41).

A preliminary bank of 17 questions was formulated. Questions from the existing health literacy tests were either adopted in their original form or were slightly modified for inclusion in the Item Bank (Table 3.3). New questions were designed informed by items from existing health literacy tests.

Table 3.3 Health literacy tests where questions were extracted and modified or adopted for inclusion in Item Bank-Version 1

Year	Authors	Test name	Test aim	Key concepts aligned with the definition and framework of health literacy	Questions
2013	Osborn <i>et al</i> (113)	General Health Numeracy Test (GHNT)	Examines understanding of number hierarchy, performing calculations, assessing health risk and correctly estimating probability when making decisions about disease prevention, nutrition management, medication and adherence.	<ul style="list-style-type: none"> • Understanding information (numerical) • Confidence to take action through decision making 	<ol style="list-style-type: none"> 1. Call your doctor if you have a temperature of 100.4° F. The thermometer looks like the following (100.2° F). Do you call the doctor?² 2. If 4 people out of 20 have a chance of getting a cold, what is the risk of getting a cold?¹ 3. Suppose the maximum heart rate for a 60 year old woman is 160 beats per minute and that she is told to exercise at 80% of her maximum heart rate. What is 80% of that woman's maximum heart rate? 4. You ate half the container of carrots. How many grams of carbohydrates did you eat? 5. Your doctor tells you that you have high cholesterol. He informs you that you have a 10% risk of having a heart attack in the next 5 years. If you start on a cholesterol-lowering drug you can reduce your risk by 30%. What is your 5 year risk if you take the drug? 6. A mammogram is used to screen women for breast cancer. False positives are tests that incorrectly show a positive result. 85% of positive mammograms are actually false positives. If 1000 women receive mammograms, and 200 are told there is an abnormal finding, how many women are likely to actually have breast cancer?
2013	Massey <i>et al</i> (119)	The Multidimensional Measure of Adolescent Health Literacy (MAHL)	Explores patient-provider encounter, interaction with healthcare system, rights and responsibilities, health information seeking.	<ul style="list-style-type: none"> • Social skills through patient-provider interaction • Access through interaction with the healthcare system, and health information seeking 	<p>As you answer the following questions, think about your health care experience in the last 12 months:</p> <ol style="list-style-type: none"> 1. Did doctors or other health care providers listen to you? 2. Did doctors or other health care providers explain things so you could understand?¹ 3. Did doctors or other health care providers show respect for you? 4. Did doctors or other health care providers spend enough time with you? <p>As you answer the following questions, please tell us about how confident you feel about:</p> <ol style="list-style-type: none"> 5. Being able to speak privately with your doctor or other health care provider about your health issues? 6. Being able to make an appointment to see your doctor or other health care provider? 7. Being able to fill a prescription at a pharmacy? 8. That your doctor or other health care provider will keep what you say to him or her

					<p>confidential?</p> <p>9. That your doctor or other health care provider will send you to a specialist if you need one?</p> <p>As a patient with health insurance, how much do you agree or disagree with the following statements:</p> <p>10. It is my responsibility to make sure I or my parent schedules a check-up every year with my doctor or other health care provider.</p> <p>11. When I need other medical care it is my responsibility to make an appointment with my regular doctor or other health care provider or ask someone to make it for me. It is my right to be able to talk to my regular doctor or other health care provider privately.</p> <p>12. It is my responsibility to only use the emergency room when it's really an emergency (for example, for an accident or serious illness).</p> <p>13. It is my right that my doctor or other health care provider keeps information about my health confidential.</p> <p>14. My doctor or other health care provider is supposed to discuss things with me that are bad for my health and what to do about them.</p> <p>15. My doctor or other health care provider is supposed to send me to a specialist if I need to see one.</p> <p>How confident are you about using health information from the following sources:</p> <p>16. Family</p> <p>17. Friends</p> <p>18. Teachers</p> <p>How confident are you about using health information from the following sources:</p> <p>19. Internet</p> <p>20. Magazines or Newspapers</p> <p>21. Movies, Television or Radio</p> <p>How much do you agree or disagree with the following statements:</p> <p>22. I know how to use the Internet to answer my health questions</p> <p>23. I know what health resources are available on the Internet.</p>
2010	Cameron <i>et al</i> (122)	Medication Understanding and Use Self-Efficacy (MUSE)	Examines the ability to understand medication instructions, medication use and medication self-efficacy.	• Understanding medicines information	<p>1. It is easy for me to take my medicine on time.</p> <p>2. It is easy for me to ask my pharmacist questions about my medicine.</p> <p>3. It is easy for me to understand my pharmacist's instructions for my medicine.²</p> <p>4. It is easy for me to understand instructions on medicine bottles.²</p> <p>5. It is easy for me to get all the information I need about my medicine.</p> <p>6. It is easy to remember to take all my medicine.</p> <p>7. It is easy for me to set a schedule to take my medicines each day.</p> <p>8. It is easy for me to take my medicines every day.</p>

2006	Morris <i>et al</i> (124)	Single Item Literacy Screen (SILS)	Single question to estimate reading ability.	<ul style="list-style-type: none"> • Mediators of health literacy acquisition explored (basic literacy –reading ability) 	1. How often do you need someone help you read instructions, pamphlets or other written materials form you doctor or pharmacy? ²
2004	Chew <i>et al</i> (175)	Brief Health Literacy Screener (BHLS)	Assesses confidence in filling out forms, problems with learning and difficulty reading.	<ul style="list-style-type: none"> • Understanding health information • Mediators of health literacy acquisition are explored (basic literacy –reading and writing ability) 	1. How often do you have someone help you read hospital materials? ² 2. How often do you have problems learning about your medical condition because of difficulty understanding written information? ² 3. How confident are you filling out medical forms by yourself? ²

¹ Questions were extracted and modified for inclusion in the Item Bank-Version 1

² Questions were adopted in their original form for inclusion in Item Bank-Version 1

The developmental stage of the Item Bank was an iterative and dynamic process with numerous changes made to question content and the need for new questions identified. On-going discussion through email correspondence and rigorous evaluation of these original questions was conducted periodically by the research team with feedback being provided electronically. Individuals from the target population were also informally consulted for guidance on issues such as cultural relevance, general familiarity with health information and health concepts, and mechanism of health services delivery. Based on input from these individuals as well as the literacy development expert and African languages expert, some of the original questions (Q1-Q17) were modified, and seven new questions were added (18-24) for Version 2 of the Item Bank. The rationale for modifying the questions and for developing additional questions appears in Table 3.4.

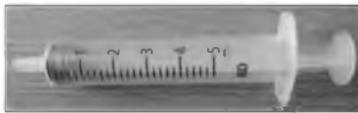
Table 3.4 Changes from Item Bank-Version 1 to Item Bank-Version 2

#	Version 1	Version 2	Reasons for changes and addition of new questions
1	If you go to the clinic on the 7 th of March and you are asked to return a week later what will the date be?	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be?	<p>Navigation of the healthcare system is a principal health-related task that has a profound effect on an individual's health and wellbeing. Patients with inadequate health literacy face the greatest difficulty when accessing and using the healthcare system. Literacy problems can inhibit a patient's ability to attend appointments because they may not be able to follow directions to the doctor's office or interpret the return date, locate services (e.g. x-rays) and fill out complex forms (176).</p> <ul style="list-style-type: none"> • In order to moderately increase the numeracy difficulty level of the question, 'a week later' was changed to 'two weeks later'. • The word 'clinic' was added for the return destination to improve clarity of the question.
2	If 4 out of 20 people have a chance of getting a cold, what is the risk of getting a cold?	You read in a health leaflet that 4 out of 20 people this winter have a chance of getting a cold. What is the percentage risk of getting a cold?	<p>Adequate understanding of risk and probability is critical for decision making in all domains of healthcare, ranging from disease prevention and screening through to treatment (177,178). This question was taken in its original form from the GHNT from the USA (113).</p> <ul style="list-style-type: none"> • An indication that this health information was taken from a health leaflet was included.
3	If you take one tablet in the morning, in the afternoon and at night for 5 days, how many tablets would you have taken after 5 days?	You have to take one tablet in the morning, one tablet after lunch and one tablet at night for 5 days. How many tablets would you have taken after 5 days?	<p>Numeracy plays an important role in health decisions, whether it relates to determining the number of pills to take, what time of day to take them or identifying numbers on equipment in order to make a measurement. Health literacy affects how individuals understand numeracy-related concepts. Many patients with limited literacy and numeracy problems are unable to follow medication instructions; medicine is often taken at incorrect intervals and in incorrect quantities (179). This question was included to assess patient numeracy skills in relation to dosage information found on medication labels.</p> <ul style="list-style-type: none"> • The question was reworded to make it a direct instruction and avoid the uncertainty of the word 'if'. • 'One tablet' was added in front of each time of day (morning, afternoon and night) in order to improve the clarity of the instruction.

4	<p>Medicine label shown to participant: What are the 3 most important things you learn about taking the medicine from this label?</p> <div> <div>21 FLAGYL® 200MG TABLETS</div> <div> TAKE ONE TABLET THREE TIMES A DAY FOR 7DAYS FINISH THE COURSE </div> <div>MR A N T BIOTIC</div> <div> WELLNESS PHARMACY, 50 CHURCH STREET GRAHAMSTOWN C MARIMWE (BPHARM) TEL: 461911 18/04/2015 EXP. 02/02/2017 </div> </div>	<p>From the medicine label shown to you:</p> <p>a) Is this medicine safe to drink with beer?</p> <p>b) How many days must you take this medicine for?</p> <div> <div> WELLNESS PHARMACY TEL: 461911 FAX: 461922 </div> <div> FLAGLY® 200MG TAB 15 S4 TAKE ONE (1) TABLET THREE TIMES A DAY MR ANT BIOTIC 02/02/2017 DISPENSER: C MARIMWE </div> </div>	<p>This question aims to identify whether participants are able to identify pertinent information on a medicine label regarding dosage, dosing frequency and precautions. The medicine label is often the sole source of specific dosage/usage instructions given to and repeatedly used by the patients. Patient misunderstanding of instructions on medication labels is common and a likely cause of medication error and less effective treatment (180,181).</p> <ul style="list-style-type: none"> The original version had attempted to elicit two discrete responses about information contained on a medicine label with one question. This question was broken down into two distinct parts, with each part having its own focus. The medicine label was changed to better mimic simpler labels which are used in the public sector clinics.
5	<p>When someone is obese, do they have a higher risk of getting diabetes?</p>	<p>Do overweight people have a higher chance of getting diabetes?</p>	<p>Health literacy requires knowledge of health-related topics, and individuals with inadequate health literacy have significantly less knowledge about chronic diseases and how to manage their illness compared to those who have adequate health literacy (7,8). The lack of knowledge can also affect knowledge of lifestyle choices such as diet and exercise in relation to health outcomes. In 2014 it was estimated that 9% of the global population had diabetes (182), with the projection that, in 20 years, 80% of all people with diabetes will be in developing countries (182). According to the International Diabetes Federation, approximately 7% of South Africa's adult population has diabetes (183) and those most at risk because of rapid lifestyle and cultural changes are from the black community (184). This question aims to assess knowledge on risk factors of diabetes.</p> <ul style="list-style-type: none"> The word 'obese' was replaced by 'overweight'. The term 'risk' was replaced by the more familiar word 'chance' to facilitate comprehension.
6	<p>When taking antibiotics, one must always finish the course. This means you should stop taking the medicine once you feel better.</p>	<p>When taking antibiotics, you must always finish the course. Does this mean that you should stop taking the antibiotics as soon as you start to feel</p>	<p>WHO has identified antibiotic resistance as a major global threat to public health (185). This question attempts to assess whether participants understand one of the most common aspects of correct antibiotic use i.e. completing a course of prescribed antibiotics.</p>

		better?	<ul style="list-style-type: none"> The question was personalised by replacing the word ‘one’ with ‘you’ and using the direct voice. The second part of the sentence was changed from a statement to a question, clarifying that an answer was required.
7	Eating healthy foods such as fruit and vegetables, and regular physical activity are all important for keeping healthy.	Do you think walking for 30 minutes a day can help you stay healthy?	<p>An unhealthy diet has been identified as one of the key risk factors for the major NCDs such as cardiovascular diseases, cancer and diabetes. Adopting healthy lifestyle modification is integral in reducing the burden of NCDs (186).</p> <ul style="list-style-type: none"> The original dual focus on both eating and physical activity was changed to a sole focus on the latter. As planned physical exercise is not part of the lifestyle of many in this population, it was felt that additional information should be offered to explain what was meant by physical activity. The option offered was ‘walking for 30 minutes a day’.
8	If you are given the option to eat a meal which consists of pap, beans and beef and another meal which consists of fried chips and chicken and a coke, which meal would be better to eat and why?	<p>You have to choose which plate of food you think is healthier:</p> <p>Plate 1: beef stew pap and butternut</p> <p>Plate 2: fried chicken and chips</p>	<p>See Question 7 for theory supporting this question.</p> <ul style="list-style-type: none"> After consultation with a few individuals from the target population, the food options were changed to more closely align with commonly eaten foods. The second sentence in the original version consisted of a two-part question asking which meal was better, as well as why this was so. The question was simplified to only ask for a direct choice of one of the two meals, with no further explanation required.
9	It is easy for me to understand the pharmacist’s instructions for my medication.	Is it easy for you to understand the instructions for your medication?	<p>The communication barrier between patients and healthcare professionals often goes unnoticed and this can have detrimental consequences on patient health and safety (187). In South Africa, healthcare consultations are generally not conducted in the patient’s home language and are often done by HCPs who are English speaking. This forms a barrier to effective patient-provider communication and compromises the ability for HCPs to be empathic and approachable (188).</p> <ul style="list-style-type: none"> The question was taken in its original form from the MUSE (122). The statement was changed into a question. The term ‘pharmacist’ was removed from the statement as we wanted to cover both verbal instructions (which are not always necessarily given by the pharmacist) and written instructions which patients have to read themselves.
10	How often do you have problems learning about your medical conditions because of difficulty understanding	How often do you have problems learning about your medical conditions because of difficulty	Healthcare systems rely on printed materials as one of the many ways to convey directions and instructions related to procedures, medicines, side effects and self-care. However, as these materials are often written at levels that exceed the

	written information?	understanding written information?	reading ability of the average adult (above grade 10 level) (189,190), individuals with limited health literacy are therefore greatly disadvantaged. This question is from the BHLS and was used in its original form (175).
11	How often do you need someone to help you read instructions, pamphlets or other written materials from your doctor or pharmacy?	How often do you need someone to help you read instructions, pamphlets or written materials from your doctor or pharmacy?	Limited literacy is the most common reason for experiencing difficulty with reading, and it is closely linked to socioeconomic status and level of education (191). Health information in South Africa is mostly available in English, although only a minority have this as their first language. Many individuals are unable to understand health information without the assistance of a second party. This question was adopted in its original form from the SILS (124) and aims to explore how often assistance is required in interpreting and understanding health information.
12	Can you estimate your reading ability with one of the following? I frequently read and complete the book; I read the newspaper; I frequently need help reading the newspaper.	-----	<p>Reading skills are important for accessing and understanding health information, managing personal health, using the healthcare system and ultimately achieving desirable health outcomes (124).</p> <ul style="list-style-type: none"> This question was removed from the list. Many of the people in our target population have limited literacy and cannot afford to buy books and newspapers; therefore they are unlikely to read these materials on a regular basis. This type of question is therefore likely to be too crude an indicator of reading ability.
13	Call your doctor if you have a temperature of 100.4° F. The thermometer looks like the following (100.2° F). Do you call the doctor?	What is a normal body temperature?	<ul style="list-style-type: none"> This question was removed from the list. Input from our target population advisors indicated that it is unusual to find a thermometer at home as the only place where their temperature is taken is at the clinic.
14	<p>Show image of the passage. Read the passage below and complete or choose the correct words.</p> <p>a) Having ____ or ____ for a long time can cause loss of important fluids from the ____</p> <p> a. Diarrhoea Sugar</p> <p> b. Fluid Body</p> <p> c. Salt Vomiting</p> <p>b) Drinking homemade sugar-salt solution helps to prevent and treat</p>		<p>Diarrhoea is the third leading cause of death in South Africa (192). The Eastern Cape is one of three provinces with the lowest access to private water which puts them at risk for microbial contamination and associated diarrhoeal diseases. The use of home-made sugar and salt solution is often promoted at PHCs to mitigate the effects of diarrhoea (192).</p> <ul style="list-style-type: none"> This question was removed. The bank of questions is intended to form a verbal, interviewed-administered test. Requiring a passage to be read would not be in keeping with this aim, and it would also be time consuming and difficult to administer these sub questions orally.

	<p>the loss of important _____ from the body.</p> <p>a. Salt</p> <p>b. Fluids</p> <p>c. Sugar</p> <p>c) The three ingredients needed to make homemade sugar-salt solution are _____ , _____ and _____</p>	-----	
15	It is easy for me to understand instructions on medicine bottles.	-----	<p>Patient misunderstanding of instructions on medication labels is a safety and health literacy concern (193,194). The Institute of Medicine Report of 2007 (195) revealed that poor patient comprehension and subsequent unintentional misuse of medication as a root cause of medication error, poor adherence, and worse health outcomes.</p> <ul style="list-style-type: none"> • This question was removed, as it was deemed too similar to Question 9.
16	How often do you have someone help you read hospital materials?	-----	<p>See Question 11 for theory supporting this question.</p> <p>This question was adopted in its original form from the BHLS (175).</p> <ul style="list-style-type: none"> • This question was subsequently removed as it interrogates the same concept as Question 11. Some participants may not have been in a hospital setting and may not be familiar with the materials referred to in the question.
17	How confident are you filling out medical forms by yourself?	-----	<p>See Question 1 for theory supporting this question.</p> <p>This question is taken from the BHLS (175).</p> <ul style="list-style-type: none"> • This question was subsequently removed as patients using public sector healthcare facilities are not frequently required to fill in medical forms.
18	-----	<p>Show image of graduated syringe: You are required to give a child 2 ml of a liquid medicine. On the syringe please show me where you will fill it up to.</p> 	<p>Studies suggest that caregivers frequently misunderstand instructions for administering medicine to their children correctly, with a large number of caregivers making errors in administering liquid formulations (196–199). Limited numeracy skills have been linked to a higher incidence of dosing errors in administering medication to children (200). This question assesses the ability to read a numerical scale as it relates to dosing of a liquid via a syringe.</p>
19	-----	Can you explain what diabetes is?	See Question 5 for theory supporting this question.

			This question was meant to assess whether patients have some basic understanding of the pathophysiology of diabetes.
20	-----	Can HIV/AIDS be cured?	At the end of 2014, 36 million people globally were living with HIV. Sub-Saharan Africa is the most affected region, accounting for almost 70% of new HIV infections (201). A local study found that approximately 20% stated that HIV/AIDS can be cured (202). Given that this is one of the most common conditions treated at PHCs, it was included as a good indicator of general health knowledge.
21	-----	If you are with a friend with TB, can you get TB if you share his/her clothes?	Tuberculosis (TB) is second only to HIV/AIDS as the greatest killer worldwide. In 2013, nine million people contracted TB and 1.5 million died from the disease. Over 95% of TB deaths occur in LMICs. TB is a leading killer of HIV-positive people individuals causing one fourth of all HIV-related deaths (203). In a study conducted in a local lay community (204), this question was poorly answered.
22	-----	If someone has HIV/AIDS, is it easier for them to get TB?	See Question 21 for theory supporting this question.
23	-----	Do you know how to use the internet to answer your health related questions?	Health information seeking is often mediated by an individual's level of literacy and health literacy. It influences the manner in which people look for, understand, and use health information (205,206). The number of people who seek health information on the internet has been steadily increasing as the internet has become more accessible. Most current health education materials are written at a 10th grade or higher reading level and this is not suitable for people with limited health literacy (207,208). Inability to access or understand health education materials inhibits important preventive or treatment measures, and may decrease the likelihood of identifying a symptom of disease. This question was meant to assess the ability of individuals to seek, find, understand, and appraise health information from electronic sources.
24	-----	Can you use you cell phone to look for health information?	See Question 23 for theory supporting this question.

3.10 Aligning Item Bank-Version 2 within the ISHA-Q framework

The Information and Support for Health Actions Questionnaire (ISHA-Q) (209) is a health literacy measure that is currently under development in Australia. Its main focus is assessing health literacy in individuals living in LMICs. It identifies health literacy strengths and limitations of individuals, as well as communities, especially for cultures where decisions about health are a communal rather than an individual activity. The ISHA-Q has 14 core scales reflecting three scale categories: support and abilities scales, barriers scales and health action scales (Table 3.5).

Table 3.5 ISHA-Q scales

The 14 ISHA-Q scales	
1	Support for health in the community ¹
2	Ability to access health services ¹
3	Communication skills to get what you want from health professionals ¹
4	Family support for health ¹
5	Ability to access health information ¹
6	Recognising rights ¹
7	Evaluating trustworthiness of health information ¹
8	Taking responsibility for own health ¹
9	Physical/ travel barriers to taking care of health ² .
10	Eating for good health ³
11	Exercising for good health ³
12	Managing stress ³
13	Using medicines ³
14	Using herbs and supplements ³

¹ Support and abilities scales

² Barrier scales

³ Health action scales

In discussions with my supervisor, who has experience in health literacy development and testing in the local population, the 14 ISHA-Q health domains were closely scrutinised for their relevance to the South African public healthcare system and its patients. The ISHA-Q is reportedly being tested in selected countries, so attempts were made to access the individual questions from the authors in order to use them to inform the development of the Item Bank questions. However, it appeared that they were not generally available for use by other researchers. As a result of this restriction, a decision was made to adopt the ISHA-Q scales as a framework for further development of health literacy questions for this project.

Subsequently, the modified health literacy questions contained in Item Bank-Version 2 were individually considered in relation to the ISHA-Q framework, with each of the 19 questions being allocated to one of the 14 core scales. It was found that questions appeared in only six of the 14 health scales (see non-italicised questions in Item Bank-Version 3), indicating the need to develop further questions in order to cover the remaining eight core. These remaining questions were developed by the researcher (CM) and distributed to the expert panel of consultants. Feedback was obtained electronically, compiled, and the necessary changes made to finalise the questions making up Item Bank Version 3 scales (see italicised questions). Evaluation of Version 3 of the Item Bank was carried out over several weeks which resulted in the numerous changes, leading to Item Bank-Version 4 (Table 3.6).

Table 3.6 Changes from Item Bank-Version 3 to Item Bank-Version 4

#	Version 3	Version 4	Rationale for adding new questions and reasons for changes
1. Support for health in the community			
1	<i>There are people who talk to you and your community about how to care for yourself.¹</i>	There are people who visit your community to talk about health and illness and how to care for yourself.	<p>Many people have difficulty using health information to improve their health. It has been identified that community-based peer support can be effective in improving health literacy (210), as communities provide residents with information, education, social support and services. Organisations within the community can also aid in determining local needs and incorporate health literacy strategies and activities to contribute to the well-being of community members (210).</p> <ul style="list-style-type: none"> • It was felt that the phrase ‘talk to you and your community’ may be interpreted as only representing a formal presentation delivered by a health professional, so the emphasis was changed in Version 4 to ‘visit your community’. • The phrase ‘talk about health and illness’ was added to describe general health promotion concepts addressed by care workers who visit communities.
2	<i>If I am sick and I need help, someone from the community will come and visit me at home.¹</i>	If you are sick and you need help, someone from the community will visit you and take care of you at home.	<p>See Question 1 for theory supporting this question.</p> <ul style="list-style-type: none"> • In order to align with language usage in other questions, the ‘I’ in Version 3 was changed to ‘you’. • The phrase ‘visit me at home’ was modified to ‘take care of you at home’ in order to differentiate between a social visit and a visit from a member of the community that included a component of active care for the patient.
2. Ability to access health services			
3	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be?	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be?	<ul style="list-style-type: none"> • No changes from Version 3 question.
3. Communication skills to get what you want from health professionals			
4	<i>I ask the nurse/doctor questions about my health problem.¹</i>	How often do you ask the nurse/doctor questions about a problem with your	<ul style="list-style-type: none"> • Effective patient-provider communication is the cornerstone to establishing a successful patient-provider relationship and ultimately achieving the best

		health?	<p>possible health outcomes (211). Much literature highlights effective strategies for HCPs to communicate with their patients, however very little insight is offered into the skills and competencies needed by patients to communicate effectively with their HCPs. The patient role has advanced from being one of a passive recipient of knowledge to one of sharing responsibility for one's own health (64). Patients need to be able to articulate their health concerns, ask for clarification if they do not understand what they have been told, ask pertinent questions, share truthful information about any medical tests or symptoms and stand up for themselves if their concerns are not addressed (64).</p> <ul style="list-style-type: none"> • The statement was converted to a question to enable insight into the frequency with which participants ask questions of their doctor or nurse.
5	<i>If I don't understand what the nurse/doctor says I usually ask them to give me more information and explain things to me.¹</i>	If I don't understand what the nurse/doctor says, I usually ask them to give me more information and explain things to me.	<p>See Question 4 for theory supporting this question. No changes from Version 3 question.</p>
4. Family support for health			
6	<i>If you get sick is there someone who lives with you or near you who can help you?¹</i>	If you get sick is there someone who lives with you who can help you?	<p>An increasing body of literature suggests that social support may improve an individual's health by improving the ability to acquire and understand health information as well as to negotiate the healthcare system. This is particularly helpful to individuals with limited health literacy as it helps them establish healthy lifestyle choices, increases the use of preventative services and ultimately improves health status (212–214). Equally, the lack of social support has the potential to amplify the poor health outcomes of patients with limited health literacy because they are more vulnerable than those with higher health literacy (67). This questions aims to assess the impact of social support on health literacy.</p> <ul style="list-style-type: none"> • The phrase 'near you' was removed, to exclude the participants referencing neighbours or other people living in the community.
5. Ability to access health information			
7	How often do you have problems learning about your medical conditions because of	How often do you have problems learning about your medical conditions because of difficulty understanding	<ul style="list-style-type: none"> • No changes from Version 3 question.

	difficulty understanding written information?	written information?	
8	Do you know how to use the internet to answer your health related questions?	Do you know how to use the internet to answer your health related questions?	<ul style="list-style-type: none"> No changes from Version 3 question.
9	How often do you need someone to help you read instructions, pamphlets or written materials from your doctor or pharmacy?	How often do you need someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?	<ul style="list-style-type: none"> No changes from Version 3 question.
10	Can you use your cell phone to look for health information?	-----	<ul style="list-style-type: none"> The question was removed. Data on the ability to use a cell phone to look for health information were instead collected in the demographics section of the questionnaire.
6. Recognising rights			
11	<i>When you see the nurse/doctor at the clinic, he/she can tell other people what is wrong with you if they ask¹</i>	After you have seen the nurse/doctor at the clinic, it is ok for him/her to tell other people what is wrong with you if they ask?	<p>Human rights violations include denying the right to health care services. To ensure all South Africans have access to basic healthcare, the Patients Right Charter is used to uphold, promote and protect patient rights to effective health services (215).</p> <ul style="list-style-type: none"> The wording was changed to improve the clarity of the question.
12	<i>When you are sick, you can choose which clinic to go to or doctor to see¹</i>	When you are sick, you can choose which clinic to go to or which doctor/nurse to see	<p>See Question 11 for theory supporting this question.</p> <ul style="list-style-type: none"> The term ‘nurse’ was added as nurses are involved with the majority of HCP-patient interactions at the clinic.
7. Evaluating trustworthiness of health information			
13	<i>When I want to find out about some health problems I usually ask my friends and neighbours.¹</i>	When I want to find out about some health problem, I ask my friends and neighbours first as they give me good information	<p>Healthcare professionals are no longer the gate keepers of health information (216). Many people are able to inform and empower themselves using health information from the internet, friends family, coworkers, television, radio, newspapers and various other resources(217–219). Some of the information patients obtain from such sources is up to date and reliable, however some is not. This question was meant to assess whether patients are able to evaluate the trustworthiness of information they get from various resources about their health.</p> <ul style="list-style-type: none"> In order to assess whether the participants trust the information that they are

			given by their friend and neighbours, the phrase ‘as they give me good information’ was added.
14	<i>I trust the health information that comes from the internet.¹</i>	Health information from the internet is good information that I trust.	See Question 13 for theory supporting this question. <ul style="list-style-type: none"> The term ‘good’ was added to imply that the quality of information sought from the internet is trustworthy. Furthermore, the phrase ‘I can trust’ was added to assess whether patients finds this as a source of reliable information.
8. Taking responsibility for own health			
15	You read in a health leaflet that 4 out of 20 people this winter have a chance of getting a cold. What is the percentage risk of getting a cold?	You read in a health leaflet that 4 out of 20 people this winter have a chance of getting a cold. What is the percentage (%) risk of getting a cold?	<ul style="list-style-type: none"> No changes from Version 3 question.
16	What is a normal body temperature?	What is a normal body temperature?	<ul style="list-style-type: none"> No changes from Version 3 question.
17	Do overweight people have a higher chance of getting diabetes?	Certain people have a higher risk of developing diabetes. Is a very thin person more likely to develop diabetes than an overweight person?	<ul style="list-style-type: none"> The former close-ended question was changed to elicit greater thinking skills from the participants by requiring a choice to be made between two options.
18	Can you explain what diabetes is?	Can you explain what diabetes is?	<ul style="list-style-type: none"> No changes from Version 3 question.
19	Can HIV/AIDS be cured?	Can HIV/AIDS be cured?	<ul style="list-style-type: none"> No changes from Version 3 question.
20	If you are with a friend with TB, can you get TB if you share his/her clothes?	Can you get TB if you use the same toilet as someone with TB?	<ul style="list-style-type: none"> The option of sharing clothes with another person with TB as a mode of transmitting TB was replaced with that of sharing the same toilet. In a local study evaluating TB knowledge (204), the majority of the participants (75%) knew that TB was not spread by sharing clothes; however, very few could give the correct response when it came to using the same toilet as someone with TB. This would require the participant to have a greater knowledge of the disease.
21	If someone has HIV/AIDS, is it easier for them to get TB?	Is someone with HIV/AIDS protected from getting TB or is it easier for them to get TB?	<ul style="list-style-type: none"> The question in the Version 3 was close-ended and it was modified to elicit greater thinking skills from the participant by requiring a choice to be made between two options.

9. Physical/travel barriers to taking care of health			
22	<i>Are you always able to get to the clinic when you need to?</i> ¹	Are you always able to get to the clinic when you need to?	<p>Access barriers to healthcare such as distance, expensive travel costs, high out-of-pocket spending for care, and disempowered patients (220) are some of the barriers created by social inequities which resonate throughout many LMICs (221) leading to overall poor health. Understanding the implications of access barriers from the user perspective is important in expanding healthcare coverage to South Africa as well as other LMICs (222). This question aims to assess whether transport is a significant barrier in segments of our population.</p> <ul style="list-style-type: none"> No changes from Version 3.
10. Eating for good health			
23	You have to choose which plate of food you think is healthier: Plate 1: beef stew pap and butternut Plate 2: fried chicken and chips	Choose which plate of food you think is healthier: Plate 1: beef stew, rice and butternut or Plate 2: fried chicken and chips.	<ul style="list-style-type: none"> Pap was not widely recognised as food that would be eaten in combination with beef stew and butternut, so the carbohydrate component was changed to rice.
11. Exercising for good health			
24	<i>Do you think walking for 30 minutes a day can help you stay healthy?</i>	I make the time to exercise at least three times every week.	<ul style="list-style-type: none"> The frequency at which exercise is done (three times a day) was added to the question.
12. Managing stress			
25	<i>When I am stressed, I often do activities which I like that stop me from thinking about problems.</i> ¹	-----	<p>Stress can have detrimental effect on an individual's well-being. Prolonged stress can exacerbate ongoing health conditions, people often lose motivation to sustain a healthy lifestyle and it may also lead to the use of harmful substances such as drugs and alcohol (223).</p> <ul style="list-style-type: none"> This question was removed.
26	<i>I often find someone who I can talk to and who can help me with my problems when I feel overwhelmed.</i> ¹	If you feel stressed or worried about some problem, do you feel you are able to deal with it yourself and reduce stress?	<p>See Question 25 for theory supporting this question.</p> <ul style="list-style-type: none"> The wording of the question was changed to improve clarity.
27	<i>I find ways to make my problem better when I am stressed.</i> ¹	-----	<p>See Question 25 for theory supporting this question.</p> <ul style="list-style-type: none"> This question was removed.

13. Using medicines			
28	You have to take one tablet in the morning, one tablet after lunch and one tablet at night for 5 days. How many tablets would you have taken after 5 days?	Take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?	<ul style="list-style-type: none"> The question was removed, as it was long, repetitive and potentially confusing. In order to numeracy skills in relation to knowledge on dosing frequency, the question was replaced with a similar question from an existing health literacy test, the S-TOFHLA (81).
29	Show image of graduated syringe: You are required to give a child 2 ml of a liquid medicine. On the syringe please show me where you will fill it up to.	Show image of graduated syringe: You are required to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	<ul style="list-style-type: none"> No changes from Version 3 question.
30	From the medicine label shown to you: a) This safe to drink with beer. b) How many days must you take this medicine for?	----- -	This question was removed. In the public sector healthcare clinics, medication instruction labels are available on the packaging and the pharmacist/assistant fills in the necessary dosage instructions. The label designed for this question did not mimic ones found in the public sector, and because various manufacturers design different labels for different medication, finding a single label that would be familiar to most patients was challenging.
31	When taking antibiotics, you must always finish the course. Does this mean that you should stop taking the antibiotics as soon as start to feel better?	When taking antibiotics, you are told to finish the course. Does this mean that you can stop taking the antibiotics as soon as you start to feel better?	<ul style="list-style-type: none"> No changes from Version 3 question.
32	Is it easy for you to understand the instructions for your medication?	Is it easy for you to understand the instructions for your medication?	<ul style="list-style-type: none"> No changes from Version 3 question.
14. Using herbs and supplements			
	<i>You get medicine from the clinic but you also continue to take you traditional medicine that you have at home. Is this the right thing to do?</i> ¹	At the clinic you are given medicine to take, but you also continue to take your traditional medicine or the medicine that you bought for yourself. Is it okay to do this?	Traditional herbal medicines are widely used in all regions of the developing world and play an important role in meeting the primary healthcare needs of the population (224) and it is estimated that 80% of African populations use some form of traditional/herbal medicine (224). Many patients consider the use of traditional/herbal medicines to be as safe and effective as they come from natural sources. However, they can be harmful and cause severe side effects. Furthermore people have very little understanding on what to do when they are

			<p>taking traditional/herbal medicine along with contemporary medicine. These questions aim to assess knowledge with regards to safety and appropriate use of traditional/herbal medicines.</p> <ul style="list-style-type: none"> • The question was reworded to improve clarity and understanding.
	<i>Herbal medicines are safe to use because they are natural and are from plants.¹</i>	Herbal medicines are safe to use because they are natural and are from plants.	<p>See Question 33 for theory supporting this question.</p> <ul style="list-style-type: none"> • No changes from Version 3 question.

¹ Italicised questions are those that were newly developed after adoption of the ISHA-Q framework

3.11 Evaluating content and face validity of Versions 4, 5 and 6 of the Item Bank

Content and face validity were assessed using English versions of the Item Bank questions.

3.11.1 Content validity evaluation of Item Bank–Version 4

The expert team as well as lay individuals were consulted to assess content validity of the Item Bank questions. The group of lay individuals comprised a trained isiXhosa interpreter, an African language translator, and five support staff from Rhodes University who were cleaners, groundsman, kitchen staff or lab assistants, and were from the target isiXhosa population.

Feed-back from these two groups was obtained via email correspondence and formal small group discussions. Changes were made to question content of the majority of questions in order to improve clarity and understanding. Four questions were removed as they were either repetitive, redundant, or were not context specific. The amended version (Item Bank-Version 5) is presented in Table 3.7.

3.11.2 Face validity evaluation of Item Bank-Version 5

Version 5 of the Item Bank which comprised 30 questions was administered to first-year pharmacy students as a preliminary screening exercise to interrogate face validity of Version 5 questions. As the aim of this exercise was to assess ease of comprehension, plain language usage, cultural acceptability and difficulty levels of individual questions, and to identify any potential problem translation issues, first year students were selected for ease of communication between them and the researcher (CM) in order to obtain valid and reliable feedback. These first year students also complied with the inclusion criteria in terms of the educational attainment required for the study, as they had a maximum 12 years of schooling.

An electronic invitation was sent out to 210 first-year pharmacy students giving a brief summary of the study, what the session would entail and the date and time of the session. Agreement to respond to the questionnaire and attendance at the session was taken as consent

to participate. One hundred and eighty students were in attendance, and approximately 50% shared the same cultural background as our target population.

The session was held in a lecture theatre. Each student was given an answer sheet for recording their responses. The concept of health literacy was explained to the students, and its importance in all patients emphasized. Their attention was drawn to the particular relevance of this construct in the public sector patient population. Before commencing, students were given a chance to ask any questions. The researcher (CM) read aloud each question from Item Bank-Version 5 displayed on the PowerPoint slide and gave the students sufficient time to record their answer. After all 30 questions had been administered, an evaluation of each question was conducted.

Individual results from the questions were not statistically analysed, as the session was not intended to assess health literacy, but rather to elicit feedback with regard to the acceptability, clarity, comprehension, difficulty and the range of issues addressed by the questions.

Comments from the students are reported below:

- Questions were considered appropriate for assessing health literacy.
- All questions were easily understood and had good clarity, with no confusing terms.
- Questions were not too long or complicated.
- The language was easily comprehended.
- A few students felt that the question pertaining to the use of traditional medicines could be embarrassing for some people who may be reluctant to admit to seeing a traditional healer, and instead would simply report that they do not use traditional medicines. The researcher (CM) clarified that in such a case, the participants would be assured that the question does not imply that they use traditional medicines; rather, it is attempting to get an opinion of what the participant would do in such a situation.
- Discussions with a group of isiXhosa first-language students on translation issues revealed the same concerns raised by the African language expert with regard to the use of 'how often'. It is a collective concept which is not one that is common or commonly used in the language.
- Question 9: Instead of having the source of written information limited to choices of only the doctor and the pharmacy, they suggested including nurses as an additional

source of information since they are the most commonly seen healthcare professionals at primary care clinics and bear the major patient load (Item Bank-Version 6).

Table 3.7 Changes from Item Bank-Version 4 to Item Bank-Version 5

#	Version 4	Version 5	Comments from HCPs and reasons for changes
1. Support for health in the community			
1	There are people who visit your community to talk about health and illness and how to care for yourself.	Are there people who visit your community to talk about health and illness and how to care for yourself?	<ul style="list-style-type: none"> Recommendations were made to phrase the statement as a question. Concerns about using the term ‘people’ were raised; most of the HCPs preferred using the term community healthcare worker (CHCW). However, this question intended to encompass a broader network of people. CHCWs as well as representatives from NGOs and pharmacy students who often conduct health promotion activities in the local community.
2	If you are sick and you need help, someone from the community will visit you and take care of you at home	If you are sick and you need help, is there anyone from the community who will visit you and take care of you at home?	<ul style="list-style-type: none"> Recommendation was to phrase the statement as a question.
2. Ability to access health services			
3	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be?	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be?	<ul style="list-style-type: none"> Most patients on chronic medicines are given a return date written in their health passport and this is often at the end of the month. The HCPs were concerned that they would have no understanding of the concept of a two week follow-up appointment. The main aim of this question, however, was to test numeracy skills. No changes from Version 4 question.
3. Communication skills to get what you want from health professionals			
4	How often do you ask the nurse/doctor questions about a problem with your health?	How often do you ask the nurse/doctor questions about a problem with your health?	<ul style="list-style-type: none"> No changes from Version 4 question.
5	If I don’t understand what the nurse/doctor says, I usually ask them to give me more information and explain things to me.	If you don’t understand what the nurse/pharmacist/doctor says, do you usually ask them to give you more information and explain things to you?	<ul style="list-style-type: none"> HCPs recommended that this statement be converted to a question. The term ‘pharmacist’ was added.

4. Family support for health			
6	If you get sick is there someone who lives with you who can help you?	If you get sick is there someone who lives with you who can help you?	<ul style="list-style-type: none"> No changes made from Version 4 question.
5. Ability to access health information			
7	How often do you have problems learning about your medical conditions because of difficulty understanding written information?	How often do you have problems learning about your medical conditions because of difficulty understanding written information?	<ul style="list-style-type: none"> No changes made from Version 4 question.
8	Do you know how to use the internet to answer your health related questions?	Do you know how to use the internet to answer your health related questions?	<ul style="list-style-type: none"> No changes made from Version 4 question.
9	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?	<ul style="list-style-type: none"> No changes made from Version 4 question.
6. Recognising rights			
10	After you have seen the nurse/doctor at the clinic, it is ok for him/her to tell other people what is wrong with you if they ask?	After you have seen the nurse/doctor at the clinic, it is okay for the nurse/doctor to discuss your health issue with next patient?	<ul style="list-style-type: none"> The use of 'him/her' was replaced with 'nurse/doctor'. The HCPs indicated that the phrase 'wrong with you' was not good terminology, thus it was changed to 'health issues'. HCPs were concerned that using the term 'other people' would be misinterpreted to include health professionals as well; therefore we replaced it with the word 'patients'.
11	When you are sick, you can choose which clinic to go to or which doctor/nurse to see	When you are sick, can you choose which clinic to go to or which doctor/nurse to see?	<ul style="list-style-type: none"> The statement was rephrased as a question.
7. Evaluating trustworthiness of health information			
12	When I want to find out about some health problem, I ask my friends and neighbours first as they give me good information.	When you want to find out about some health problems, do you ask your friends and neighbours first as they give you good information?	<ul style="list-style-type: none"> The statement was rephrased as a question.

13	Health information from the internet is good information that I trust.	Do you think that health information from the internet is good information that you can trust?	<ul style="list-style-type: none"> The statement was rephrased as a question.
8. Taking responsibility for own health			
14	You read in a health leaflet that 4 out of 20 people this winter have a chance of getting a cold. What is the percentage (%) risk of getting a cold?	You read in a health leaflet that 4 out of 20 people have a chance of getting a cold this winter. What is the percentage (%) chance of getting a cold?	<ul style="list-style-type: none"> The question was reworded to improve clarity. Recommendation to keep the terminology consistent throughout the question; this was in reference to the use of the term 'chance' instead of 'risk'. Subsequently, the term risk was replaced with 'chance' in all the questions.
15	What is a normal body temperature?	What is a normal body temperature?	<ul style="list-style-type: none"> No changes from Version 4 question.
16	Can you explain what diabetes is?	Can you explain what diabetes is?	<ul style="list-style-type: none"> No changes from Version 4 question.
17	Certain people have a higher risk of developing diabetes. Is a very thin person more likely to develop diabetes than an overweight person?	Certain people have a higher risk of developing diabetes. Is a very thin person more likely to develop diabetes than an overweight person?	<ul style="list-style-type: none"> No changes from Version 4 question.
18	Can HIV/AIDS be cured?	Can HIV/AIDS be cured?	<ul style="list-style-type: none"> No changes form Version 4 question.
19	Can you get TB if you use the same toilet as someone with TB?	Can you get TB if you use the same toilet as someone with TB?	<ul style="list-style-type: none"> No changes form Version 4 question.
20	Is someone with HIV/AIDS protected from getting TB or is it easier for them to get TB?	Is someone with HIV/AIDS more or less likely to get TB?	<ul style="list-style-type: none"> This question was rephrased to improve understanding.
9. Physical/travel barriers to taking care of health			
21	Are you always able to get to the clinic when you need to?	Are you always able to get transport to go to the clinic when you need to?	<ul style="list-style-type: none"> The inability to travel to a clinic can be caused by a number of factors. The HCPs suggested that if there was a certain barrier to getting to the clinic which we wanted to investigate we should be more specific when asking the question. The question was rephrased to include transport as the barrier in this case.
10. Eating for good health			
22	Choose which plate of food you think is healthier: Plate 1: beef stew, rice and butternut or Plate 2: fried chicken and chips.	Choose which plate of food you think is healthier: Plate 1: chicken stew, butternut and spinach or Plate 2: fried chicken and chips.	<ul style="list-style-type: none"> One of the HCPs indicated that often patients are advised not to eat a lot of red meat as part of their diet. In order to tailor the first food choice to the advice given to the patients, 'beef stew' was replaced with 'chicken stew'. The vegetable in the first plate option was changed from butternut to spinach.

			Spinach is familiar amongst the population and often recommended as a healthy and cost effective vegetable by HCPs.
11. Exercising for good health			
23	I make the time to exercise at least three times every week.	Do you make time to exercise (Walk, play sport for about 30 minutes) at least three times every week?	<ul style="list-style-type: none"> The statement was rephrased as a question. The HCPs were concerned that this question may be alienating for lower income groups that cannot afford the luxury of participating in organized exercise, but still do physical activity on a regular basis. Examples such as walking and playing sport were added as other forms of physical activity.
12. Managing stress			
24	If you feel stressed or worried about some problem, do you feel you are able to deal with it yourself and reduce stress?	If you feel stressed or worried about a problem, do you feel you are able to deal with it yourself?	<ul style="list-style-type: none"> This question was rephrased to improve clarity.
13. Using medicines			
25	Show image of graduated syringe: You are required to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	Show image of graduated syringe: You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	<ul style="list-style-type: none"> The term 'required' was replaced with 'told'.
26	Take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?	You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?	<ul style="list-style-type: none"> In an attempt to personalize the question, the phrase 'you are told' was placed at the beginning of the question.
27	When taking antibiotics, you are told to finish the course. Does this mean that you can stop taking the antibiotics as soon as you start to feel better?	When taking antibiotics, you are told to finish the course. Does this mean that you can stop taking the antibiotics as soon as you start to feel better?	<ul style="list-style-type: none"> No changes from Version 4 questions.
28	Is it easy for you to understand the instructions for your medication?	Is it easy for you to understand the instructions for your medication?	<ul style="list-style-type: none"> No changes from Version 4 questions.

14. Using herbs and supplements			
29	At the clinic you are given medicine to take, but you also continue to take your traditional medicine or the medicine that you bought for yourself. Is it okay to do this?	You go to the clinic and you are given medicine, but you also have your own herbal medicine, what should you do?	<ul style="list-style-type: none"> The question was reworded to improve understanding.
30	Herbal medicines are safe to use because they are natural and are from plants.	Are all herbal medicines always safe to use because they are natural and are from plants?	<ul style="list-style-type: none"> Herbal medicines are not always safe to take, so in order to get a definitive yes or no answer from the participants, the word ‘always’ was added.

3.12 Progression from Item Bank-Version 5 to Item Bank-Version 6

A final intensive scrutiny of the questions was conducted by the research team. Version 5 Item Bank questions were distributed electronically to all members of the team, the feedback obtained was compiled, and the necessary changes effected to questions. This process was repeated over several weeks and culminated in Item Bank-Version 6 (Table 3.8), which was subsequently used in the pilot study.

Table 3.8 Changes from Item Bank-Version 5 to Item Bank-Version 6

#	Version 5 (Post HCP)	Version 6 (Pilot)	Reasons for changes
1. Support for health in the community			
1	Are there people who visit your community to talk about health and illness and how to care for yourself?	Are there people who visit your community to talk about health and illness and how to care for yourself?	<ul style="list-style-type: none"> No changes from Version 5.
2	If you are sick and you need help, is there anyone from the community who will visit you and take care of you at home?	If you have TB, feel very weak and need help, and there is no one to care for you at home, is there anyone from the community who will visit you and take care of you?	<ul style="list-style-type: none"> In order to put the word 'sickness' into context, the phrase 'if you are sick' was replaced with 'if you have TB, and feel very weak' In an effort to place emphasis on the fact that reference is being made to a community member and not a family member visiting the patient, we added the phrase 'there is no one to care for you at home.'
2. Ability to access health services			
3	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be?	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be?	<ul style="list-style-type: none"> No changes from Version 5 question.
3. Communication skills to get what you want from health professionals			
4	How often do you ask the nurse/doctor questions about a problem with your health?	When you go and see the doctor/nurse, do you ever ask them questions about a problem with your health?	<ul style="list-style-type: none"> The question was slightly reworded to improve clarity.

5	If you don't understand what the nurse/pharmacist/doctor says, do you usually ask them to give you more information and explain things to you?	If you don't understand what the nurse/doctor/ pharmacist says, do you usually ask them to give you more information and explain things to you?	<ul style="list-style-type: none"> No changes from Version 5 question.
4. Family support for health			
6	If you get sick is there someone who lives with you who can help you?	If you have an operation, is there a family member who can care for you after you leave the hospital?	<ul style="list-style-type: none"> Instead of using the phrase 'if you get sick' we put the ailment into context and replaced it with 'if you have an operation'.
5. Ability to access health information			
7	How often do you have problems learning about your medical conditions because of difficulty understanding written information?	How often do you have problems learning about your medical conditions because it is difficult to understand written information	<ul style="list-style-type: none"> No changes from Version 5 question.
8	Do you know how to use the internet to answer your health related questions?	Do you know how to use the internet to answer your health-related questions?	<ul style="list-style-type: none"> No changes from Version 5 question.
9	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist?	<ul style="list-style-type: none"> The nurse was added as an additional source where patients get written health information as they often encountered at PHCs.
6. Recognising rights			
10	After you have seen the nurse/doctor at the clinic, it is okay for the nurse/doctor to discuss your health issue with next patient?	After you have seen the nurse/doctor at the clinic, is it acceptable for the nurse/doctor to discuss your health issue with other people who are not health colleagues?	<ul style="list-style-type: none"> The word 'okay' was regarded as too colloquial and was replaced with the word 'acceptable'. In order to make the question clearer, the phrase 'next patient' was replaced with 'people who are not health colleagues'.
11	When you are sick, can you choose which clinic to go to or which doctor/nurse to see?	-----	<ul style="list-style-type: none"> This question was removed as people often visit the clinic closest to them and would be unfamiliar with the concept.

7. Evaluating trustworthiness of health information			
12	When you want to find out about some health problems, do you ask your friends and neighbours first as they give you good information?	When you want to find out more about a health problem, do you think your friends and neighbours would give you good information and advice about your problem?	<ul style="list-style-type: none"> The question was reworded to improve clarity.
13	Do you think that health information from the internet is good information that you can trust?	Do you think that health information from the internet is always good information that you can trust?	<ul style="list-style-type: none"> As there are valid, accurate sources of information available from the internet, the word 'always' was added to get a definitive yes or no answer.
8. Taking responsibility for own health			
14	You read in a health leaflet that 4 out of 20 people have a chance of getting a cold this winter. What is the percentage (%) chance of getting a cold?	Next winter 4 out of 20 people have a chance of getting a cold. What is the percentage (%) chance of getting a cold?	<ul style="list-style-type: none"> No changes from Version 5 question.
15	What is a normal body temperature?	What is a normal body temperature?	<ul style="list-style-type: none"> No changes from Version 5 question.
16	Can you explain what diabetes is?	Can you explain what diabetes is?	<ul style="list-style-type: none"> No changes from Version 5 question.
17	Certain people have a higher risk of developing diabetes. Is a very thin person more likely to develop diabetes than an overweight person?	Certain people have a higher risk of developing diabetes. Is a thin person more likely to develop diabetes than an overweight person?	<ul style="list-style-type: none"> The term 'thin' was used as opposed to 'very thin', as the latter could be misinterpreted as portraying someone who is sick.
18	Can HIV/AIDS be cured?	Can HIV/AIDS be cured?	<ul style="list-style-type: none"> No changes from Version 5 question.
19	Can you get TB if you use the same toilet as someone with TB?	Can you get TB if you use the same toilet as someone with TB?	<ul style="list-style-type: none"> No changes from Version 5 question.
20	Is someone with HIV/AIDS more or less likely to get TB?	Is someone with HIV/AIDS at a high or low risk of getting TB?	<ul style="list-style-type: none"> The phrase 'more or less likely to get TB' was replaced with 'high or low risk of getting TB'.
9. Physical/travel barriers to taking care of health			
21	Are you always able to get transport to go to the clinic when you need to?	Are you always able to get transport to go to the clinic when you need to?	<ul style="list-style-type: none"> No changes from Version 5 question.
10. Eating for good health			
22	Choose which plate of food you	Choose which plate of food you think	<ul style="list-style-type: none"> The first plate option contained two vegetables: butternut and spinach. The

	think is healthier: Plate 1: chicken stew, butternut and spinach or Plate 2: fried chicken and chips.	is healthier: Plate 1: chicken stew, rice and spinach; Plate 2: fried chicken and chips.	butternut was removed and replaced with another food group (carbohydrates) in the form of rice.
11. Exercising for good health			
23	Do you make time to exercise (Walk, play sport for about 30 minutes) at least three times every week?	Do you make the time to exercise (walk, play sport for about 30 minutes) at least three times every week?	<ul style="list-style-type: none"> No changes from Version 5 question.
12. Managing stress			
24	If you feel stressed or worried about a problem, do you feel you are able to deal with it yourself?	If you feel stressed or worried about a problem, would you require someone who would help you or would you be able to face this yourself?	<ul style="list-style-type: none"> Apart from being able to deal with a stressful situation alone, most people often find it helpful to ask someone for help when feeling stressed or worried. Hence, the question was slightly modified to add the latter option.
13. Using medicines			
25	Show image of graduated syringe: You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	Show image of graduated syringe: You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	<ul style="list-style-type: none"> No changes from Version 5 question.
26	You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?	You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?	<ul style="list-style-type: none"> No changes from Version 5 question.
27	When taking antibiotics, you are told to finish the course. Does this mean that you can stop taking the antibiotics as soon as you start to feel better?	When taking antibiotics, you are told to finish the course. Does this mean that you can stop taking the antibiotics as soon as you start to feel better?	<ul style="list-style-type: none"> No changes from Version 5 question.
28	Is it easy for you to understand the instructions for your medication?	Is it easy for you to understand the instructions for your medication?	<ul style="list-style-type: none"> No changes from Version 5 question.

14. Using herbs and supplements			
29	You go to the clinic and you are given medicine, but you also have your own herbal medicine, what should you do?	You are given a new medicine at the clinic. At home you have been taking herbal/traditional medicine. What should you do?	<ul style="list-style-type: none"> The question was reworded to improve understanding.
30	Are all herbal medicines always safe to use because they are natural and are from plants?	Herbal/traditional medicines are natural and are from plants. Are they always safe to take?	<ul style="list-style-type: none"> Apart from herbal medicines, traditional medicines were added as they are commonly used within the population.
		Addition question	Reasons for additional questions
	-----	If your blood pressure reading is 160/100, what does that mean?	The majority of the common chronic diseases often encountered at PHCs had been addressed except hypertension. The following question was added: 'If your blood pressure reads 160/100 what does this mean?' It is meant to assess if patients are familiar with the numbers relating to a desirable blood pressure reading. The question would fall under the eighth ISHA-Q scale: taking responsibility for own health.

3.13 Identifying health literacy domains

The ISHA-Q had provided a framework where the 14 scales were useful in ensuring coverage of a range of health literacy constructs. The subsequent step aimed to group questions into health literacy domains (Table 3.9) which focused on the health literacy skills interrogated.

An extensive search of literature identified a model which draws closely on the general concept of literacy proposed by Schulz and Nakamoto (225) in which they outline the knowledge and skills required in health literacy. Skills and knowledge are arranged in numerous tiers and grouped from the basic to the most complex (Figure 3.3). In the model, the basic level includes reading and numeracy skill, which forms the basis of health literacy. Declarative and procedural knowledge comprise the advanced levels, and this is followed by skills classified as complex, which involves the integration of knowledge, and adaptation to changes in knowledge (225,226).

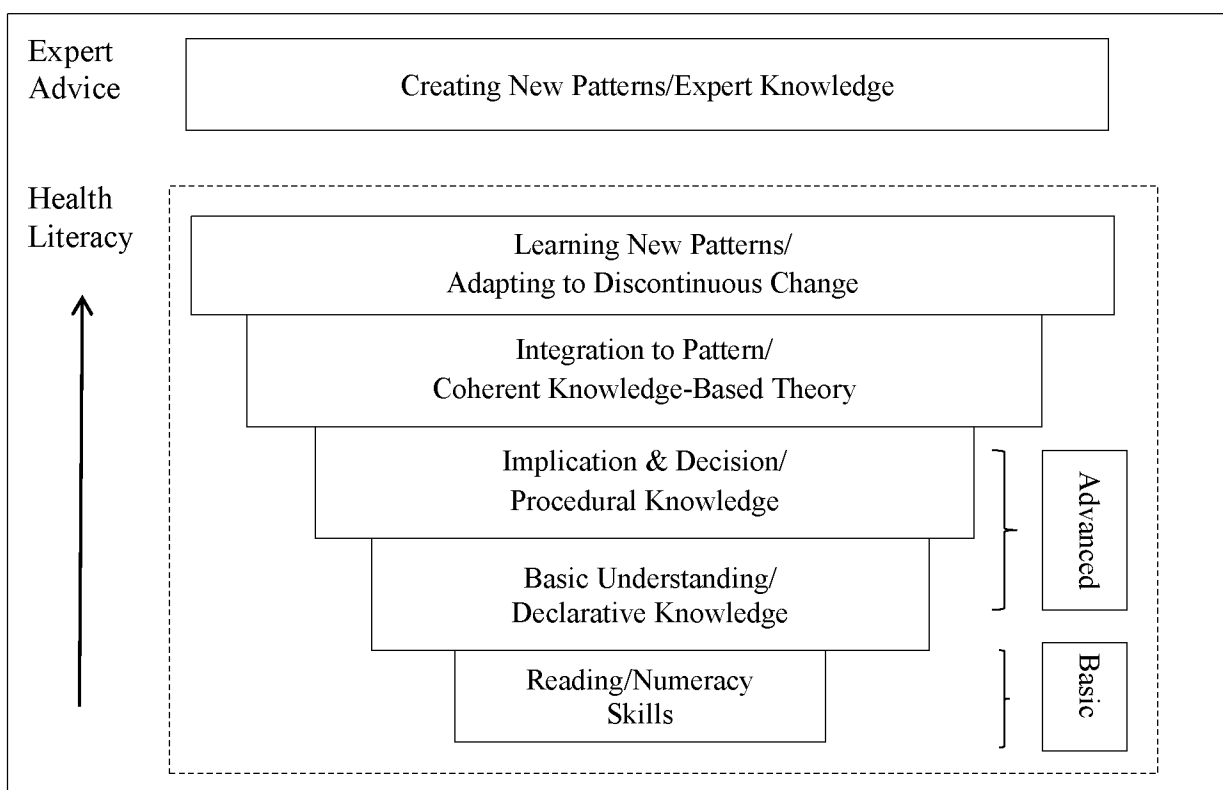


Figure 3.3 Skill attainment view of health literacy [Adapted from Schulz and Nakamoto] (225)

Taking into consideration the limited literacy level of our population, two of our domains were informed by the first three tiers of the model (reading and numeracy skills, declarative knowledge, and procedural knowledge) which encompassed only the basic and advanced levels.

Declarative knowledge refers to the basic knowledge and understanding of information about health and ways to approach a health condition (225,226). For the purposes of this project, declarative knowledge was renamed as the factual knowledge domain (FACT) for clarity. Procedural knowledge (PROC), addresses the skills required to successfully apply factual knowledge to use health information to make informed decisions (226). The reading and numeracy skills which made up the first tier of the skills hierarchy were collapsed into the procedural knowledge domain (PROC).

A third domain was introduced - access to healthcare, services and social support (ACCESS). This domain relates to relative empowerment and is closely linked to factual knowledge as, in order to learn how to approach a health condition or gain a basic understanding of health-related information, individuals rely on accessing information from healthcare providers, healthcare facilities or other resources.

Table 3.9 Classification of Item Bank questions into three health literacy domains

Health literacy domain and individual questions
Access to healthcare, health services and health information (ACCESS) <ol style="list-style-type: none"> 1. Are there people who visit your community to talk about health and illness and how to care for yourself? 2. If you have TB, feel very weak and need help, and there is no one to care for you at home, is there anyone from the community who will visit you and take care of you? 3. If you have an operation, is there a family member who can care for you after you leave the hospital? 4. When you go and see the doctor/nurse, do you ever ask them questions about a problem with your health? 5. If you don't understand what the nurse/doctor/ pharmacist says, do you usually ask them to give you more information and explain things to you? 6. When you want to find out more about a health problem, do you think your friends and neighbours would give you good information and advice about your problem? 7. Do you know how to use the internet to answer your health-related questions? 8. Are you always able to get transport to go to the clinic when you need to?
Procedural knowledge (PROC) <ol style="list-style-type: none"> 9. If you feel stressed or worried about a problem, would you require someone who would help you or would you be able to face this yourself? 10. Is it easy for you to understand the instructions for your medication? 11. How often do you have problems learning about your medical conditions because it is difficult to understand written information?

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12. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist?
 13. If you go to the clinic on the 7th of March and you are asked to return to the clinic two weeks later, what will the date be?
 14. Next winter 4 out of 20 people have a chance of getting a cold. What is the percentage (%) chance of getting a cold?
 15. You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?
 16. You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.
 17. Choose which plate of food you think is healthier: Plate 1: chicken stew, rice and spinach; Plate 2: fried chicken and chips.

Factual knowledge (FACT)

18. After you have seen the nurse/doctor at the clinic, is it acceptable for the nurse/doctor to discuss your health issue with other people who are not health colleagues?
 19. Do you think that health information from the internet is always good information that you can trust?
 20. What is a normal body temperature?
 21. Can you explain what diabetes is?
 22. Certain people have a higher risk of developing diabetes. Is a thin person more likely to develop diabetes than an overweight person?
 23. If your blood pressure reading is 160/100, what does that mean?
 24. Can HIV/AIDS be cured?
 25. Can you get TB if you use the same toilet as someone with TB?
 26. Is someone with HIV/AIDS at a high or low risk of getting TB?
 27. Do you make the time to exercise (walk, play sport for about 30 minutes) at least three times every week?
 28. When taking antibiotics, you are told to finish the course. Does this mean that you can stop taking the antibiotics as soon as you start to feel better?
 29. You are given a new medicine at the clinic. At home you have been taking herbal/traditional medicine. What should you do?
 30. Herbal/traditional medicines are natural and are from plants. Are they always safe to take?
-

CHAPTER 4

EVALUATION OF THE ITEM BANK

4.1 Introduction

The previous chapter detailed all steps in the development of the Item Bank of health literacy questions. This chapter describes the piloting and subsequent evaluation of the Item Bank in the target population of limited literacy public sector patients in Grahamstown.

4.2. Study setting

South Africa has a population of 55.91 million people (154). Black Africans make up the majority (80.7%) of the population, with the minority groups being coloured (8.8%), white (8.1%), and Indian (2.5%) (154). South Africa faces a quadruple burden of disease characterised by 1) HIV/AIDS and TB, 2) non-communicable diseases, 3) maternal and child mortality and 4) violence and injury. As outlined in Section 3.2, the South African healthcare system has two distinct tiers: the public and private sectors. The poorly funded public health sector caters for 84% of the population (149). The emergence of non-communicable diseases in both rural and urban areas, and most prominently in poor people living in urban settings, as well as the increase in HIV prevalence and TB incidence, have resulted in increasing pressure on acute and chronic healthcare services, most of which are provided by public PHCs (227).

The study site was Grahamstown, located in the in the Eastern Cape Province which is one of the nine provinces in South Africa. There are 6.5 million people in the province, accounting for 12.7% of the South African population (155). The majority of the population (86.3%) is black African and other minority groups include Coloured (8.3%), White (4.7%) and Indian (0.4%). The Eastern Cape is the poorest province and has one of highest unemployment rates (32.2%), higher than the national figure of 27.7% (228). The employment status of each population group shows that black Africans (16.3%) were mostly unemployed (155). In the peri-urban local population from which the participants were drawn, more than three quarters of the population speak isiXhosa (77,6%) as their first language, followed by Afrikaans (10,4%), English (5,5%) and seSesotho (2,4%). Only 19.8% have completed Grade 12, while 10.5% have no formal schooling at all (155).

4.3 Questionnaire development

A questionnaire consisting of four sections was developed.

Section 1: This consisted of the Time to Sign test which measures the time taken to write a full signature, and assesses the relationship between time taken and health literacy (121). It is a rapid and unobtrusive marker of literacy and has been suggested as an indicator of health literacy which could potentially prove effective in a practice setting. Adequate health literacy was displayed by individuals who completed their signature in six seconds or less. No modifications were required for this measure (121).

Section 2: This enabled the collection of demographic data (age, gender, race, home language, employment). Data on income earned through employment or government grant system were collected to determine financial status. Self-reported language proficiency in isiXhosa and English was recorded. Health-related data were collected to identify chronic diseases and prescribed chronic medicines and to collect comments on self-reported overall health. As the internet is increasingly being used as a source of health information, questions were included that collected information on the ability to access and use information from electronic devices.

Section 3: This section consisted of an existing health literacy test, the Multidimensional Screener of Functional Health Literacy (MSFHL) developed in Brazil, which is based on demographic characteristics, simple questions about literacy habits, and ratings of perceived difficulties. The measure was used as a comparator, researchers have highlighted the importance of selecting health literacy measures which have been validated in similar target population Haun *et al* (52). The MSFHL was modified for this study and reasons for changes are described below.

Question 1: What grade did you complete at school?

- No changes from the original question.

Question 2: What grade did your mother complete at school?

- No changes were made to the question. However, the scoring criterion was adjusted. Information from US Department of Health and Human Services has cautioned the

use of the numbers of years spent in school as an accurate indicator of health literacy, saying that a person may have achieved the required number of years in school and still have limited health literacy (147).

- In the original MSFHL, 0-3 years scored no marks, 4-7 years scored one mark, 8-11 years scored two marks and ≥ 12 years of schooling scored three marks. A prior local study (229) had revealed that a number of participants did not know the educational level of their mother, merely offering a vague estimate. This may have led to both over- and underestimation which would compromise the validity of the health literacy score. Given the high likelihood of responses being guessed, we downgraded its contribution to the total score from a maximum possible score of three to one, allocating a score of 1 to the two upper educational levels (8-11 years and >12 years) and a score of 0 to the two lower levels (0-3 years and 4-7 years).

Question 3: What sort of work/job have you done for most of your life?

- No changes from the original question.

Question 4: How often do you use a computer?

- No changes from the original question.

Question 5: Do you have difficulty writing that stops you from getting a better job?

- The original question assessed patient difficulty in writing which precludes them from getting a better job. In limited literacy individuals of poor socioeconomic status, employment opportunities are likely to be limited to some form of manual work (housekeeping, cleaning, garden maintenance, and farming) for which writing skills are not required. The question was replaced with the following: ‘If there was a job which involved a lot of writing, do you think you would be able to do it?’ Additionally, the scoring criteria were changed from a dichotomous response of ‘0 = difficulty’ or ‘1 = no significant difficulty’ to a 3-point scale with the following response: ‘0 = difficulty with writing’, ‘1 = some difficulty writing’, ‘2 = no difficulty writing’.
- Modified question: If there was a job that involved a lot of writing, do you think you would be able to do it?

Question 6: Do you have difficulty reading subtitles while watching a foreign movie?

- The original question assessed reading ability with regard to reading subtitles while watching foreign movies. In South Africa, most of the programmes on the local broadcasting network are in the language of the participants, with the subtitles appearing in English. The emphasis on reading subtitles was replaced by instructions for taking medicines that are found in or on the box as this information is always in English and may therefore provide us with a better indicator of reading ability. The scoring was also changed to a 3-point scale as in Q5.
- Modified question: If you buy medicine at a shop or a pharmacy do you have difficulty reading the information leaflet inside the box, or reading the instructions on how to take the medicine?

Section 4: The final section of the questionnaire consisted of Version 6 of the Item Bank with a total of 30 health literacy questions. The responses to the questions were in the form of either a 3-point Likert Scale or a correct/incorrect response. For the Likert Scale questions, a score of two was assigned to the most favourable response, a score of one to the next favourable response, and a score of zero to the least favourable response. For the questions requiring a specific answer, a score of two was assigned to the correct answer and zero was assigned to the wrong answer. The total score was calculated by summing the scores of each question in the Item Bank.

4.4 Translation of research instrument

To account for the local language of the population, which plays a key role in developing a culturally appropriate health literacy measure (18,140), the Item Bank was translated into isiXhosa. It is one of the 11 official languages in South Africa and it is the language spoken by over three quarters of the population in the peri-urban town from which the participants were drawn (155).

Prior to the pilot study, the Item Bank health literacy questions and the MSFHL were translated into isiXhosa using a multistage approach which included translation and back-translation. The translation was done by a language expert in the African Languages

Department at Rhodes University. The back-translation was done by a member of the Faculty of Pharmacy technical staff who is fluent in both isiXhosa and English.

4.5 Training of the interpreter

The researcher's first language is English. To address the language differences between the researcher and the participants, an interpreter was trained in order to assist with all interviews. The interpreter was a black male of the same cultural background as the target population, and was fluent in both English and isiXhosa. He had completed secondary education and had attended a tertiary education college. The interpreter was trained by the researcher (CM) and her supervisor (RD), with his first task being to self-complete the questionnaire. This enabled him to familiarise himself with the research tool used in the study. The role of the interpreter and the researcher's expectations of his contribution to the study were clarified.

The interpreter was asked to adhere to the following procedures at all times during the interview process:

- To accurately report the exact responses provided by the respondents, to make sure the results were not compromised.
- To ensure that the respondents felt at ease and comfortable before and during the interview process, as any reservations about the interview process could influence their responses.
- To refrain from leading the participant to give a particular response.
- To remain a neutral participant and prevent 'taking over' the role of the interviewer.

The researcher, supervisor and interpreter then worked through each English version question in the Item Bank to ensure that the original meaning had been retained in the translated version. Any anomalies were recorded and the necessary changes to the isiXhosa version were made. The final isiXhosa version of the Item Bank was formatted to look identical to the English version. The interpreter was observed while conducting a practice interview to ensure that he adhered to all procedures required by the researcher.

4.6 Ethical approval

Ethical approval to conduct the study was obtained from the Rhodes University Faculty of Pharmacy Ethics Committee (PHARM 2015-8) (Appendix A). Approval to work in the public clinics was obtained from the National Department of Health Eastern Cape ethics committee (EC_2015RP40_351) (Appendix B).

4.7 Study design

This study design was cross-sectional, quantitative and descriptive. Quantitative research focuses on the collection of numerical data and its analysis through the use of statistics to examine relationships between variables (229). A questionnaire was used to collect data from the participants through structured interviews.

4.8 Pilot study: Evaluation of the Item Bank

The pilot study was conducted to further investigate content validity of the health literacy measure, to evaluate clarity and comprehension of individual questions in the Item Bank and to establish the time taken to administer the Item Bank.

4.8.1 Study site and study population

The pilot interviews were conducted at the Assumption Development Centre. This is a community based organisation, situated in Joza Township in Grahamstown. The centre works in partnership with various organisations to create opportunities and support for entrepreneurs and local community members seeking employment.

Twenty participants for the pilot study were drawn from members who were attending workshops and courses at the Assumption Development Centre. All participants had to satisfy the following criteria:

- ≥ 18 years old
- Speak isiXhosa as their home language
- Have maximum 12 years of schooling
- Attend public sector healthcare facilities

Participants were excluded from the study if they showed any evidence of cognitive, hearing or visual impairment.

4.8.2 Recruitment and interview process

A convenience sampling technique was adopted for this study. Convenience sampling, also referred to as opportunity sampling, is a nonprobability approach, where data collection is conducted with the nearest population members (230). The interpreter addressed patients either waiting to see the nurse/doctor or to collect their medicines as follows:

“Good morning/afternoon, my name is Xolani (interpreter) and I am here with Chipiwa (researcher) from Rhodes University. She is doing a study on health literacy and she would like to ask you questions about how well you can read and understand things to do with your health, visiting the clinic, looking after your health and taking medicines. I would like to invite you to take part in the study if you are interested”

Once participants agreed to take part in the study, all interviews were conducted in isiXhosa by the researcher (CM) with the assistance of the interpreter. These were done in a private room. Following initial introductions, the interpreter went through the invitation letter with the participants, beginning by explaining the purpose of the study and the approximate duration of the interview. All participants were reminded that the interview was not a test; they were encouraged to relax and feel at ease and were asked to answer all questions honestly. Participants were guaranteed that anything discussed during the interview would be kept private. It was also made clear that they were free to decide not to take part in the study or to end the interview at any time. After ensuring the participants had a clear understanding of the contents of the invitation letter, they were asked to sign the consent form (Appendix C).

The questionnaire (Appendix D) was administered verbally, apart from Section 1 (TTS). The TTS required participants to sign their name, and the time taken to do so was recorded. The participants were then required to provide demographic information (Section 2), complete the MSFHL (Section 3) and then respond to questions in the Item Bank (Section 4). The interpreter was instructed to read the exact translated version of the MSFHL and the Item

Bank questions to avoid variability and to ensure consistency in the data collection process. The participants were given a R50 (\$3.80) voucher for a local supermarket for participating in the study.

4.8.3 Results from the pilot study

4.8.3.1 Demographic characteristics

Table 4.1 Demographic characteristics (n=20)

Demographic characteristics	Participants, n (%)
Gender	
Female	17 (85.0)
Male	3 (15.0)
Age (years)	
18-29	1 (5.0)
30-44	5 (25.0)
45-59	10 (50.0)
≥60	4 (20.0)
Education	
Grade 0-4	5 (25.0)
Grade 5-7	3 (15.0)
Grade 8-10	8 (40.0)
Grade 11-12	4 (20.0)
Long term health condition	
Yes	12 (60.0)
No	8 (40.0)
Number of chronic medicines	
0	8 (40.0)
1	1 (5.0)
2	3 (15.0)
≥3	8 (40.0)
Perceived overall health	
Poor	1 (5.0)
Fair	16 (80.0)
Good	3 (15.0)
Do you have a computer?	
Yes	1 (5.0)
No	19 (95.0)
Do you know how to use a computer?	
Yes	3 (15.0)
No	17 (85.0)
Do you have a cellphone?	
Yes	14 (70.0)
No	6 (30.0)
Can you use it to look for health information?	
Yes	1 (5.0)
No	19 (95.0)

Twenty participants were interviewed for the pilot study, and the demographic characteristics are presented in Table 4.1. Eighty five percent (85%) were female, with a mean age of 51.6 ± 13.0 years. All had some formal education, with 60% having secondary school education.

The majority of the participants (60%) reported having a chronic condition. Eight of the 20 participants were taking three or more medicines. Despite a large proportion of participants having a chronic condition, 80% reported that their overall health was fair.

Of the 20, only one had a computer and three knew how to use computers. Over two thirds (70%) had cellphones, but only one participant was able to look for health information using a cellphone.

4.8.3.2 Results from the Time-to-Sign (TTS)

The time required to provide a signature ranged from 2.6 to 25.9 seconds. Thirty-five percent of the participants were able to provide their signature in six seconds or less, indicating adequate health literacy.

4.8.3.3 Results from the Multidimensional Screener for Health Literacy (MSFHL)

When asked about their mother's educational attainment, some participants were unsure and offered tentative education levels. Over half (55%) had only primary school education. Almost all participants 19 (95%) had never used a computer, which aligns with their type of work as being mainly manual. Of the 20 participants, five (25%) and four (20%) reported having no difficulty reading and writing, respectively. Fifty percent of the participants were classified as having inadequate health literacy, 30% had marginal health literacy and only 20% had adequate health literacy.

4.8.3.4 Results for the Item Bank of health literacy questions

Table 4.2 shows results for the individual questions of the Item Bank. Participants had the greatest difficulty in answering three of the four numeracy-related questions. The easily answered question required participants to indicate the 2 ml mark on a syringe, and 90% responded correctly. Other numeracy questions asked about the date to return to the clinic after two weeks (20% correct), calculating a percentage risk (5% correct) and correctly calculating the spacing of doses (15% correct).

The majority of the participants showed good knowledge of appropriate antibiotic use (90%), patient rights (95%), use of traditional medicines (90%) and choosing which of two plates of food reflected a more nutritious diet (100%).

The overall mean health literacy score of 58% was fairly high; those with primary education achieved a mean score of 52% and those with secondary education achieved 62%. The time taken to administer questions from the Item Bank ranged between 12.1 and 32.0 minutes.

Table 4.2 Item Bank of health literacy questions and correct/appropriate responses (n=20)

Health literacy domain and individual questions ¹	n (%)
Access to healthcare, health services and health information (ACCESS)	
1. Community-based health talks	3 (15.0)
2. Community support available when sick with TB	20 (100.0)
3. Family support available after an operation	19 (95.0)
4. Asking the doctor for information about health problems	3 (15.0)
5. Asking the doctor questions during consultation	6 (30.0)
6. Sceptical about health information from friends and neighbours	10 (50.0)
7. Ability to use the internet to find health information	0 (0)
8. Ability to access transport to the clinic	12 (60.0)
Procedural Knowledge (PROC)	
9. Deal with stressful situations	18 (80.0)
10. Understand instructions to take medication	9 (45.0)
11. No difficulty understanding written information.	5 (25.0)
12. No help needed when reading written health materials.	2 (10.0)
13. Date of clinic return visit 2 weeks after 7 March.	4 (20.0)
14. 4 out of 20 people may get a cold; give the percentage (%) chance.	1 (5.0)
15. One tablet to be taken three times a day. If the first tablet is at 8am, give the time of the next dose.	3 (15.0)
16. Indicate 2 ml on a graduated syringe.	16 (80.0)
17. Choose the healthy meal option.	20 (100.0)
Factual Knowledge (FACT)	
18. Not acceptable for HCPs to discuss your health with other patients.	19 (95.0)
19. Distrust of quality of internet-based information.	2 (10.0)
20. State normal body temperature.	3 (15.0)
21. Explain what diabetes is.	3 (15.0)
22. Comparative risk for thin or overweight person of developing diabetes.	13 (65.0)
23. Meaning of the blood pressure reading 160/100.	16 (80.0)
24. State if HIV/AIDS can be cured.	10 (50.0)
25. State if TB is transmitted by using the same toilet as a TB patient.	13 (65.0)
26. Comparative risk of getting TB if person has HIV/AIDS.	14 (60.0)
27. Making time to exercise at least three times a week.	9 (45.0)
28. Need to finish the course of antibiotics.	18 (90.0)
29. Concurrent use of herbal/traditional medicine with prescribed medicine.	18 (80.0)
30. Safety of herbal/traditional medicines.	13 (65.0)

¹See Appendix D for detailed questions

4.8.3.5 Post-pilot modifications to the research instrument

Minor modifications were made only to Section 4. A modified version of the questionnaire was produced for use in the evaluation of the Item Bank (Appendix E).

Section 4: Item Bank

A question was included to record the type of chronic condition in individuals who had acknowledged having a chronic condition. This enabled any potential association between the different disease states and health literacy to be explored.

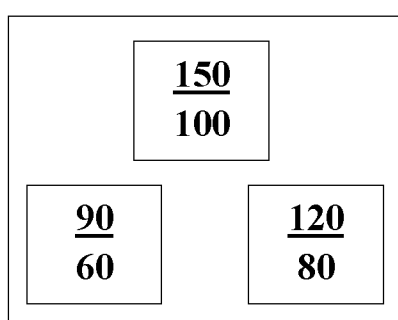


Figure 4.1 Three blood pressure readings from which to choose the one closest to normal

Only one question was changed as a result of the pilot study. Q23 originally asked: ‘If your blood pressure reading is 160/100, what does that mean’. During the interviews, the researcher had reservations about the question being answered with understanding. The question was changed to: ‘Which of the three blood pressure readings is closest to a normal blood pressure reading?’. This required some insight into blood pressure readings, with participants having to choose between three readings (Figure 4.1).

4.9 Main study: Evaluation of the Item Bank

4.9.1 Study site and population

For this part of the study, 120 participants were recruited, with inclusion and exclusion criteria identical to those outlined in Section 4.8.1. The study site for the evaluation of the Item Bank was Settlers Day Hospital, a public sector primary healthcare clinic in Grahamstown. A preliminary meeting was held with the staff at the clinic to inform them

about the study. The researcher (CM) had a second meeting with the clinic's managerial staff in order to organise a room at the site in which the interviews would be conducted.

4.9.2 Interview process

The interview protocol was the same as that used in the pilot study (Section 4.8.2). The modified questionnaire compiled after the pilot study was used for data collection (Appendix E).

4.10 Data analysis

Each question in the Item Bank was worth a maximum of two marks, with the maximum score being allocated to the correct response or the most appropriate response reflecting higher health literacy. The maximum score for the Item Bank was 60. Individual scores were calculated and categorised into three health literacy categories: inadequate (0-24), marginal (25-40) and adequate (41-60). The cut-off values were determined by comparing cut-off values for tests which collapsed health literacy categories into two (adequate and inadequate). The percentage score which demarcates the lower and upper levels were used to tailor the three categories accordingly. Due to the difference in content of the Item Bank and other health literacy tests, the cut-off points were adjusted accordingly. Frequency data were generated for all variables. Pearson Chi-square test (χ^2) and analysis of variance (ANOVA) were used to identify associations between the questions in the Item Bank and selected variables (age, education, gender and English literacy). Pearson's correlation was used to find the correlation between the MSFHL and Item Bank domains. Internal consistency of the three domains of the Item Bank was analysed using Cronbach's alpha. All analyses were conducted with SPSS Version 25, and the level of significance was set at $\alpha=0.05$.

CHAPTER 5

RESULTS AND DISCUSSION: 30 ITEM BANK QUESTIONS

5.1 Introduction

This chapter reports findings from the Item Bank relating to the performance of individual questions, as well as associations between selected demographic and socioeconomic variables with the Item Bank questions. The correlation of the Item Bank domains with the comparator (MSFHL) is also presented along with comparative health literacy results from the TTS, MSFHL and the Item Bank of health literacy questions.

5.2 Demographics

The demographic characteristics of the 120 participants are presented in Table 5.1. All the participants were Black and spoke isiXhosa as their home language, and the majority were female (83.3%). The mean age was 49.1 ± 14.5 years. Just under half the participants (45.8%) were employed. Of those who were employed, three quarters (75.0%) had manual occupations which did not require intensive training. More than half (55.8%) of the participants received government grants, mainly grants for older persons (24.1%) and child support (25.0%).

Table 5.1 Participant demographic characteristics (n=120)

Demographics	Total n (%)
Gender	
Male	20 (16.7)
Female	100 (83.3)
Age(years)	
18-29	16 (13.3)
30-44	35 (29.2)
45-59	38 (31.7)
≥60	31 (25.8)
Education	
Grade 0-4	25 (20.8)
Grade 5-7	21 (17.5)
Grade 8-10	30 (25.0)
Grade 11-12	44 (36.7)
Employed	
Yes	55 (45.8)
No	65 (54.2)
Type of employment	

Not employed	64 (53.3)
Predominantly manual	42 (35.0)
Predominantly non-manual	14 (11.7)
Recipient of a social grant¹	
Yes	67 (55.8)
No	53 (44.2)
Self-reported isiXhosa literacy	
Only listen	0 (0.0)
Listen and respond	18 (15.0)
Listen, speak and read	102 (85.0)
Self-reported English literacy	
No understanding	15 (12.5)
Only listen	12 (10.0)
Listen and respond	15 (12.5)
Listen, speak and read	78 (65.0)

¹Social grants are administered by the South African Social Security Agency (SASSA) to ensure the provision of comprehensive social security services against vulnerability and poverty. Grants available include: child support, older persons, disability, grant-in-aid care dependency, war veterans and foster child.

Most of the participants (85.0%) were able to read in their home language of isiXhosa, with a fairly large proportion (65.0%) reporting an ability to read in English. A minority (12.5%) could not understand English at all.

Table 5.2 Health-related characteristics of participants (n=120)

Participant characteristics	Total n (%)
Long- term health condition	
Yes	85 (70.8)
No	35 (29.2)
Number of conditions	
0	35 (29.1)
1	53 (44.2)
2	29 (24.2)
3	3 (2.5)
Type of condition	
Hypertension	56 (46.7)
Diabetes	29 (24.2)
HIV/AIDS	25 (20.8)
TB	1 (0.8)
Asthma	7 (5.8)
Epilepsy	1 (0.8)
Number of prescribed medicines	
0	35 (29.1)
1-3	48 (40.0)
4-6	33 (27.5)
7-8	4 (3.3)
Perceived overall health rating	
Poor	11 (9.2)
Fair	61 (50.8)
Good	48 (40.0)

The majority (70.8%) of the participants had one or more chronic conditions (Table 5.2), the most common being hypertension (46.7%), diabetes (24.1%) and HIV/AIDS (20.8%). The number of medicines being taken for chronic conditions ranged between one and eight. When asked to rate their overall health, half (50.8%) reported that it was fair.

Table 5.3 Extent of use of technology (n=120)

Use of technology	Total n (%)
Do you have a computer?	
Yes	4 (3.3)
No	116 (96.7)
Do you know how to look for information on a computer?	
Yes	22 (18.3)
No	98 (81.7)
Do you have a cellphone?	
Yes	106 (88.3)
No	14 (11.7)
Is your cellphone a smartphone?	
Yes	57 (47.5)
No	49 (40.8)
N/A	14 (11.7)
Can you use your cellphone to look for health information?	
Yes	29 (24.1)
No	77 (64.2)
N/A	14 (11.7)

Results reflecting the ability to use electronic devices to obtain health information (Table 5.3) showed that only 9.1% had computers, with a slightly higher percentage (18.3%) reporting that they could use computers to find health information. In contrast, many more had cellphones (88.3%), with 47.5% being smartphones, although only about half of these (24.1%) could use them to look for health-related information.

5.3 Item Bank results

Results from the 30 Item Bank questions are presented in Table 5.4. However, validation analysis has not been conducted for the Item Bank as it does not constitute the final health literacy test. Detailed analysis relating to the validation of the final health literacy measure will be presented in Chapter 7.

Responses to individual questions were graded as either correct (where there was only one correct response) or appropriate (where a higher score was associated with higher health

literacy). The mean total Item Bank score was 33/60 (55.5±11.4%). The average time taken to administer the 30-question Item Bank was 12.4±3.6 minutes.

Table 5.4 Item Bank correct responses or responses reflecting higher health literacy in three health literacy domains (n=120)

Health literacy domain and individual questions	Score (%)
Access to healthcare, health services and social support (ACCESS)	
1. Community-based health talks offered	8 (6.7)
2. Community support available when sick with TB	97 (80.8)
3. Family support available after an operation	108 (90.0)
4. Asking the doctor for information about health problems	24 (20.0)
5. Asking the doctor questions during consultation	27 (22.5)
6. Sceptical about health information from friends and neighbours	56 (46.7)
7. Ability to use the internet to find health information	25 (20.8)
8. Ability to access transport to the clinic	76 (63.3)
Mean score = 57.4±15.5%	
Procedural knowledge (PROC)	
9. Deal with stressful situations	40 (33.3)
10. Understand instructions to take medication	99 (82.5)
11. No difficulty understanding written information	33 (27.5)
12. No help needed when reading written health materials	23 (19.2)
13. Date of clinic return visit 2 weeks after 7 March	37 (30.8)
14. 4 out of 20 people may get a cold; give the percentage (%) chance	0 (0.0)
15. One tablet to be taken three times a day; if the first tablet is at 8am, give the time of the next dose	20 (16.7)
16. Indicate 2 ml on a graduated syringe	94 (78.3)
17. Choose the healthy meal option	119 (99.2)
Mean score = 48.5±15.3%	
Factual knowledge (FACT)	
18. Not acceptable for HCPs to discuss your health with other patients	117 (97.5)
19. Distrust of quality of internet-based information	19 (15.8)
20. State normal body temperature	18 (15.0)
21. Explain what diabetes is	16 (13.3)
22. Comparative risk for thin or overweight person of developing diabetes	88 (73.3)
23. Identify blood pressure reading closest to normal	63 (52.5)
24. State if HIV/AIDS can be cured	62 (51.7)
25. State if TB is transmitted by using the same toilet as a TB patient	62 (51.7)
26. Comparative risk of getting TB if person has HIV/AIDS	86 (71.7)
27. Making time to exercise at least three times a week	63 (52.5)
28. Need to finish the course of antibiotics	104 (86.7)
29. Concurrent use of herbal/traditional medicine with prescribed medicine	112 (93.3)
30. Safety of herbal/traditional medicines	87 (72.5)
Mean score = 59.4±14.5%	

¹ See Appendix E for detailed questions

The Factual knowledge domain had the highest mean score (59.2±14.6%) of the three domains. Participants also performed well in the Access domain, with a mean score of

57.5±15.5%. The more cognitively demanding Procedural knowledge domain had a lower mean score of 48.4±15%.

Access to healthcare, health services and social support (ACCESS)

Reported access to verbal health information in the community was low (6.7%), although support for providing care was good from both family (90.0%) and community (80.8%). Similar results were obtained for Questions 4, 5 and 7, with only a fifth (20.8%) reporting being able to access health information from the internet, and reporting asking questions from their HCPs during consultations (22.5%).

Procedural knowledge (PROC)

The four numeracy questions (Q13-Q16) in this category were poorly answered, with no one being able to calculate the percentage risk of getting a cold. The exception was the numeracy question requiring the correct volume to be indicated on a syringe (Q16), with 78% offering the correct response. Results indicative of lower health literacy were also generated from questions assessing self-reported understanding of written information (Q11; 27.5%) and the ability to read instructions, pamphlets and health-related materials without aid (Q12; 19.2%). All except one were able to correctly identify the healthier meal (Q17; 99.2%), making this the question with the highest correct/appropriate response in all three domains.

Factual knowledge (FACT)

Questions in this category had the highest number of correct/appropriate responses. Participants had particularly good knowledge regarding patients' rights (Q18; 97.5%) and medication taking (Q28; 86.7%) and the appropriate use of herbal/traditional medicines (Q29; 93.3%). Despite body temperature being checked at every clinic visit, few were able to identify a normal body temperature (Q20; 15.0%). They also had great difficulty explaining what diabetes was (Q21; 13.3%).

5.3.1 Item Bank health literacy categories

Table 5.5 shows that the majority of the participants (73.3%) were classified as having marginal health literacy. The minimum and maximum scores ranged between 17 and 51, out of a total of 60.

Table 5.5 Item Bank health literacy categories (n=120)

Health literacy categories ¹	n (%)
Inadequate (0-24)	11 (9.2)
Marginal (25-40)	88 (73.3)
Adequate (31-60)	21 (17.5)

¹Maximum score = 60

5.4 MSFHL and TTS health literacy categories

The MSFHL test consists of six questions based on self-reported demographic data and screening questions to assess functional health literacy. Questions were revised to ensure local relevance (Section 4.1). The results obtained for this test are presented in Table 5.6.

Table 5.6 Responses to MSFHL questions (n=120)

Questions	Score n (%)
Educational attainment (years)	
0-3	18 (15.0)
4-7	28 (23.3)
8-11	48 (40.0)
≥12	26 (21.7)
Mother's educational attainment (years)	
0-7	91 (75.8)
8-12	29 (24.2)
Life time occupation	
Predominantly manual ¹	106 (88.3)
Predominantly non-manual	14 (11.7)
Use of technology	
Never or occasionally	110 (91.7)
At least once a week	14 (11.7)
Writing	
Difficulty with writing	38 (31.7)
Some difficulty with writing	35 (29.2)
No difficulty with writing	47 (39.1)
Reading	
Difficulty with reading	43 (35.8)
Some difficulty reading	32 (26.7)
No difficulty reading	45 (37.5)

¹Numbers of participants include those who have never had a job.

Thirty eight percent of the study population had seven years or less formal education, whereas a larger 75.8% reported this level of education for their mothers. Only a small proportion (11.7%) of the participants had jobs which were predominantly non-manual (requiring intensive training or supervisory elements). Most (91.7%) reported occasional or

no use of computers. When asked if they would face any difficulty if they had a job which required a lot of writing, over a third (39.1%) reported no difficulty, and just under a third (31.7%) said they would find it difficult. Reading information leaflets which came with medicines was self-reported as being difficult for 35.8% of the participants, despite 65.0% having reported being able to read English.

The mean MSFHL score out of 10 was 4.2 ± 2.9 . Participants were almost equally distributed between the inadequate (41.7%) and adequate (38.3%) health literacy categories, with the remaining 20.0% categorised as having marginal health literacy.

Pearson's Chi-square test revealed no gender effect on the MSFHL score. However, a significant association between education ($p < 0.001$), age ($p < 0.001$) and employment ($p < 0.001$) was found. A strong, significant correlation ($r = .675$, $p = 0.001$) was found between the MSFHL and the Item Bank. The average time taken to complete the test was 1.2 ± 0.4 minutes.

The time taken to sign (TTS) ranged between 0.3-54.9 seconds, with a mean of 7.9 ± 6.3 seconds. Taking ≥ 7 seconds to sign indicates inadequate health literacy, while signing in ≤ 6 seconds denotes adequate health literacy. Over half (51.7%) the participants were found to have inadequate health literacy, with the remaining 48.3% being considered to have adequate health literacy.

Education had a significant effect on the time taken to sign ($p < 0.001$). Adequate health literacy was prominent in participants who had higher educational attainment; of the 58 participants found to have adequate health literacy, 75.9% had secondary education. In comparison, of the 62 participants categorised as having inadequate health literacy, over half (51.6%) had only primary education.

5.5 Association between individual Item Bank questions and variables

Table 5.7 presents the association between age, education, English literacy and employment with individual questions in the Item Bank.

Table 5.7 Significant associations of gender, age, education, English literacy and employment with Item Bank questions

Questions	p value ¹			
	Age	Education	English literacy	Employment
Access to healthcare, health services and social support				
1. Community-based health talks	-----	-----	-----	-----
2. Community support available when sick with TB	-----	-----	-----	-----
3. Family support available after an operation	0.011	-----	-----	0.020
4. Asking the doctor for information about health problems	-----	-----	-----	-----
5. Asking the doctor questions during consultation	-----	-----	-----	-----
6. Sceptical about health information from friends and neighbours	-----	-----	-----	-----
7. Ability to use the internet to find health information	<0.001	<0.001	0.011	<0.001
8. Ability to access transport to the clinic	-----	-----	-----	-----
Procedural Knowledge				
9. Dealing with stressful situations	-----	-----	-----	-----
10. Understanding instructions to take medication	-----	-----	0.028	-----
11. No difficulty understanding written information	<0.001	<0.001	<0.001	0.001
12. No help needed when reading written health materials	<0.001	<0.001	<0.001	<0.001
13. Date of clinic return visit 2 weeks after 7 March	0.042	0.004	-----	0.016
14. 4 out of 20 people may get a cold. What is the percentage (%) chance	-----	-----	-----	-----
15. One tablet to be taken three times a day. If the first tablet is at 8am, when is the next taken	0.041	0.002	-----	-----
16. Indicate 2ml on a graduated syringe	-----	0.007	0.001	-----
17. Choosing a healthy meal option	-----	-----	-----	-----
Factual Knowledge				
18. Not acceptable for HCPs to discuss your health with other patients	0.022	-----	-----	-----
19. distrust of quality of internet-based information	-----	-----	-----	-----

20. Normal body temperature	-----
21. Explain what diabetes is	
22. Comparative risk for thin or overweight person of developing diabetes	-----
23. Identify blood pressure reading closest to normal	-----
24. Can HIV/AIDS be cured	0.010
25. TB not transmitted by using the same toilet as a TB patient	0.001
26. Comparative risk of getting TB if person has HIV/AIDS	0.038
27. Making time to exercise at least three times a week.	-----
28. Finish the course of antibiotics	-----
29. Concurrent use of herbal/traditional medicine with prescribed medicine	-----
30. Safety of herbal/traditional medicines	-----

¹ Only significant associations of $p < 0.05$ are included

0.001	0.038	-----
-----	-----	-----
-----	-----	-----
-----	-----	-----
-----	-----	-----
-----	0.013	0.004
-----	0.002	0.024
-----	-----	-----
-----	-----	-----
-----	-----	-----
-----	-----	-----

5.5.1 Education

The majority of the questions influenced by education were from the Procedural knowledge domain. Two of the four numeracy questions (Q13, Q15) were significantly associated with education, as were the abilities to understand written health information (Q11), to read health information without assistance (Q12) and to use computers to access health information (Q7).

There was fairly good congruence between age and education effects, with five questions being significantly influenced by both age and education. Of these, two were numeracy (Q13, Q15), two asked about written health information (Q11, Q12) and one was about the ability to use the internet (Q7).

An analysis of the influence of education on the mean domain scores for all four educational levels within each of the three domains showed a significant education effect in all cases. An increase of scores was noted with each increasing educational level (Table 5.8).

Table 5.8 Education effect on Item Bank health literacy domains

Health literacy domain	n	Mean \pm SD	p-value
ACCESS (total score = 16)			0.012
Grade 0-4	26	8.4 \pm 2.1	
Grade 5-7	21	8.7 \pm 1.9	
Grade 8-10	31	8.9 \pm 2.2	
Grade 11-12	42	10.1 \pm 2.6	
PROC (total score = 18)			<0.001
Grade 0-4	26	5.8 \pm 2.1	
Grade 5-7	21	7.5 \pm 2.3	
Grade 8-10	31	9.1 \pm 1.7	
Grade 11-12	42	10.8 \pm 1.9	
FACT (total score = 26)			<0.001
Grade 0-4	26	13.2 \pm 3.4	
Grade 5-7	21	14.3 \pm 3.5	
Grade 8-10	31	15.5 \pm 3.6	
Grade 11-12	42	17.4 \pm 3.3	

The most significant increase from one educational level to the next occurred in the Procedural domain; these questions required greater cognitive ability to answer, which is usually acquired through formal education. The lowest educational level (Gr 0-4) with a mean score of 5.8 \pm 2.1 almost doubled (10.8 \pm 1.9) in the Gr 11-12 educational category. A Tukey post hoc test revealed that in the Access domain, those with a Grade 11-12 had a

significantly higher mean score than participants with a Grade 0-4 education. Similarly, the mean score for the Factual domain was significantly higher for Grade 11-12 (17.4 ± 3.3) than for Grade 0-4 (13.2 ± 3.4 , $p < 0.001$) and Grade 5-7 (14.3 ± 3.5 , $p = 0.006$).

5.5.2 Age

The influence of age was observed for 11 of the 30 questions. As expected, age significantly influenced the ability to use the internet to look for health information (Q7; $p < 0.001$) with none of the participants ≥ 60 years being able to use the internet, while only 5% in the 45-59 year category could do so. A similar significant trend with increasing age was noted when self-reporting difficulty understanding written information (Q11; $p < 0.001$), and requiring assistance to read written information (Q12; $p < 0.001$).

5.5.3 Self-reported English literacy

The ability to read, understand and speak English is essential in being able to navigate healthcare systems, primarily those where information and instruction is given in English. English literacy was found to be significantly associated with the ability of an individual to understand written information (Q11; $p < 0.001$), the use of internet to access information (Q7; $p = 0.011$), assistance required to read written health information (Q12; $p < 0.001$), and understanding instructions on how to take medication (Q10; $p = 0.028$). English literacy was also associated with the ability to carry out basic numerical operations such as reporting clinic return date (Q13; $p < 0.001$) and identifying the 2 ml mark on a graduated syringe (Q16; $p = 0.001$).

5.5.4 Employment

Employment status was found to influence the ability to understand written information (Q11; $p = 0.001$) as well as the ability to use the internet to obtain health information (Q7; $p < 0.001$). Individuals with occupations requiring intense training or supervisory elements performed significantly better in both the questions than did their counterparts who were unemployed or had manual occupations. Less than two-thirds (64.3%) of the participants could search on the internet for health information compared to only 11.9% who had manual jobs. Over half (57.1%) of the participants with non-manual employment required no

assistance reading information, in comparison to individuals with manual jobs (16.7%) and those who were unemployed (12.5%).

5.5.5 Chronic condition

The influence of chronic and long-term conditions (hypertension, diabetes, HIV/AIDS, TB) on disease-specific questions in the Item Bank was analysed. It was found that having hypertension significantly improved the ability to identify a normal blood pressure reading (Q23; $p=0.040$). Significantly more HIV/AIDS patients knew whether or not HIV could be cured (Q24; $p=0.02$). However, no significant association was found between having HIV/AIDS and knowing whether this was linked to a higher risk of contracting TB (Q26; $p=0.299$). No association was found between having diabetes and being able to describe the disease (Q21; $p=0.180$), or being able to identify the higher risk of getting diabetes if an individual is overweight versus the desired weight (Q22; $p=0.898$).

5.6 Association between mean Item Bank score and demographic variables

No significant association was found between the mean Item Bank score and variables such as age, employment status and having a chronic condition. However, education, language proficiency in English, as well as in isiXhosa, and the ability to look for health information on a computer or a cellphone were significantly associated with the mean Item Bank score ($p<0.05$) (Table 5.9).

Table 5.9 Association between mean Item Bank score and demographic variables

Variable	Total n (%)	p value
Age (years)		0.056
18-29	16 (13.3)	
30-44	35 (29.2)	
45-59	38 (31.7)	
≥60	31 (25.8)	
Education		0.015 ¹
Grade 0-4	25 (20.8)	
Grade 5-7	21 (17.5)	
Grade 8-10	30 (25.0)	
Grade 11-12	44 (36.7)	
Employed		0.098
Yes	55 (45.8)	
No	65 (54.2)	

Self-reported isiXhosa literacy		0.002 ¹
Only listen	0 (0.0)	
Listen and respond	18 (15.0)	
Listen, speak and read	102 (85.0)	
Self-reported English literacy		0.049 ¹
No understanding	15 (12.5)	
Only listen	12 (10.0)	
Listen and respond	15 (12.5)	
Listen, speak and read	78 (65.0)	
Long term health condition		0.050
Yes	85 (70.8)	
No	35 (29.2)	
Do you know how to look for information on a computer?		0.002 ¹
Yes	22 (18.3)	
No	98 (81.7)	
Can you use your cellphone to look for health information?		0.025 ¹
Yes	29 (24.1)	
No	77 (64.2)	
N/A	14 (11.7)	

¹Significant influence on mean Item Bank score (p<0.05)

5.7 Correlation of Item Bank domain scores and MSFHL score

Table 5.10 Spearman's rank correlation coefficient between the three domains of the Item Bank and the MSFHL

		MSFHL score	ACCESS	PROC	FACT
MSFHL score	Correlation coefficient	1.000	.375	.670	.442
	Significance (2-tailed)	-	<0.001	<0.001	<0.001
ACCESS	Correlation coefficient	.375	1.000	.247	.416
	Significance (2-tailed)	<0.001	-	0.007	<0.001
PROC	Correlation coefficient	.670	.247	1.000	.337
	Significance (2-tailed)	<0.001	0.007	-	<0.001
FACT	Correlation coefficient	.442	.416	.337	1.000
	Significance (2-tailed)	<0.001	<0.001	<0.001	-

The MSFHL was significantly correlated with all three categories of the Item Bank (Table 5.10). A moderate correlation of the MSFHL score was seen with the Access ($r=.375$, $p<0.001$) and Factual Item Bank categories ($r=.422$, $p<0.001$), while a strong correlation was seen with the Procedural category ($r=.670$, $p<0.001$). Although all three domains contained different question content, they were all significantly associated and the strength of the correlation range from weak to moderate.

5.8 Discussion

The development of the Item Bank lays the groundwork for the development of a health literacy measure unique for South Africa. It is, as far as the author is aware, the first in Africa, and is one of very few studies emanating from LMICs to develop health literacy questions addressing the multidimensional nature of health literacy which is deeply rooted in the broader definitions of this construct. It interrogates a number of skills relating to health literacy tasks critical to achieving health related outcomes, and also explores the contribution of the collective social environment in informing health literacy.

Recommendations for developing as well as adapting health literacy measures for LMICs emphasize the importance of questions reflecting the local context (18,30,140,143). This ensures that key aspects are addressed which are unique to the local population, and which may have been obscured when a test is developed in a different population (231). This may include access to health information and resources, language, communication with HCPs, disease burden and social influences.

Health literacy tests, whose intended purpose is to identify individuals with limited health literacy, often exclude individuals with lower educational levels who tend to be the most at risk for poorer health outcomes. Researchers have therefore highlighted the need to take into account the educational level of respondents when developing health literacy measures (18,232), as the cognitive and numeracy demands of the tests currently available are often too advanced (18). In a Malaysian study the NVS, a test which is relatively cognitively demanding, was administered to caregivers with primary and secondary education and the average score obtained for the test was 0.54/6 (233). In contrast, when the same test was administered to children from the US with only primary level education, a much higher average score of 4.8/6 was obtained (234). This is a clear indication to limit the number of questions which place a high cognitive demand on populations with widespread low educational attainment.

Accordingly, to cater for low literate individuals in the target population of the current study, only nine of the 30 Item Bank questions required a higher level of cognitive processing and thinking, eight elicited self-reported opinions regarding different abilities relating to health literacy, and the remaining 13 questions were factually based which require existing

knowledge rather than advanced cognitive processes, as they elicit simple and straightforward answers based on obvious facts.

Education helps to develop critical cognitive skills that contribute to the ability to solve more difficult, complex and cognitively demanding problems (235,236), thereby enabling individuals to mediate a relationship between education and health. Because of the widespread limited literacy in South Africa and many other developing countries, individuals with lower educational attainment increasingly encounter greater health disadvantages (237). In South Africa almost 20% of the population has not progressed beyond primary level (38) and most fall in the lower end of the literacy scale and are likely to face difficulty with health literacy tasks. In the current study, the ability to answer the more cognitively demanding questions that required application of literacy skills were typically those in the Procedural Knowledge domain, which had the highest number of questions influenced by education. The majority of participants had difficulty performing basic numeric tasks required to function in a healthcare environment, with three of the four numeracy questions in this domain being poorly answered, and responses ranging from 0% to 31%. Not a single participant was able to calculate the 20% chance of getting a cold if 4 out of 20 people are at risk, despite a third having either Grade 11 or 12 schooling.

Poor literacy creates a barrier which prevents individuals from actively participating in the care process (127). Official figures place the percentage of the South African population that possesses only marginal reading skills and would be considered functionally illiterate as 14.6% (38). However, a much larger 34% of our study participants reported always requiring help when reading general health information, with only 19% needing no help with the examples we showed to them. Given the official national functional literacy figure of 94.4% (38), our findings reflect much lower functional literacy when attempting to read and understand health-related materials. Similar findings have been reported from a USA study on predominantly indigent and minority patients, where a high proportion of patients were unable to read and understand basic written medical instructions, with almost a quarter requiring surrogate readers to help them read materials from the hospital (238).

Access to healthcare is often equated with an individual's ability to access the physical healthcare environment (239). However, it also extends to requiring active engagement with the process of care; it is concerned with helping people to effectively use appropriate

healthcare resources in order to preserve or improve their health (240). With increased accessibility to the internet, many more people are now able to access healthcare information which is relevant, reliable and up to date (241). Unfortunately the digital divide between HICs and LMICs still persists (242) and hinders access to web-based health information, a barrier that is compounded by lack of prior exposure to and an inability to use the internet (243), language barriers (244,245), and socioeconomic status (244). These inequities in access to information exacerbate the growing gap in healthcare between HICs and LMICs countries (241).

In our study, only 4/120 participants had a computer, and less than 20% reported being able to look for health information on the computer. Mobile phones have made it easier to access the internet for those who do not have computers. Of the 88% of the participants who had mobile phones, just under a quarter could use them to look for health information, a slightly higher figure compared to those who could do so using a computer. Predictably, education and age were significant predictors of the successful use of the internet to answer health-related questions. Unlike studies that have reported the internet as the most common source of health information (246,247), only 2/120 of our participants reported this as their source of information. Over a third of participants (69.2%) appeared unaware of the varying reliability of information from the internet as they reported always trusting the information they obtained from this source.

Even if health information can be accessed via various channels, be it the internet or print, there is always a risk that it is not fully understood (248), and this problem can be particularly acute in populations where limited literacy is prevalent. Most information from various sources uses medical jargon unfamiliar to many users, and the required reading level is also too advanced (189,207). A study conducted by Williams *et al* (238) found that a large proportion of patients were unable to read and understand basic medicine instructions pertaining to dosage interval and directions for use, as well as general information on informed consent form and information regarding appointment scheduling. A similar trend could be seen in our study, where almost a third of the participants reported that they always have problems understanding written health information, and 40% reporting that they occasionally have difficulty. Numerous studies have provided strategies to minimise the difficulties faced by patients regarding written information, the most common being the use of easy to read instructions and plain language (187,249). However, in a study conducted by

Davis *et al* (250) it was found that simplifying instructions was beneficial only for good readers. Several researcher have identified the use of visual aids such as pictograms to be successful in improving comprehension among individuals with limited literacy (251–253).

Comprehension problems can also be attributed to lack of availability of the information in a first language. South Africa is a multilingual country with 11 official languages. English, despite being ranked only fourth and being spoken by only 9.6% as a first language, is the language of choice in media, higher education, political and legal institutions (155). At a national level there is a mandate by the Medicines and Related Substances Act 101 of 1965 (as amended) that information leaflets and labelling on medicines should be in English and one other official language (254). Local research has reinforced the importance of health information being available in the patient's first language (255) as its lack constitutes a barrier to health literacy. In the current study, good English literacy skills were strongly associated with a reported ability to read and understand written health information unaided, a common finding from countries where English is the dominant language (238). Compared to individuals with high English proficiency, those with low English proficiency experience worse access to care (256). The ability to read, understand and speak English is essential in being able to navigate healthcare systems where information and instruction is largely available and is displayed in English. Despite the importance of appropriate language usage being so apparent, the use of interpreters in healthcare facilities is uncommon due to the high cost and inconvenience, with the unfortunate result that language barriers are likely to persist (257,258).

Limited English proficiency, particularly among second language English speakers, results in difficulty communicating with HCPs (259–261). In South Africa, nurses are often the first point of contact in public healthcare facilities and they often speak the same language as many of the patients, so the language barrier is usually only of significance when interacting with doctors and pharmacists. However, the provider-patient power differential is particularly evident in the South African public health sector and constitutes a barrier to communication. Nurses from this health sector have been reported as adopting an authoritarian approach when interacting with patients (262,263) which hinders the patients' capacity to verbalize their needs. In our study less than a quarter (22.5%) of the participants reported that they often asked HCPs questions during consultations. Despite these communication barriers, 96% of study participants cited the nurse as the preferred source of health information, findings

typical of lesser-resourced countries (264), as nurses within primary healthcare settings have been identified as providing an increasing proportion of chronic disease management and preventive lifestyle advice (265). Research within the same local community as our study found that patients did not ask HCPs questions, were not encouraged to do so, and in fact did not know that it was their right to ask questions (137). This patient disempowerment, often encountered in limited literacy patients, was exacerbated by a general lack of basic medicine- and disease-related knowledge, rendering patients unsure of what questions they should be asking (137).

The unequal division in South Africa between the private and public healthcare sectors has meant that the greatest burden of disease is carried by the public sector, the target population for which the health literacy test is being developed. This includes the dual burden of HIV and TB as a large component of the disease burden in South Africa (266), with approximately 12.5% of the population infected with HIV (154), and a TB incidence of 0.8% (203).

Low health literacy is a factor found to influence chronic disease knowledge, self-care and management (140,267). Improving chronic disease knowledge is central to improving health literacy and preventing and delaying the onset of chronic diseases, preventing unhealthy behaviours, promoting healthy lifestyles and managing chronic diseases (264). The Item Bank knowledge-based questions were designed to reflect the national disease burden, dominated by communicable diseases such as HIV and TB. The national HIV prevalence is 11.2% (154) compared with the 20% prevalence in our study sample. Disconcertingly, only half the study population knew that HIV/AIDS cannot be cured, although a significantly higher proportion of those with HIV/AIDS answered this question correctly.

It was interesting to note, however, that increased disease-specific health literacy was not always evident for those with certain diseases; for example, with diabetes, no such association was established for questions requiring a basic explanation of diabetes, and identifying risk factors for diabetes. Just over half of the study participants showed good hypertension-related knowledge by correctly identifying the normal blood pressure reading amongst three different readings, although a higher 63% of those being treated for hypertension answered successfully. Our findings of relatively poor disease knowledge support findings of a study conducted in rural China, where more than 70% had inadequate health knowledge, including those with secondary school level education or higher (264).

It is important to look beyond individual-level health literacy skills assessment and patient-provider interactions that can influence health literacy to the broader social environment. In this context, the roles of families and communities are investigated in activities such as the ability to access health information, comprehend and act on the information and in decision-making about health concerns (26,67,268). Two thirds of study participants lived in households of between four and nine people; the two questions inquiring about the availability of support if sick or recently hospitalised elicited highly positive responses, indicating good social support. The social environment has a significant influence on health, with those living in large households experiencing higher levels of social support (269). This is particularly beneficial for those with poor health literacy in helping them to achieve positive health outcomes (67). However, in the current study, close social contacts such as family and friends were only cited by a small minority as being the preferred source of health information, with trust for such information being fairly low.

The Brazilian MSFHL (118), also developed for an LMIC population, was used as the comparator. It was interesting to note the differences in the health literacy categories between this test and the Item Bank, despite some of the MSFHL questions having been modified to suit the South African context. However, the demographic questions and screening questions nevertheless address many issues which are expected to be problematic in this type of population.

An important aim driving this research project was to develop a health literacy test that was able to discriminate between different levels of health literacy *within the limited literacy group*, thereby rendering the different health literacy categories more meaningful, and ultimately better informing the support of these patients. As this Item Bank does not constitute a final health literacy test, the following stage of this project was to further analyse the data to develop a shortened form of these Item Bank questions to constitute a final health literacy test.

CHAPTER 6

REFINEMENT OF ITEM BANK

6.1 Introduction

The previous chapter presented results generated after administration of the 30 questions of the Item Bank to 120 participants. Developing shorter versions of health literacy instruments increases the likelihood that they will be used in intervention research and other assessments, including surveillance at the local and national levels (125). It also achieves several efficiencies related to data collection and decreases respondent burden (173). In this chapter, the performance of each individual question in the Item Bank is evaluated to select appropriate questions for inclusion in the truncated version of the final health literacy test. In addition to psychometric analysis, selection of questions was also guided by opinions from an expert panel. The truncated version consists of 12 questions which form the Health Literacy Test for Limited Literacy (HELT-LL).

6.2 Evaluating the performance of individual questions

6.2.1 Ceiling and floor effects of individual questions

Floor effects are present when most of the subjects score near the bottom for a particular test question. A ceiling effect occurs when a high proportion of subjects have maximum scores for a question. Questions exhibiting floor or ceiling effects have very little variability and are considered undesirable for inclusion in a measure (270).

The percentage of correct responses obtained for each question in the Item Bank was used to determine whether a question exhibited floor or ceiling effects. Questions were deemed to have a floor effect if fewer than 20% were correct and a ceiling effect if more than 80% were correct. The cut-off values were selected to ensure that a wide range of responses could be detected.

6.2.2 Internal consistency reliability

Cronbach's alpha coefficient is a measure of internal consistency, with the acceptable value being 0.60 or higher (271,272). A high value for Cronbach's alpha indicates that items within a test are measuring the same general construct (273).

'Cronbach's alpha if item deleted' indicates the resulting Cronbach's alpha value for a measure if a particular item is removed. It estimates the direct contribution of that item to the reliability of a measure (274). When the resultant alpha value is higher than the current alpha value of the measure, consideration should be given to deleting the item in order to improve the reliability of the test (273).

6.2.3 Item difficulty

Item difficulty refers to how easy or difficult each item in the measure is. For binary/dichotomously scored items (e.g. correct/incorrect, yes/no), item difficulty is also referred to as the p-value, as it is the proportion of participants with the answer correct divided by the number of participants who answered (275,276). Item difficulty ranges from 0-1, with a high p-value (close to 1) indicating an easy item, and values closer to 0 indicating that the item is difficult. Values positioned at the two extremes indicate that all respondents answered the question either correctly or incorrectly and they show little variability in the item scores (276).

For continuous scored items, item difficulty is the arithmetic mean (275,276). Difficulty ranges from the minimum score to the maximum that can be obtained (275). The Item Bank questions were scored as either 0, 1 or 2, so the mean ranges from 0-2. The closer the mean score is to zero, the more difficult the question, while the opposite is true for a mean closer to the maximum score of 2. Similar to binary items, it is possible to convert the item difficulty for polytomous items to a proportion, by dividing the item mean by the maximum possible score (275). The term 'item difficulty' is applicable only to questions having a correct answer. However, in the case of Likert-type questions, where a person provides an opinion, the term is inappropriate (275). It has been recommended to rather view the 'item difficulty' value as an indication of item endorsability i.e. the degree to which the highest response option is endorsed (275).

An ideal test should have a spread of items with moderate difficulties, as it is unlikely that every item will have a difficulty of 0.5. Acceptable item selection criteria have been proposed. According to the jMetrik software manual, binary items should have a difficulty value near 0.5, however items with a difficulty within 0.2 points are acceptable (275). For questions where guessing may influence question response, setting the difficulty value slightly over halfway has been recommended (275).

6.2.4 Item discrimination

Item discrimination is the correlation between an item score and the total score for the test (275,276). Item discrimination values can range from -1 to +1 (274,276). The higher the value, the more discriminating an item is deemed to be. Items with values near to or less than zero should be removed from the test as they indicate an item inconsistent with the test as a whole, which is an undesirable characteristic (277). According to selection guidelines, the item discrimination values should be between 0.3-0.7 (275).

6.3 Evaluation of individual questions in the Item Bank

The researcher (CM), her supervisor, and the expert panel interrogated all 30 questions to identify those suitable for inclusion in the final test. During this process, the following were considered:

- Score for each question (mean \pm SD)
- Comparison of results of questions assessing similar skills or opinions
- Repetitive questions
- Possible problems with question content resulting in participant confusion
- The need to reword questions to avoid confusion or clarify a focus
- The need to ensure a selection of questions that covered all three health literacy domains (access, procedural and factual).

6.3.1 Statistical parameters used in the evaluation of question performance

The statistical parameters employed in aiding question selection included percentage (%) of correct response, alpha value if item is deleted, item difficulty and item discrimination parameters. Two statistical software programmes were used to generate these data. SPSS version 25 was used to determine the % correct/appropriate response for each question in the item bank. It was also used to generate the Cronbach's alpha value for the entire item bank and the alpha if deleted values for the individual questions. The Item Response Theory (IRT) was used to determine the difficulty and discrimination parameters of individual questions. Data obtained for all 30 questions were exported to jMetrik 4.0.6 software to generate these parameters.

6.3.2 Selection of questions for the HELT-LL

The decision to include or exclude Item Bank questions when creating the HELT-LL was based on both results from the psychometric analyses (Table 6.1), and feedback from the consultant panel of experts. This process resulted in an initial selection of twelve questions. Detailed below is the outcome for each question in the Item Bank, and the reasons for its removal or retention.

Question 1: removed

Are there people who visit your community to talk about health and illness and how to care for yourself?

There is inadequate information regarding the extent to which the distribution of information during community visits, by community healthcare workers, and other individuals penetrates communities. Coupled with poor discriminating ability of the question ($\text{Disc}=0.044$)¹ as shown through item analysis, the question was not considered for inclusion in the final test.

Question 2: removed

If you have TB, feel very weak and need help, and there is no one to care for you at home, is there anyone from the community who will visit you and take care of you?

¹ Disc: item discrimination

Although this question is a good indicator of accessibility to care from the surrounding community, and potentially reveals isolation from the community, family and friends, it remains unclear whether interaction with these individuals has any influence on individual health literacy. Item analysis indicated a low discrimination value, which further influenced the decision to exclude it.

Table 6. 1 Psychometric properties of the Item Bank questions

Health literacy domain and individual questions	% Correct ¹	Item Difficulty (Dif) ²	Item Discrimination (Dis) ³	Alpha if item deleted ⁴
Access to healthcare, health services and social support (ACCESS)				
1. Community-based health talks offered	6.7	0.35	0.044	0.662
2. Community support available when sick with TB	80.8	0.82	0.037	0.666
3. Family support available after an operation	90.0	0.92	0.197	0.656
4. Asking the doctor for information about health problems	22.5	0.55	0.282	0.648
5. Asking the doctor questions during consultation	20.0	0.57	0.315	0.647
6. Sceptical about health information from friends and neighbours	46.7	0.49	0.294	0.641
7. Ability to use the internet to find health information	20.8	0.21	0.422	0.636
8. Ability to access transport to the clinic	63.3	0.69	0.019	0.673
Procedural Knowledge (PROC)				
9. Deal with stressful situations	33.3	0.34	-0.168	0.692
10. Understand instructions to take medication	82.5	0.87	0.222	0.654
11. No difficulty understanding written information	27.5	0.48	0.338	0.627
12. No help needed when reading written health materials	19.2	0.43	0.461	0.622
13. Date of clinic return visit 2 weeks after 7 March	30.8	0.31	0.304	0.639
14. 4 out of 20 people may get a cold; give the percentage (%) chance	0.0	0.00
15. One tablet to be taken three times a day. If the first tablet is at 8am, give the time of the next dose	16.7	0.17	0.183	0.654
16. Indicate 2 ml on a graduated syringe	78.3	0.78	0.267	0.646
17. Choose the healthy meal option	99.2	0.99	-0.003	0.662
Factual Knowledge (FACT)				
18. Not acceptable for HCPs to discuss your health with other patients	97.5	0.98	-0.051	0.664
19. Distrust of quality of internet-based information	15.8	0.24	0.265	0.644
20. State normal body temperature	15.0	0.15	0.226	0.651
21. Explain what diabetes is	13.3	0.13	0.109	0.657
22. Comparative risk for thin or overweight person of developing diabetes	73.3	0.73	0.255	0.646
23. Identify blood pressure reading closest to normal	52.5	0.53	0.102	0.662
24. State if HIV/AIDS can be cured	51.7	0.52	0.236	0.649

-
- 25. State if TB is transmitted by using the same toilet as a TB patient
 - 26. Comparative risk of getting TB if person has HIV/AIDS
 - 27. Making time to exercise at least three times a week
 - 28. Need to finish the course of antibiotics
 - 29. Concurrent use of herbal/traditional medicine with prescribed medicine
 - 30. Safety of herbal/traditional medicines
-

¹ Acceptable range for % correct: 20%-80%

² Acceptable range for item difficulty (Dif): 0.25-0.75

³ Acceptable range for item discrimination (Dis): ≥ 0.3

⁴ Acceptable range for alpha when item deleted: ≥ 0.666

51.7	0.52	0.419	0.627
71.7	0.71	0.329	0.633
52.5	0.63	0.136	0.661
86.7	0.87	0.155	0.657
93.3	0.92	-0.100	0.668
72.5	0.78	0.116	0.660

Question 3: removed

If you have an operation, is there a family member who can care for you after you leave the hospital?

The high number (90.0%) of participants who responded in the affirmative indicates good family support for individuals. However, there is no indication to what extent family support actually has an influence on an individual's health literacy; therefore the question was not retained. Furthermore, the question showed a poor discrimination parameter ($\text{Disc}=0.197$), which made it a poor candidate for inclusion in the final test.

Question 4: removed

When you go and see the doctor/nurse, do you ever ask them questions about a problem with your health?

This was one of two questions interrogating patient-provider communication (the other being Q5). Both questions exhibited similar psychometric properties, with those for Q5 being slightly higher. This question was removed and Q5 retained as the latter was more explicit, and included a wider range of HCPs.

Question 5: retained

If you don't understand what the nurse/doctor/pharmacist says, do you usually ask them to give you more information and explain things to you?

Refer to Q4 for reason for inclusion.

Question 6: retained

When you want to find out more about a health problem, do you think your friends and neighbours would give you good information and advice about your problem?

In the study population, health decision-making is often a communal one (43). This question was deemed particularly important as it assessed the individual's ability to analyse the trustworthiness of information from family and friends, a skill which is essential for health literacy. The question met the set statistical criteria and was slightly modified to improve understanding.

Revised: If you are worried about a health problem do you usually ask your friends and neighbours first for information and advice before going to the clinic?

Question 7: retained

Do you know how to use the internet to answer your health-related questions?

The question examines the use of the internet as a source of health information, often the first source explored by patients looking for health information in HICs. In Africa, this technology is only gradually beginning to be accessed by the average patient, but penetration is rapidly increasing. However, many people are still unfamiliar with its use as was evident with the participants in this study. The question showed good discrimination ($\text{Disc}=0.422$) and, coupled with the importance of the emerging use of technology in health information seeking, this question was included in the final test after it was altered to improve clarity.

Revised: Do you know how to use a computer or cellphone to answer your health-related questions?

Question 8: removed

Are you always able to get transport to go to the clinic when you need to?

The question showed poor psychometric properties; the discrimination parameter was low, and removal of the question resulted in a significant increase in alpha value, therefore improving reliability of the final measure. A large proportion of the participants reported usually walking to the clinic therefore requiring no transportation, rendering this an irrelevant question.

Question 9: removed

If you feel stressed or worried about a problem, would you require someone who would help you or would you be able to face this yourself?

A review of this question indicated confusion by the participants as well as a possible cultural difference in interpretation of the construct of stress. The question also displayed undesirable psychometric properties: it had very poor discrimination and, if removed would result in a significant increase in Cronbach's alpha value. Based on this, the question was excluded from the final test.

Question 10: removed

Is it easy for you to understand the instructions for your medication?

Over 80% of the participants reported being able to understand instructions for taking their medication. However, prior research in this limited literacy population (278,279) has shown that the majority of the patients do not have a clear understanding of instructions for taking

their medication. This suggests that the question displays social desirability bias. A decision was made to remove the question as it was not a true reflection of the population who often have difficulty comprehending simple medication instructions.

Question 11: removed

How often do you have problems learning about your medical conditions because it is difficult to understand written information?

Both this question and Q12 explored issues relating to understanding written health information. Although both questions showed acceptable psychometric properties, Q12 was retained as it offered additional insight into the frequency with which surrogate readers are used to assist in understanding written health information.

Question 12: retained

How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist?

Refer to Q11 for reason for inclusion.

Question 13: retained

If you go to the clinic on the 7th of March and you are asked to return to the clinic two weeks later, what will the date be?

Research has shown that many patients have difficulty understanding medical directions containing numerical information, such as instructions on medication bottles and appointment slips (272). Given the frequency with which patients are required to apply this type of basic numeracy skill in the healthcare system (272), it was considered an essential question to include. The question met all statistical criteria, making it a good candidate for inclusion.

Question 14: removed

Next winter 4 out of 20 people have a chance of getting a cold. What is the percentage (%) chance of getting a cold?

Not a single participant out of the 120 interviewed was able to give the correct answer, and it therefore exhibits a floor effect. The question was considered inappropriate for inclusion as it was not discriminatory, nor did it offer any differential insight into the ability to conduct risk-related numerical calculations.

Question 15: retained

You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one?

This important question assessed numeracy skills in relation to dosage frequency information on medication labels. Although statistics relating to this question were undesirable, the expert panel decided to retain this question because of the importance of correct dosing intervals in managing many conditions.

Question 16: retained

You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.

Item analysis showed that the question was too easy, with a difficulty parameter of 0.78. However, number identification is an important component of numeracy, and a decision was made to include this question along with other more challenging and discriminatory numeracy-based questions.

Question 17: removed

Choose which plate of food you think is healthier: Plate 1: chicken stew, rice and spinach; Plate 2: fried chicken and chips.

The question was excluded based on psychometric analysis. Almost all patients answered correctly, and therefore it showed ceiling effects and poor discriminatory properties.

Question 18: removed

After you have seen the nurse/doctor at the clinic, is it acceptable for the nurse/doctor to discuss your health issue with other people who are not health colleagues?

The question exhibited ceiling effects, was answered correctly by 97.5% and therefore was poorly discriminating. Analysis of the Cronbach's alpha value revealed that removal of the question would result in an increase in Cronbach's alpha. Based on its poor psychometric performance, the question was removed.

Question 19: retained

Do you think that health information from the internet is always good information that you can trust?

The question was included to assess whether people could trust health information they obtained from other information sources apart from the traditional sources such as friends, family and HCPs. The psychometric properties for the questions were slightly lower than the recommended values. This question was selected for inclusion in the final test after slight modifications were made.

Revised: Do you think that health information from the internet on your cellphone or computer is always good information that you can trust?

Question 20: removed

What is a normal body temperature?

The results revealed that very few people relying on public sector facilities are likely to have access to a thermometer in their homes. Psychometric properties show that the question was difficult to answer (15% correct) and was poorly discriminating (Disc=0.226). The question was therefore deemed inappropriate for retention.

Question 21: removed

Can you explain what diabetes is?

This question elicited a broad variety of responses, many of which were vague. It was unclear as to whether the participants had any knowledge regarding diabetes. This question would have been an ideal candidate for a multiple-choice type question. The psychometric properties for the question were undesirable, with the question being both difficult to answer (Dif=0.13)² and poorly discriminating (Disc=0.109).

Question 22: removed

Certain people have a higher risk of developing diabetes. Is a thin person more likely to develop diabetes than an overweight person?

Psychometric analysis showed most of the values were borderline acceptable. However, the decision to exclude the question was based on its format which required a yes/no response option. The panel felt that this question was open to guess work and did not adequately explore factual knowledge.

² Dif: Item difficulty

Question 23: retained**Which blood pressure reading is closest to a normal blood pressure reading?**

Hypertension is one of the most common chronic diseases encountered in PHC patients in South Africa (280,281). Despite its poor discriminating ability, the question was included because of its relevance to local chronic disease burden. Having to choose between three different BP values was observed to result in a good engagement with the choices offered and was an effective method of assessing hypertension-related knowledge.

Question 24: retained**Can HIV/AIDS be cured?**

Given that HIV/AIDS is one of the most common conditions treated at PHCs, this question was deemed essential to retain as a good indicator of locally relevant health knowledge. The question also showed favourable IRT parameters which reinforced its inclusion.

Question 25: retained**Can you get TB if you use the same toilet as someone with TB?**

Over 95% of TB deaths occur in LMICs (203), and TB is a common condition treated in local PHCs. This question was retained as IRT parameters indicated good acceptability, and it was considered an important disease-related knowledge question that investigates correct or incorrect opinions of how TB is transmitted.

Question 26: removed**Is someone with HIV/AIDS at a high or low risk of getting TB?**

This question was removed to avoid the final test being top-heavy in disease knowledge-related questions relating to HIV and TB. In addition, the phrasing of the question was closed-ended and was open to eliciting a guessed answer.

Question 27: removed**Do you make time to exercise (walk, play sport for about 30 minutes) at least three times a week?**

Exercise as a deliberate activity appears to be interpreted differently in different cultures (282). In this population, very few people deliberately undertake planned, regular exercise activities; however, many are physically active during their daily activities. It was unclear

from their responses whether daily activities such as walking, housework, gardening or their jobs were considered as a form of physical activity.

Question 28: removed

When taking antibiotics, you are told to finish the course. Can you then stop taking the antibiotics as soon as you start to feel better?

Recent findings have questioned the necessity of completing a course of antibiotics (283). The question was found to be too easy ($Dif=0.87$) to answer and the discriminating ability of the question was poor ($Disc=0.155$). The question was therefore deemed inapplicable and excluded from the final test.

Question 29: removed

You are given a new medicine at the clinic. At home you have been taking herbal/traditional medicine. What should you do?

The question exhibited a ceiling effect with 93.3% of the participants giving the correct answer, resulting in poor discrimination ($Dis=-0.100$). An increase in Cronbach's alpha could be seen if this question was deleted. Based on the poor psychometric performance, the question was excluded.

Question 30: retained

Herbal/traditional medicines are natural and are from plants. Are they always safe to take?

Despite showing poor discrimination, the question addresses use of a complementary treatment system different from the allopathic medicine practice employed within the healthcare system. This is particularly pertinent in our population where traditional /herbal medicines are widely used. The question was therefore retained.

6.4 Final version of the Health Literacy Test for Limited Literacy (HELT-LL)

Table 6.2 shows the final questions included in the Health Literacy Test for Limited Literacy (HELT-LL). Review of the twelve questions showed adequate representation of the three health literacy domains; three questions were from the Access domain, four from the Procedural knowledge domain and five questions from the Factual knowledge domain.

Table 6. 2 Health Literacy Test for Limited Literacy patients (HELT-LL)

Health literacy domain and individual questions	Score
Access to healthcare, health services and health information (ACCESS)	
1. If you don't understand what the nurse/doctor/ pharmacist says, do you usually ask them to give you more information and explain things to you?	0=never 1= sometimes 2=often
2. Do you know how to use a computer or cellphone to answer your health-related questions?	0=no 2=yes
3. If you are worried about a health problem do you usually ask your friends and neighbours first for information and advice before going to the clinic?	0=yes 1=sometimes 2=no
Procedural Knowledge (PROC)	
4. If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be? <i>Correct answer: 21st of March</i>	0=incorrect 2=correct
5. How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist? <i>(Show image of the information leaflet)</i>	0=always/ often 1=occasionally/ sometimes 2=never
6. You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one? <i>Correct answer: 3pm</i>	0=incorrect 2=correct
7. You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	0=incorrect 2=correct
Factual Knowledge (FACT)	
8. Do you think that health information from the internet on your cellphone or computer is always good information that you can trust? <i>Correct answer: No</i>	0=incorrect 2=correct
9. Which blood pressure reading is closest to a normal blood pressure reading? <i>(show image of the blood pressure reading)</i> <i>Correct answer: 120/80.</i>	0=incorrect 2=correct
10. Can HIV/AIDS be cured? <i>Correct answer: No</i>	0=incorrect 2=correct
11. Can you get TB if you use the same toilet as someone with TB? <i>Correct answer: No</i>	0=incorrect 2=correct
12. Herbal/traditional medicines are natural and are from plants. Are they always safe to take? <i>Correct answer: No</i>	0=incorrect 2=correct

CHAPTER 7

VALIDATION OF THE HEALTH LITERACY TEST- LIMITED LITERACY (HELT-LL)

7.1 Introduction

This chapter describes the validation of the HELT-LL in a limited literacy population from different sites around the Eastern Cape. The purpose of the validation process is to ensure that the test measures what it is intended to measure (284). This applies to tests that have been developed in English by other authors and validated in different languages and countries, as well as self-developed instruments or those that have been adapted (284). The method used to validate the measure is described. The results section presents the demographic, socioeconomic and health-related characteristics of the participants as well as the results obtained from the HELT-LL, MSFHL and NVS-SA tests. The chapter concludes with the validity and reliability analysis of the HELT-LL.

7.2 Objectives

The objectives of this stage are:

- To assess health literacy levels in the target population
- To validate the HELT-LL in the target population.

7.3 Methods

7.3.1 Study setting, site and population

The study setting has been described in Chapter 4, Section 4.2.

This cross-sectional validation study was conducted in four public primary healthcare clinics (PHCs) in two towns in the Eastern Cape. Three of the clinics, Settlers Day Hospital, Raglan Road Clinic and Extension 7 Clinic are located in Grahamstown. The fourth clinic, Nkwenkwezi Clinic, is located in the small coastal town of Port Alfred.

Theoretically, a sample size of 120 participants was required to support a ratio of 10 subjects per item for the measure to be validated (271,285). However, a convenience sample of 210 participants, almost double the required sample size, was used to increase the power of the test (7,30). This is commensurate with the suggested number of at least 200 conveyed in personal communication with two international, widely-published health literacy experts from the USA. Small sample sizes may have an effect on whether significant associations will be detected between health literacy and other variables (7,30)

From the study population, 40 participants were retested two weeks after the baseline interview to evaluate test-retest reliability. During the follow up interview only the HELT-LL was administered to the participants.

All participants had to be above the age of 18 years, speak isiXhosa as their home language, have a maximum of 12 years of schooling and attend public sector healthcare facilities. Patients were excluded if they showed any evidence of cognitive, hearing or visual impairment. The participants were stratified into four educational groups of no schooling to Grade 4, Grade 5-7, Grade 8-10 and Grade 11-12. During the recruitment process, the researcher ensured that each educational category contained an adequate number of participants.

7.3.2 Data collection instrument

The questionnaire previously developed for the assessment of the Item bank (Chapter 4, Section 4.3.1) was modified for this stage of the study. The final questionnaire consisted of five sections.

Sections 1 - 3: TTS, Demographics, MSFHL

As for Section 4.3.1

The primary comparator to assess validity of the HELT-LL was the MSFHL.

Section 4: Health Literacy Test for Limited Literacy (HELT-LL)

Twelve items were selected for inclusion in the HELT-LL (Appendix F) based on psychometric analyses and evaluation by an expert panel (Chapter 6, Section 4). Each item in the test has a maximum possible score of 2.

Section 5: Newest Vital Sign - South Africa (NVS-SA)

The Newest Vital Sign (NVS) is a test used to assess health literacy (16). It uses a scenario based on an ice-cream nutrition label with six follow-up questions and takes about three minutes to administer. The NVS assesses math, reading and comprehension skills, as well as abstract reasoning. In order to adapt the NVS for the South African population, cultural and contextual relevance issues were addressed. The ice-cream label was replaced with a nutrition label found on a can of pilchards (canned fish), a food commonly eaten by many South Africans. Many people in developing countries do not have refrigerators or freezers and are less likely to purchase ice-cream. The original structure of the NVS was retained, with the NVS-SA also consisting of six questions equally divided into numeracy and reading comprehension questions (286).

The NVS-SA is currently being validated and is the only test available in South Africa that assesses numeracy and reading literacy and has been culturally and contextually adapted for this country. The argument for its inclusion in this study was to compare the performance of a more cognitively demanding test with that of the HELT-LL, as the latter does not rely solely on numeracy and literacy skills and is specifically tailored for limited literacy populations.

The NVS-SA was included as a secondary comparator in order to compare this more cognitively demanding test with the HELT-LL, which has a different structure and includes question structure spanning a range of difficulty.

7.3.3 Translation of instruments

The HELT-LL and NVS-SA were translated into isiXhosa by an African language specialist and back-translated by a different language expert fluent in both English and isiXhosa. The translated versions of the tests were used by the interpreter during the interview. The NVS-SA label content was also translated into isiXhosa using the same two-stage process. Prior to administering the NVS-SA, the participants were given a choice to read either the English (Appendix G) or the isiXhosa version of the label (Appendix H).

7.3.4 Interview process and recruitment

Data for this study were collected in August and September 2017. All 210 patients were recruited using the standardised approach previously described in Chapter 4, Section 4.4.2. Signed consent was obtained once the interpreter had ensured understanding of the contents of the information letter (Appendix I).

The questionnaire (Appendix F) was administered in chronological order of the five sections. At the conclusion of the interview, all participants were remunerated for taking part in the study with a R50 (\$3.70) gift voucher from a local supermarket.

7.3.5 Ethical approval

The study was approved by the Faculty of Pharmacy Ethics Committee (PHARM-2017-03) (Appendix J) and the National Department of Health Eastern Cape Ethics Committee (EC_2015RP40_351) (Appendix K). Permission to work in the clinics in Grahamstown and Port Alfred was granted by the respective District Health Coordinators.

7.3.6 Data analysis

Descriptive statistics, as well as the mean and standard deviation for the HELT-LL score, were calculated. HELT-LL scores for allocation into health literacy categories were inadequate (0–10), marginal (11–20) or adequate (21–24). The association of selected demographic and socio-economic variables with the HELT-LL score was computed using one-way ANOVA. Correlations between the HELT-LL, MSFHL and NVS-SA scores were determined using Pearson's correlation test. The criteria for interpreting the correlation were as follows: 0.0–0.25 weak correlation, 0.26–0.50 moderate correlation, 0.51–0.75 strong correlation, and >0.75 very strong correlation (287).

To assess reliability, internal consistency of items within the HELT-LL was assessed by Cronbach's alpha coefficient. A Cronbach's alpha value of greater than 0.60 was considered to be acceptable to establish internal consistency (271). The reliability of the test was also evaluated through the test-retest approach. The HELT-LL was re-administered to 40 participants two weeks after initial administration. The participants for the test-retest were

stratified equally into the four educational levels. Pearson's correlation was used to determine the relationship between each item at the two phases. All analyses were performed with SPSS Version 25. Statistical significance was set at $p < 0.05$.

7.4 Results

7.4.1 Participant characteristics

The demographic characteristics of the 210 participants are presented in Table 7.1. The majority of participants were female (85.2%), the mean age was 42.9 ± 14.4 years, and approximately 40% had only a primary school education. Over three quarters (76.7%) of the participants reported being able to listen, read and speak English, while 8.1% had no understanding of English at all.

Table 7.1 Participant demographic characteristics (n=210)

Demographics	Total n (%)
Gender	
Male	31 (14.8)
Female	179 (85.2)
Age (years)	
18-29	44 (21.0)
30-44	70 (33.3)
45-59	68 (32.4)
≥ 60	28 (13.3)
Education	
Grade 0-4	41 (19.5)
Grade 5-7	45 (21.4)
Grade 8-10	57 (27.2)
Grade 11-12	67 (31.9)
Self-reported isiXhosa literacy	
Only listen	0 (0.0)
Listen and respond	0 (0.0)
Listen, speak and read	210 (100.0)
Self-reported English literacy	
No understanding	17 (8.1)
Only listen	13 (6.2)
Listen and respond	19 (9.0)
Listen, speak and read	161 (76.7)

The number of unemployed participants was extremely high, with 147 patients (70.0%) being unemployed at the time of the interview (Table 7.2). Only five (2.4%) of the participants

received more than R 5 000 in a month, with 17.6% receiving less than R2 000 income per month.

More than half (57.6%) of the participants received government grants, and the most commonly received grants were child support (35.2%) and older persons (12.4%) grants. Over three quarters of the participants (79.5%) reported having five residents or less per household while the remaining 43 participants (20.5%) had six or more.

Table 7.2 Participant socioeconomic characteristics (n=210)

Socioeconomic characteristics	Total n (%)
Employed	
Yes	63 (30.0)
No	147 (70.0)
Type of employment	
Not employed	147 (70.0)
Predominantly manual	60 (28.6)
Predominantly non-manual	3 (1.4)
Recipient of social grant	
Yes	121 (57.6)
No	89 (42.4)
Income	
< R2 000	37 (17.6)
R2 000-R5 000	21 (10.0)
>R 5 000	5 (2.4)
N/A	147 (70.0)
Number of people living in the house	
1-5	167 (79.5)
6-10	41 (19.5)
>10	2 (1.0)

7.4.2 Health-related characteristics

Over two-thirds of the participants had a chronic condition, with almost half (49.5%) diagnosed with only one chronic condition. HIV/AIDS (70.5%), hypertension (35.7%) and diabetes (12.9%) were the most commonly reported conditions.

Almost half (47.6%) the participants were taking between one and three medicines for their condition. When asked about their overall health, 15.2% reported it was poor, while equal proportions of the participants reported it as either fair or good.

Table 7.3 Health-related characteristics of participants (n=210)

Health related characteristics	Total n (%)
Long term health condition	
Yes	141 (67.1)
No	69 (32.9)
Number of conditions	
0	69 (32.9)
1	104 (49.5)
2	35 (16.7)
3	2 (1.0)
Type of condition	
Hypertension	75 (35.7)
Diabetes	27 (12.9)
HIV/AIDS	148 (70.5)
TB	0 (0.0)
Asthma	7 (3.3)
Epilepsy	6 (2.9)
Number of prescribed medicines	
0	69 (32.9)
1-3	100 (47.6)
4-6	36 (17.1)
>6	5 (2.4)
Perceived overall health rating	
Poor	32 (15.2)
Fair	89 (42.4)
Good	89 (42.4)
Sources of health information	
Doctors	82 (39.0)
Nurse	203 (96.7)
Pharmacist	0 (0.0)
Community healthcare worker	8 (3.8)
Information leaflets	4 (1.9)
Internet	1 (0.5)
Television	6 (2.9)
Radio	15 (7.1)
Newspaper	0 (0.0)
Family	11 (5.2)
Friends	9 (4.3)

Nurses (96.7%) were the primary source of health information, followed by doctors (39.0%). Although not as popular, family (5.2%) and friends (4.3%) were also reported as sources of health information. Not one participant reported obtaining information from a pharmacist.

7.4.3 Use of technology

Table 7.4 presents responses from participants regarding the use of technology. Although less than 5% reported that they had a computer, almost a quarter were able to use a computer to look for information.

Cellphones were widely available among many of the participants, however very few (13.3%) were able to use them to look for health information. This may be due to many participants not having smart phones.

Table 7.4 Extent of use of technology (n=210)

Use of technology	Total n (%)
Do you have a computer?	
Yes	10 (4.8)
No	200 (95.2)
Do you know how to look for information on a computer?	
Yes	52 (24.8)
No	158 (75.2)
Do you have a cellphone?	
Yes	165 (78.6)
No	45 (21.4)
Can you use your cellphone to look for health information?	
Yes	28 (13.3)
No	58 (27.6)
N/A ¹	124 (59.0)

¹N/A – Participants either did not have a cellphone or it was not a smartphone

7.4.4 Health Literacy Test for Limited Literacy (HELT-LL) results

Table 7.5 presents results of the HELT-LL. The mean total score was 52.8±18.4% and the average time taken to administer the test was 3.6±0.9 minutes. The mean score for the PROC (48.6±24.9%) domain was the lowest of the three domains, with the ACCESS (50.8±24.5%) and FACT (57.4±24.2%) domains having mean scores over 50%.

Access to healthcare, health services and social support (ACCESS)

Q1 highlights the extent of patient disempowerment in the public health sector, with less than a quarter (23.4%) indicating ever asking HCPs for information. Just under a third (Q3; 30.5%) of the participants did however report trusting health information from their friends and neighbours. Unlike developed countries, where use of the internet is endemic, here only

approximately a third (Q2; 32.4%) of the participants reported knowing how to look for health information on the internet.

Table 7.5 Correct responses or responses reflecting higher health literacy in three health literacy domains (n=210)

Health literacy domain and individual questions	Score (%)
Access to healthcare, health services and social support (ACCESS)	
1. Asking the doctor questions during consultation	50 (23.8)
2. Ability to use the internet to find health information	68 (32.4)
3. Sceptical about health information from friends and neighbours	110 (52.4)
Mean score = 50.8±24.5%	
Procedural knowledge (PROC)	
4. Date of clinic return visit 2 weeks after 7 March	61 (29.0)
5. No help needed when reading written health materials	87 (41.4)
6. One tablet to be taken three times a day; if the first tablet is at 8am, give the time of the next dose	42 (20.0)
7. Indicate 2 ml on a graduated syringe	182 (86.7)
Mean score = 48.6±24.9%	
Factual knowledge (FACT)	
8. Distrust of quality of internet-based information	73 (34.8)
9. Identify blood pressure reading closest to normal	102 (48.6)
10. State if TB is transmitted by using the same toilet as a TB patient	129 (61.4)
11. State if HIV/AIDS can be cured	118 (56.2)
12. Safety of herbal/traditional medicines	177 (84.3)
Mean score = 57.4±24.2%	
Total mean score = 52.8±18.4%	
Average time = 3.6±0.9 minutes	

[†] See Appendix F for detailed questions

Procedural knowledge (PROC)

Q4 and Q6 are the two numeracy questions and are amongst the most poorly answered, with participants achieving less than 30% for both questions. The ability to read written health information was clearly difficult for most participants, with only (Q5; 40%) reporting being able to read such information with no assistance. Number identification was good, with the majority (Q7; 86.7%) being able to identify the 2 ml mark on a graduated syringe.

Factual knowledge (FACT)

These questions were better answered than the other two domains, with the highest mean score of 57.4±24.2%. Three of the questions addressing the disease burden in South Africa were based on hypertension, HIV/AIDS and TB. Less than a half of the participants could (Q9; 48.6%) identify a correct blood pressure reading, under two-thirds (Q10; 61.4%) knew that

TB could not be transmitted by sharing a toilet and a little over half (Q11; 56.2%) of the participants knew that HIV/AIDS could not be cured. The last question (Q12) addressed the local yet important issue of traditional medicine use, with 84.3% reporting that herbal/traditional medicines were not always safe to use.

7.4.4.1 Association between HELT-LL score and demographic variables

The total HELT-LL score was correlated with selected variables including age, education, and English proficiency (Table 7.6). The HELT-LL scores were significantly ($p<0.001$) associated with age, with younger individuals performing better than older individuals. The highest score of 14.6 ± 3.5 in the 18-29 year age group gradually decreased from one age group to the next. Tukey post hoc analyses showed that the difference in mean between the 18-29 year and 30-44 year age groups was not significant ($p=0.985$); however, the decrease between the 30-44 year and 45-60 year age groups was significant ($p<0.001$), as was the decrease in mean score from the 45-60 year to >60 year age group ($p=0.023$).

A significant association was also found between HELT-LL score and education ($p<0.001$). Tukey post hoc analysis showed that significant ($p<0.001$) differences in the mean scores occurred between all educational groups, apart from between the 0-4 year category and the 5-7 year category ($p=0.849$).

Table 7.6 Association between HELT-LL score and selected variables

Variable	Mean \pm SD	p value
Age (years)		<0.001
18-29	14.6 ± 3.5	
30-44	14.3 ± 4.1	
45-59	11.3 ± 4.3	
≥ 60	8.8 ± 3.4	
Education		<0.001
Grade 0-4	9.4 ± 4.2	
Grade 5-7	10.1 ± 4.1	
Grade 8-10	13.4 ± 3.2	
Grade 11-12	15.5 ± 3.2	
Self-reported English literacy		<0.001
No understanding	7.1 ± 3.0	
Only listen	8.3 ± 3.7	
Listen and respond	9.5 ± 4.1	
Listen, speak and read	13.9 ± 3.7	

English proficiency also significantly influenced total score obtained for the HELT-LL. Individuals who could speak, read and had a verbal understanding of English had a mean score of 13.9 ± 3.7 , almost double the mean score of participants who had no understanding of the English language (7.18 ± 3.06). Tukey post-hoc analysis showed that the increase in the mean score between participants who could read, speak and respond in English and those with lower English proficiency was significant ($p < 0.05$).

Employment, income and the ability to look for health information using a computer or cellphone were also found to significantly ($p < 0.001$) influence the health literacy score. Individuals who were employed or had higher incomes or those who knew how to look for information on a computer or a cellphone had higher mean health literacy scores. No significant associations were found between the HELT-LL score and isiXhosa literacy ($p = 0.542$), having a chronic condition ($p = 0.373$), and the number of people living in the house ($p = 0.116$).

7.4.5 Multidimensional Screener of Functional Health Literacy (MSFHL) results

The MSFHL results are presented in Table 7.7. The 58.6% of participants who had secondary school education is in sharp contrast to their mothers' educational level, where only 14.8% had secondary education (8-11 years). A large proportion (99.0%) of the participants either had never had a job or had a job which was predominately manual.

Table 7.7 Responses to MSFHL questions (n=210)

Questions	Score n (%)
Educational attainment (years)	
0-3	28 (13.3)
4-7	59 (28.1)
8-11	84 (40.0)
≥ 12	39 (18.6)
Mother's educational attainment (years)	
0-7	179 (85.2)
8-12	31 (14.8)
Life time occupation	
Predominantly manual ¹	208 (99.0)
Predominantly non-manual	2 (1.0)
Use of technology	
Never or occasionally	179 (85.2)
At least once a week	31 (14.8)

Writing	
Difficulty with writing	47 (22.4)
Some difficulty with writing	57 (27.1)
No difficulty with writing	106 (50.5)
Reading	
Difficulty with reading	56 (26.7)
Some difficulty reading	52 (24.8)
No difficulty reading	102 (48.6)

Mean score = 44.4±26.2

Average time = 1.2±0.3 minutes

¹Numbers of participants include those who have never had a job.

The majority of the participants (85.2%) reported that they did not use a computer or only occasionally used it or any other technological devices. Half (50.5%) of the participants had no difficulty with writing and, similarly, 48.6% of the participants reported no difficulty with reading information leaflets or instructions for taking medication.

The mean score for the MSFHL was 44.4±26.2%. Age, education and English literacy were found to significantly ($p<0.001$) influence the MSFHL score. The average time taken to administer the test was 1.2±0.3 minutes.

7.4.6 Newest Vital Signs – South Africa (NVS-SA) results

Table 7.8 presents correct responses from the NVS-SA. When participants were asked if the pilchards had flavouring, under a quarter (Q1; 24.8%) were able to confirm that they were flavoured with tomato. Forty percent were able to correctly state that the pilchards were safe to use if someone suffered from a gluten allergy (Q4) and only 19.5% reported that the fish was safe to eat if you had a problem with your heart or blood pressure (Q6).

Table 7.8 Results from NVS-SA

Questions	Score (%)
1. Are the pilchards (fish) plain or is there flavour that has been added?	52 (24.8)
2. If you eat 200g from this tin, how much of the tin will you eat?	75 (35.7)
3. If 3 slices of bread contains about 6g of protein, which will give you more protein: eating 3 slices of bread or eating some pilchards?	107 (51.0)
4. Pretend you are allergic to the following substances: penicillin, milk and gluten. Is it safe to eat this food?	83 (39.5)
5. If you eat the whole can of pilchards, how many grams of carbohydrates will you eat?	2 (1.0)
6. Pretend that you have a problem with you heart of blood pressure, according to the label how would you know if this food is good for you?	41 (19.5)
Mean score = 28.6±21.1%	
Average time = 3.1±0.9 minutes	

The NVS-SA had three numeracy questions. Over a third (35.7%) of the participants were able to identify the portion of the pilchards eaten after eating 200 g of the contents of the tin (Q2). Q3 was the best answered numeracy question, with just over half (51.0%) of the participants reporting that fish contained more proteins than three slices of bread. Only two of the 210 participants (1.0%) were able to calculate the correct total carbohydrate count in the tin of pilchards (Q5).

The NVS-SA was the most poorly answered test, with a mean score of $28.6 \pm 21.2\%$. The NVS-SA score was significantly associated with age ($p=0.010$), education ($p<0.001$) and English literacy ($p<0.01$).

7.4.7 Health literacy categories

The 210 participants were classified into three health literacy categories for all three measures (Table 7.9). The HELT-LL categorised only 17.6% as having adequate health literacy. Of the 68 participants with inadequate health literacy, almost two-thirds (65.9%) had 0-4 years of education, just under three quarters (71.4%) were over the age of 60 years, and 88.2% reported no understanding of the English language.

Table 7.9 Health literacy categories for the three measures

Test	Frequency n (%)	Minimum score obtained	Maximum score obtained
HELT-LL		1	23
Inadequate (0-10)	68 (32.4)		
Marginal (11-17)	105 (50.0)		
Adequate (18-24)	37 (17.6)		
MSFHL		0	9
Inadequate (0-3)	80 (38.1)		
Marginal (4-5)	43 (20.5)		
Adequate (6-10)	87 (41.4)		
NVS-SA		0	5
Inadequate (0-2)	155 (73.8)		
Marginal (3-4)	51 (24.3)		
Adequate (5-6)	4 (1.9)		

The MSFHL had the highest proportion (41.4%) of participants with adequate health literacy amongst all three measures. Similar to participants in the higher health literacy category, 38.1% of participants were also classified as having inadequate health literacy. Approximately 20.0% had marginal health literacy. In contrast, the NVS-SA had the highest

proportion (73.8%) of participants classified with inadequate health literacy, and only 1.9% had adequate health literacy.

7.4.8 Validation results of the HELT-LL

7.4.8.1 Validity

Content and face validity were established in the early stages of the development of the Item Bank (see Chapter 3, Sections 3.1.1-2). Concurrent validity was tested by correlating scores of the HELT-LL and those of the two comparator health literacy measures, the MSFHL and the NVS-SA (Table 7.10). The health literacy measures showed strong to moderate, significant, correlations.

Table 7.10 Correlation of health literacy scores from the three measures

		HELT-LL	MSFHL	NVS-SA
HELT-LL	Pearson's correlation coefficient	1.000	.685	.455
	Significance (2-tailed)	.	<0.001	<0.001
MSFHL	Pearson's correlation coefficient	.685	1.000	.486
	Significance (2-tailed)	<0.001	.	<0.001
NVS-SA	Pearson's correlation coefficient	.455	.486	1.000
	Significance (2-tailed)	<0.001	<0.001	.

The strongest correlation was found between the HELT-LL and the MSFHL score ($r = .685$, $p < 0.001$). Moderate but significant correlations were noted between the HELT-LL and the NVS-SA ($r = .455$, $p < 0.001$), as well as the MSFHL and the NVS-SA ($r = .486$, $p < 0.001$).

7.4.8.1 Reliability

Internal consistency of the HELT-LL was tested using Cronbach's alpha, with the value of 0.60 being within the acceptable range cited in the literature (271).

Test-retest reliability was evaluated by determining Pearson's correlation coefficient between baseline and follow-up scores. The mean total scores at baseline (13.4 ± 3.8) and follow-up (13.3 ± 3.5) were similar, with a strong and significant correlation ($r = .927$, $p < 0.001$).

A graphical comparison of the 40 participants who completed both the baseline and follow-up interviews is shown in Figure 7.1. At baseline, half (50%) of the participants were found to have marginal health literacy, with a majority at follow-up also noted to have marginal

health literacy, although the percentage was higher (70%). In comparison to baseline, where under a third (30%) had inadequate health literacy, only 20% at follow-up were inadequate. The participants with adequate health literacy in the baseline interview numbered twice as many (20%) as those in the follow-up (10%).

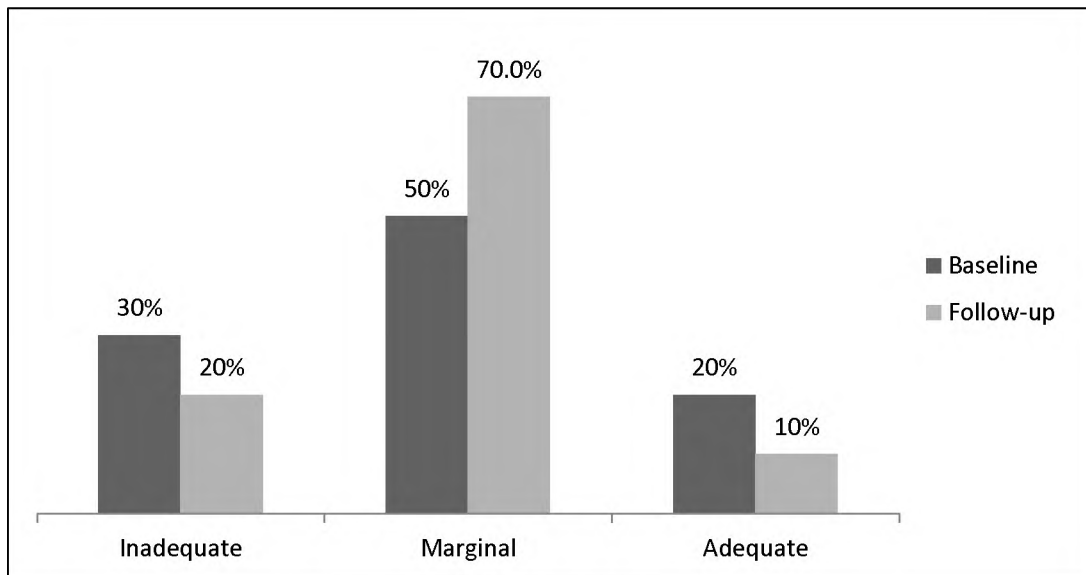


Figure 7.1 Comparison of health literacy categories between baseline and follow-up interview

CHAPTER 8

GENERAL DISCUSSION

The HeLT-LL is the first multidimensional measure to be developed and validated for measuring health literacy in limited literacy populations in South Africa. As inadequate health literacy is prevalent in LMIC populations, and the need to identify inadequate health literacy in these countries is of paramount importance, this study provides a unique contribution to the research literature in health literacy. The 12-item version of the HELT-LL interrogates a number of skills and abilities relating to health literacy, and was shown to be reliable and valid to measure literacy skills in this population with varying levels of education.

8.1 Health literacy characteristics of public sector patients in the Eastern Cape province of South Africa

There is a widespread prevalence of limited health literacy found among patients in South Africa, and it is evident that it affects the majority of public sector patients, as opposed to studies from HICs which report ethnic minorities often having inadequate health literacy. In an international commentary, Pleasant noted that health literacy is still in its infancy in South Africa, the term health literacy has not been locally defined, and very few health literacy interventions have been implemented and reported (19). Only three health literacy studies from South Africa have been reported. The first, based on the REALM, found that the majority of the words in this measure were inappropriate for the English second language study population (142). The second described a measure, also developed on the principles of a word recognition test, to assess patient comprehension of health education on hypertension received at PHCs (288). Although culturally adapted, it addresses only one component of health literacy relating to the ability to read and write health-related material and has a limited, disease-specific scope. The third, published in late 2017, emanated from this doctoral study and addressed the development and testing of the Item Bank (289). Addressing the caveats of the above-mentioned studies, the HELT-LL has been developed based on a broader definition and conceptual framework of health literacy, and is multidimensional in nature.

One of the objectives of this study was to assess the health literacy level of the study population with the newly developed health literacy measure, the HELT-LL. It was evident that limited health literacy was prevalent among public sector patients, with almost a third having inadequate health literacy, and only 17.6% being considered to have adequate health literacy skills.

Comparison of the HELT-LL with the primary comparator health literacy test, the MSFHL, revealed some similarities, but also notably some interesting differences in outcomes. Despite similar proportions in the inadequate health literacy category (38%), the MSFHL reported a much higher 41% as having adequate health literacy (vs the HELT-LL 17.6%). In the context of our limited literacy public sector population, and as a result of close personal observation during hundreds of interviews, this researcher regards this as an excessive proportion likely to have good health literacy skills. The HELT-LL, however, proved its stronger discriminatory ability by categorising only 18% as having adequate health literacy. These dissimilar results can be explained by examining the different content and structure of the two tests. The MSFHL does not include questions requiring cognitive skills, relying solely on self-reported data on demographic characteristics, and self-perceived difficulty in reading and writing. In comparison, the HELT-LL is a more complex measure that includes questions of varying difficulty, ranging from self-reported opinions to more demanding skills-based questions. This classification discrepancy is concerning, as inappropriate classification with its consequence of assuming adequate health literacy, may put incorrectly classified patients at risk of being ignored for additional assistance or counselling.

In contrast to the HELT-LL, the secondary comparator (NVS-SA, a locally modified version of the NVS) classified approximately three quarters of the participants as having inadequate health literacy. This striking difference in allocating individuals into health literacy categories could be attributed to the level of complexity and higher cognitive demands of the NVS-SA. This measure therefore reveals a similar inadequacy in the ability to differentiate between groupings within the limited literacy, limited education sectors.

This inconsistency of different measures in categorising individuals into the various health literacy categories has been previously reported (290–292). A USA study using both the NVS and S-TOFHLA showed significant inconsistencies between the two tests in identifying individuals with limited and adequate health literacy (293). This provides a cautionary note to

health literacy researchers to be aware that individuals may be classified differently across the health literacy spectrum depending on the measure used. It is likely that most of the participants in the study, if assessed using an existing health literacy test from a HIC, would be categorised as having inadequate health literacy. Such an outcome would effectively mask and avoid detection of varying levels of health literacy within this lower category.

8.2 Determinants of health literacy

Health literacy has many determinants, with the most commonly reported being education, age and English proficiency (80,294,295). Several models have been proposed describing the influence of such determinants on health literacy and health outcomes (80,296). Education has been identified as the most prevalent determinant of health literacy, with numerous studies identifying significant correlations between education and the construct (33,80,294,297–301). Similarly, the HELT-LL score was found to be significantly associated with educational level attained. The HELT-LL scores for the four educational groupings differed significantly, a finding supporting those of Paasche-Orlow *et al* (302) where significantly higher health literacy rates were noted amongst individuals who had completed high school education. The significant difference in mean scores found in the current study provides additional evidence of the ability of the HELT-LL to effectively identify varying health literacy skills within individuals whose basic education ranges from a maximum of 12 years to only very limited exposure, or none at all.

The age effect on the HELT-LL score was significant, with a similar trend found for the impact of age on both the NVS-SA and the MSFHL scores. These results are similar to a study in Korean adults, where participants over the age of forty had lower health literacy scores, and age was found to be significantly associated with health literacy (303). One explanation for the findings of the current study is that the older participant (≥ 45 years) had lower mean educational attainment (5.9 ± 2.9 years) compared to their younger counterparts (9.6 ± 2.7), a finding that has been reported by other researchers (80,97). A second explanation could be some decline in cognitive function which has been found to decrease with age (96,304,305).

Limited English proficiency is a key barrier to healthcare, often associated with poorer health status in individuals of different racial or ethnic groups (306). A study among

immigrants and ethnic minorities in the USA, found English proficiency to be a strong predictor of health literacy (307). Similarly, when the HELT-LL, MSFHL and NVS-SA were administered in our study population, English literacy was found to have a significant influence on the health literacy score. A high proportion of those unable to understand English were found within the inadequate HELT-LL health literacy category. This is similar to results reported in the USA National Assessment of Adult Literacy, which reported that adults who spoke only Spanish had the lowest average health literacy which was equivalent to “below basic” health literacy (308). In another USA study among Latinos, Asians and other ethnic groups with limited English proficiency, almost half of the participants were reported as having low health literacy (309). The combination of poor English literacy and limited health literacy makes individuals vulnerable, placing them at a higher risk of poor health status (309).

8.3 Validation of the HELT-LL

Results from this study show that the HELT-LL is a reliable and valid measure to assess health literacy in the context of limited literacy South African public sector patients. Internal consistency, as indicated by Cronbach’s alpha, was found to be within the acceptable minimum value of 0.60 as noted in the literature (271), and the highly significant correlation of the test-retest results indicates excellent reliability of the measure ($r=0.927$, $p<0.001$) and stability over multiple administration times.

Good validity of the HELT-LL was shown by the significant, strong correlation between scores of the HELT-LL and the primary comparator, the MSFHL. Despite the NVS-SA being more cognitively demanding, with a strong numeracy component, it was interesting to note that the correlation of this secondary comparator with the HELT-LL was also significant, with a moderate correlation. This implies that the trend observed for the health literacy scores in both tests was similar, despite clear differences in the categorisation of health literacy status.

8.4 Structure and content considerations in optimising test design

When designing a measure to assess a construct such as health literacy, it is essential to take into account the local context, language and culture(s), the characteristics of the healthcare

system, and the range of literacy skills of the target population. It is also recommended that special considerations for low literate individuals should include diverse tasks of varying difficulties (30). As such, one of the objectives of the HELT-LL was to ensure that it catered for the educationally diverse population in South Africa and did not rely on cognitively demanding questions, but included questions that ranged from self-reported opinion to relatively challenging ones that integrated current knowledge and others that demanded problem-solving skills.

A quarter of the questions were self-reported opinions appearing in the Access domain, almost 40% were factually-based questions and aptly found within the Factual knowledge domain. Participants obtained an average score of over 50% for questions in the Access and Factual knowledge domains. A third of the questions were cognitively demanding and appeared in the Procedural knowledge domain, with the numeracy questions proving to be the most challenging.

Many patients cannot perform basic numeric tasks required to function in the current healthcare environment (310) and in our study a similar pattern emerged. When the HELT-LL and NVS-SA were administered, the participants were largely unable to understand health information in numerical form, with the majority of the numeracy questions in both tests being poorly answered. In the HELT-LL, less than a third were able to correctly answer two of the three numeracy questions. The one successfully answered question entailed indicating the 2 ml mark on a graduated syringe, a task which patients found to be relatively easy.

The NVS-SA also had three numeracy questions. One of the questions was answered correctly by only 2/210 participants. The content of this question was challenging, requiring the participant to calculate the total carbohydrate content in a 400 g tin of pilchards, when the value stipulated on the nutrient label was for a 100 g serving. These findings, revealing the difficulty in answering numeracy-based questions, have been reported with other numeracy-related tests (16,229). The comprehension of numerical data is important to function adequately in a health system as having fewer numerical skills has been associated with lower comprehension of health information along with its consequent limited use (238), placing patients at an increased risk of poorer health outcomes. It also leads to reduced trust attached to medical information that is conveyed numerically (311). Most importantly, with the rise of communicable and non-communicable diseases, especially in LMICs, application of

numeracy skills becomes an integral part of a self-management plan for patients with chronic illness (312). These include complex recommendations for medication adherence, self-administered treatments, monitoring and interpreting blood glucose readings, and appropriately modifying dietary intake (313–316).

The content of the HELT-LL was designed to address issues relevant to the South African context and as such included questions that reflect local disease burden of communicable and non-communicable diseases. An estimated 12.6% of the population is HIV positive (154) and TB, which has an incidence of 0.8% (317), is the leading cause of death in South Africa (318). Hypertension is one of the most common non-communicable diseases treated at PHCs (280,281). These three diseases informed the content of three questions in the HELT-LL. Other questions addressing medication use, patient-provider communication and the interaction of patients with the healthcare system were grounded within the context of the South African public healthcare system. As health literacy is also shaped by social influences, the influential role that family and community play in health decision-making was acknowledged in designing health literacy questions and has been discussed in Chapter 3, Section 3.9.

Computers and other electronic and technological devices have proven to have numerous applications in business, education (319) and in the healthcare sector (320). Within the healthcare sector, HCPs and patients alike are increasingly making use of these devices (320), with patients using them to access the internet in order to fulfil the need for access to quality and relevant health information (321). The convenience of devices such as mobile phones and tablets helps individuals to access health information, and at times, health services, in any setting (322). Although the findings of this doctoral study indicate that these devices are currently not widely used by our study population, the issue was addressed to acknowledge its emerging importance in health information acquisition and dissemination.

8.5 Translation and use of interpreters

Studies on health literacy measures which have been translated for use in other populations (141,142,145) may have limited use in these populations due to phonetic differences of languages (145), and different healthcare systems, thereby lacking cultural applicability (141,142). Although the development of the HELT-LL was in English, all the items included

culturally appropriate language. The multidisciplinary expert team established for consultation throughout this study included a translation specialist and an African languages expert, which enabled the research team to conceptualise items which would retain their original meaning when translated into the local isiXhosa language. This was also aimed at aiding with improving face validity and creating questions which were easy for participants to understand and to respond to.

The use of interpreters can often present some shortcomings when communicating with individuals with little or no English proficiency. Individuals may feel excluded from conversations as they are unable to communicate directly with the interviewer (323), and the presence of a third party can introduce trust and confidentiality issues (324). In this study, the researcher was not an isiXhosa speaker which made some of the participants apprehensive at the beginning of the interview during initial greetings. Some participants immediately stated that they would not be able to proceed as they do not understand English. However, the presence of the interpreter who explained that he would be translating everything that was said, put the participants at ease during the interview. In a study reporting interpreters' perception of their roles, one was to create a safe environment for patients by ensuring patient trust and comfort. They also felt it their responsibility to explain their professional role in order to allay any fears regarding confidentiality (325).

8.6 Applicability of the HELT-LL in a research and in a clinical setting

The long length of some health literacy measures and the time taken to administer these measures has been highlighted as one of the reasons for infrequent assessment of health literacy (326,327). In a study to find the time it takes to assess health literacy in a clinical setting, the NVS took approximately three minutes to administer in English speakers, and during the subsequent validation in Spanish-speaking participants, it took an average of three and a half minutes. This short administration time was considered suitable for a clinical setting (326). The HELT-LL included 12 questions, double the number in the NVS-SA, and took on average less than 4 minutes to administer, the HELT-LL could, therefore, also be considered appropriate to administer in a clinical setting. The use of shorter measures has been found to be more feasible for measuring health literacy in a clinical setting (125).

However, assessment of health literacy as part of clinical care is not actively encouraged as there is currently no evidence linking it to improved health outcomes (328). Therefore, several tools which are available to assess health literacy are mainly used for research purposes. Due to the complexity of the health literacy construct, Baker (1) recommends that health literacy measures for research should be comprehensive in order to give a better understanding of health literacy capacities and current demands faced by patients. The HELT-LL has been developed based on the comprehensive conceptual framework of health literacy which addresses a range of health domains.

8.7 Limitations

This study has several limitations. Participants used in evaluating the Item Bank and in validating the HELT-LL were recruited through convenience sampling from different clinics in two small semi-rural towns in the Eastern Cape. These clinics fall under the public health sector, which is one of the two tiers making up the South African healthcare system. The HELT-LL was designed for individuals who use the public sector facilities, most of whom are the ethnic majority, have low literacy levels and have a low socio-economic status. Characteristics of the individuals using private sector facilities are the opposite. The findings obtained from the study do not represent the diverse ethnic and economic groups in South Africa and are therefore not an accurate representation of health literacy skills in the general population. Further testing in a more diverse population including other ethnic groups should be conducted.

The HELT-LL was tested only in isiXhosa, the most commonly spoken language in the Eastern Cape. Given that there are 11 official languages in South Africa, the results from this study should be extrapolated to the general South African population with caution.

The use of convenience sampling, where study participants are selected based on the proximity to the researcher, introduces selection bias. Male participants were under-sampled in the study, as women preponderated at all the clinics. The impact of gender on health literacy results was not evaluated as the interpretations may have been misleading. Women are generally less educated than men, particularly in our study population. As health literacy has been found to be significantly influenced by educational level this could present some bias in underreporting health literacy levels of the population.

All communication during the interviews was conducted with the aid of an interpreter as the researcher does not speak isiXhosa. The lack of direct communication between the researcher and the participant is a cause for concern as the interpreter, although trained for these interviews, may independently decide that selected information is irrelevant and not communicate this to the researcher. There is a possibility of bias in translating the results.

CHAPTER 9

CONCLUSIONS

The aim of the current study was to develop a health literacy measure which would be applicable for the South African population using public healthcare facilities. The development of an Item Bank of health literacy questions laid the foundation for the development of a final health literacy measure, the Health Literacy Test for Limited Literacy patients (HELT-LL). The measure was subsequently validated in the target population.

A significant finding to emerge from this study was the prevalence of limited literacy within the public sector population in South Africa, with over a third having inadequate health literacy. Despite the low cognitive demands of the HELT-LL compared with most other health literacy measures, less than a fifth of this population was considered to have adequate health literacy.

The HELT-LL was able to demonstrate the ability to differentiate participants into varying health literacy categories. However, there was evident misclassification of individuals into health literacy categories when using different health literacy measures. This reiterates the importance of developing appropriate health literacy measures which are unique in content and structure to suit the target population in which you wish to assess health literacy.

The participants performed poorly on the task-oriented NVS-SA, which required greater cognitive application (numeracy and comprehension). In contrast they obtained higher mean scores for the MSFHL and the HELT-LL, both of which had lower cognitive demand. Correlation analysis showed a strong correlation between the MSFHL and HELT-LL. However, there was minimal correlation between two tests and the NVS-SA, owing to the difference in content of these two tests.

Questions in the measure highlighted difficulties experienced by the study participants with performing basic numeric tasks linked to healthcare. The disempowerment experienced by patients within the public health sector was also evident, characterised by poor communication between healthcare providers and patients. Limited access to health information due to the inability to use technological devices or the inability to understand written health information could be clearly seen.

The most obvious finding to emerge from this study was the significant influence age, education and English proficiency had on health literacy. All three variables were good predictors of limited health literacy, with individuals who were older, less educated and those with little or no understanding of English were categorised within the lower health literacy categories.

The findings from the validation study indicate that HELT-LL is a reliable and valid measure of health literacy as it shows acceptable internal consistency, test-retest reliability and concurrent validity. Furthermore we found the time required to administer the HELT-LL was approximately four minutes, which makes it a potentially valuable tool in healthcare research as well as for assessing health literacy in clinical settings.

This is the first study in South Africa to develop a multidimensional health literacy measure informed by a conceptual framework and broad definition of health literacy, to assess health literacy in a selected target population. To date, there are no health literacy data available for South Africa, and although this study assessed health literacy in a sub-population of the country, it gives some insight into current health literacy levels of the lower literate, socio-economically disadvantaged, second-language English speakers in South Africa. The current study has addressed calls from international researchers who have encouraged health literacy research from LMICs, and it adds new knowledge to the health literacy database from LMICS, particularly sub-Saharan Africa.

Recommendations for further research:

- Future research could investigate health literacy using the HELT-LL in the broader public sector patient population in South Africa, and in different language and cultural groupings. This could involve translation of the HELT-LL into the three main African languages in South Africa (isiZulu, isiXhosa and Sepedi), as well as into Afrikaans and English. The translated versions could be validated in these populations, and the resultant larger database would generate preliminary national data on health literacy in this country.
- International collaborative research could aim to assess the global applicability of the HELT-LL in other countries with limited literacy populations, typically LMICs. Its usefulness could also be assessed in HICs that have ethnic minorities with limited

literacy, or populations unfamiliar with the primary language of that country, or who harbour refugee populations.

- This study only focused on patients attending public sector facilities in a semi-rural population. As the South African public and private sector populations differ significantly in terms of sociodemographic and socioeconomic characteristics, further research could involve studies comparing the applicability and outcome of the HELT-LL in these two disparate patient populations.
- A different research focus for future studies would be to shift from the identification of limited health literacy to designing and implementing suitable interventions to improve health literacy, with post-intervention health literacy studies assessing the outcome of the intervention.
- This research could serve as a base for future studies, where researchers wish to develop other health literacy measure in South Africa and Sub-Saharan Africa.

Practical application of the findings:

- The limited time required to administer the HELT-LL suggests that it could be successfully used in clinical practice.
- The HELT-LL is a validated, time-efficient tool to use in research projects in South Africa, and could be applied, with minimal modification, to other southern African neighbouring countries. It could also be used as a health literacy measure in other LMIC limited literacy populations after further modification and contextualisation.
- Validation of the HELT-LL and the collection of health literacy data on a national level will contribute to the currently sparse LMIC health literacy data, and add to the global database.

Health literacy has not been widely researched in South Africa due to lack of an appropriate measure of assessment. It is hoped that the knowledge and insights gained from the creation and use of this measure will allow other researchers to explore the significance of problems regarding low health literacy in South Africa and to facilitate the development of strategies to enhance the health literacy skills of individuals.

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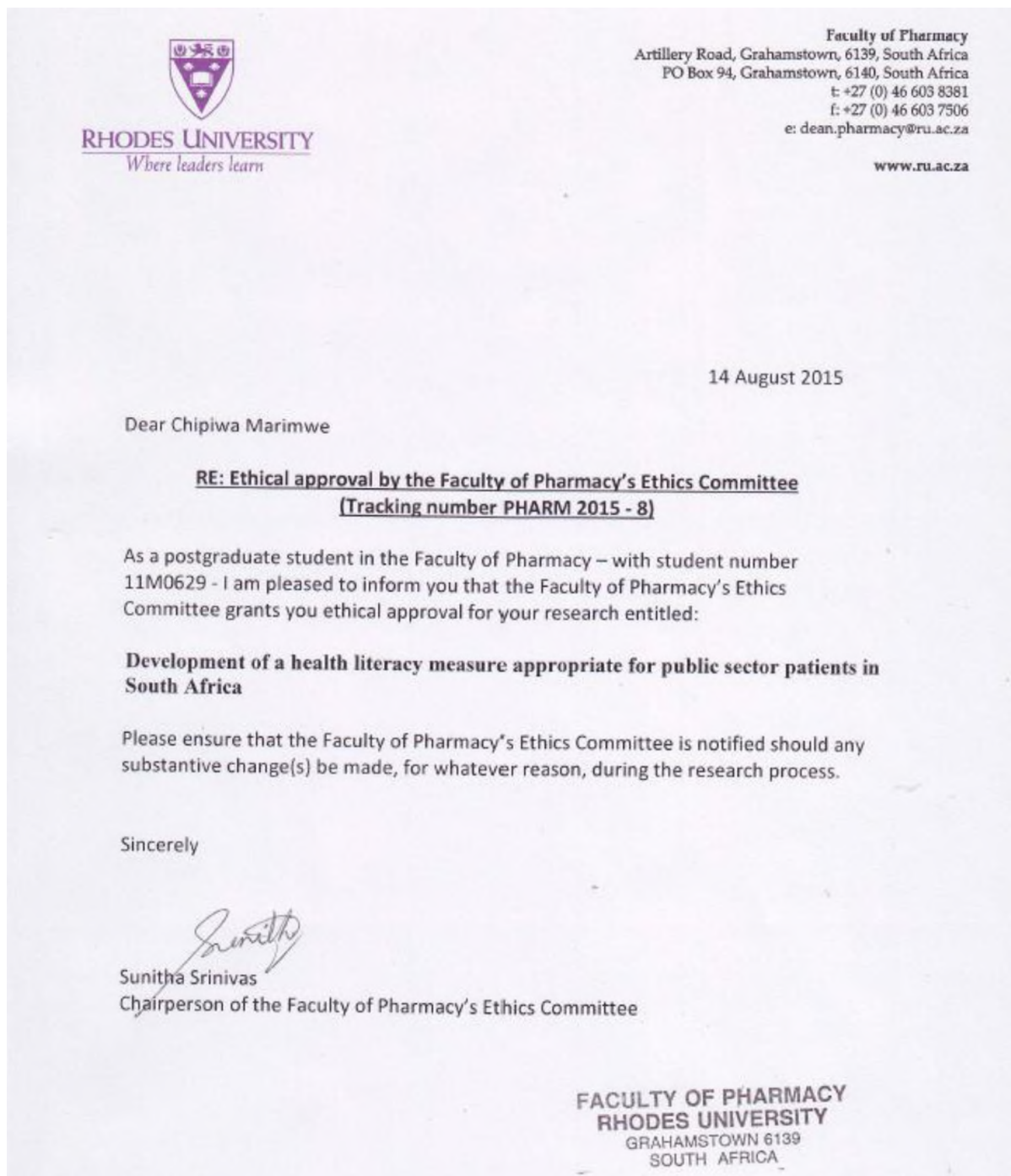
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APPENDICES

APPENDIX A



APPENDIX B

The National Health Research Database

From: NHRD Support (DO NOT REPLY) [mailto:nhrd@hst.co.za]
Sent: 26 August 2015 17:53
To: r.dowse@ru.ac.za
Subject: National Health Research Database: Important Information


Dear Ros.

This email confirms that we have received your application (*EC_2015RP40_351*).

The status of your application has changed.

The new status is: **"Approved"**.

Regards
Eastern Cape Health Research Committee



The National Health Research Database



Log offMy Account (rosdowse)Help & Support



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MY RESEARCH PROPOSALS

Submit New Proposal

You will find a list of research submissions that have been supplied and/or submitted by yourself.

Ref. No.	PHRC	Submitted?	Status of Application	Title of Study	Status of Project	Est. Completion Date	View Docs.	Comments	Amend	Conclude
EC 2015RP40_351	EC	Yes	Approved	Development of a health literacy measure appropriate for public sector patients in South Africa	On-Going	2016/11/30			Amend	Conclude



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APPENDIX C



Development of a health literacy measure appropriate for public sector patients in South Africa

My name is **Chipiwa Marimwe** and I am Doctoral student from the Faculty of Pharmacy at Rhodes University. I would like to invite you to take part in this research study. We have developed a series of questions that will tell us about your health literacy (how well you can read and understand things to do with your health, visiting the clinic and taking medicines). Once you have read and understood the information in this form, you can ask me or the interpreter any questions. I will then ask you to sign the consent form on the next page if you agree to take part.

Why are we doing this research?

The purpose of this research is to see how good our health literacy test is for patients like you who visit clinics. This will help us to measure how much you understand about looking after your health, what to do if you get sick and what you should know about taking medicines.

I am looking for people visiting the clinic who are isiXhosa-speaking and are over the age of 18. You should be able to read at least a little bit of isiXhosa.

What will you do if you take part in this study?

I will interview you with an interpreter so that you can speak in isiXhosa. I may see you before you see the doctor or nurse and get your medicines, or after you have done that. The interview will last about 20 minutes. In the interview I will ask you questions about yourself. I will then ask you to read some sentences and ask you questions about the information. You will be given a voucher from Shoprite to thank you for your time and for helping us.

How will this study help patients like me?

Your answers will help us find out which patients find it difficult to understand the information they are told at the clinic, how to take their medicines and how to stay healthy. Those patients can then be helped by the doctor or nurse to understand more about taking care of their health

Confidentiality

All the personal details you give me will be confidential. The only people who will know your name will be myself, the interpreter and my supervisor. We will not tell anyone about anything you say or the answers you give.

Do you have the right to refuse or leave the interview?

You can choose whether to take part in this study. You have the right to refuse. If you decide not to take part in this study or if you want to end the interview at any time, you are free to do that.

Now that you have read the information and have asked questions, and if you have decided that you would like to part in the study, could you please sign this Consent Form. If you have decided not to take part, thank you for reading this and I wish you well.

Contact details:

Ms Chipiwa Marimwe (researcher): 078 2356859

Prof Ros Dowse (supervisor): 046 6038071



RHODES UNIVERSITY

CONSENT FORM

TITLE OF PROJECT: Development of a health literacy measure appropriate for public sector patients in South Africa

PARTICIPANT:

I, would like to take part in this research study.
I give permission to **Chipiwa Marimwe** (researcher) and
(interpreter) to ask the necessary questions.

I understand that all information gathered from this research study will be kept confidential.

Signature:

Witness:

Date:

RESEARCHER AND INTERPRETER:

I, **Chipiwa Marimwe** (researcher) and (interpreter),
swear that all the information obtained during this research study will remain strictly confidential.

Signature:(researcher)

Signature:(interpreter)

APPENDIX D

QUESTIONNAIRE

Development of an item bank of health literacy questions for public sector patients in South Africa
Chipiwa Marimwe: 2015-2016

Date: _____	Interview site: _____
Interviewer: _____	Interpreter: _____
Participant: _____	Participant number: _____
Participant contact number: _____	

1. TIME-TO SIGN (TTS)

	Time
Time taken to sign consent form (secs) <div style="border: 1px solid black; width: 400px; height: 50px; margin: 10px auto; text-align: center; vertical-align: middle;"> _____ <i>Sign here</i> </div>	

2. DEMOGRAPHICS

We would first like to ask you some questions about yourself			Score
2.1	Gender	1 = Male 2 = Female	
2.2	Age	1 = 18 - 29 2 = 30 - 44 3 = 45 - 59 4 = ≥60 Number of years:	
2.3	Race	1 = Black 2 = White 3 = Coloured 4 = Asian	
2.4	What is your home language?	1 = Xhosa 2 = English 3 = Zulu 4 = Afrikaans 5 = Venda 6 = Ndebele 7 = Tsonga 8 = Swazi 9 = Tswana 10 = Sotho 11 = Northern Sotho	
2.5	Education	1 = Grade 0- 4 2 = Grade 5 - 7 3 = Grade 8- 10 4 = Grade 11 - 12 Grade: Number of years:	
2.6	Are you employed?	1 = Yes 0 = No	
2.7	Type of employment	1 = Not employed 2 = Predominantly manual 3 = Predominantly non-manual	
2.8	Do you receive a government grant?	1 = Yes 0 = No	
2.9	If yes, what type of grant?	1 = child support 2 = foster care 3 = disability 4 = older persons 5 = war veterans 6 = care dependency 7 = social relief of distress 8 = grants in aid 9 = N/A	
2.10	How much do you receive for your grant?		

2.11	Income	1 = < R2000 2 = R2000- R4999 3= R5000- R10000 4 = > R10000 5= N/A					
2.12	How many people are currently living in your house?						
2.13	Self-reported isiXhosa literacy	1 = Listen (verbal understanding) 2 = Listen and respond (but not able to read) 3 = Listen, speak and read					
2.14	Self-reported English literacy	0 = No understanding 1 = Listen (verbal understanding) 2 = Listen and respond (but not able to read) 3 = Listen, speak and read					
2.15	Do you have a long term health condition?	1 = Yes 0 = No					
2.16	If yes, for how many conditions?						
2.17	Chronic condition	1		Hypertension			
		2		Diabetes			
		3		HIV/AIDS			
		4		TB			
		5		Other (Specify)			
		6		None			
2.18	How many prescribed medicines do you take?						
2.19	How would you rate your overall health?	1 = Poor 2 = Fair 3 = Good					
2.20	Where do you obtain most of your health information?	1		Doctors	7		Television
		2		Nurses	8		Radio
		3		Pharmacists	9		Newspapers
		4		Community health worker	10		Family
		5		Information leaflets	11		Friends/coworkers
		6		Internet			
2.21	Do you have a computer?	1 = Yes 0 = No					
2.22	Do you know how to use a computer?	1 = Yes 0 = No					
2.23	Do you know how to look for information on a computer?	1 = Yes 0 = No					
2.24	Do you have a cellphone?	1 = Yes 0 = No					
2.25	How often do you use your cellphone?	1= Most of the time (with you most of the time) 2= Sometimes 3=Never 4=N/A					
2.26	Is your cellphone a smartphone?	0 = No 1 = Yes 2 = N/A					
2.27	Can you use your cell phone to look for health information?	0 = No 1 = Yes 2= N/A					

3. MULTIDIMENSIONAL SCREENER OF FUNCTIONAL HEALTH LITERACY (MSFHL)

			Score
3.1	Educational attainment* What grade did you complete at school? <i>*Highest grade completed (in years)</i>	0 = 0 - 3 years 1 = 4 - 7 years 2 = 8 - 11 years 3 = ≥12 years	
3.2	Mother's educational attainment* What grade did your mother complete at school? <i>*Individuals who are unable to give an exact answer should be asked to make an estimation.</i>	0 = 0 - 3 years 0 = 4 - 7 years 1 = 8 - 11 years 1 = ≥12 years	
3.3	Lifetime occupation* What sort of work/job have you done for most of your life? <i>*Manual occupations - do not require intensive training or supervisory elements (e.g. farming, mining, construction, manufacturing, mechanical maintenance, garden maintenance, housekeeping and cleaning). Or never had a paid job.</i>	0 = Predominantly manual 1 = Predominantly non-manual	
3.4	Use of technology* How often do you use a computer? <i>*Desktops, laptops, and tablets should be considered computer</i>	0 = Do not use computers or do it only occasionally 1 = Use computers at least once a week	
3.5	Writing If there was a job that involved a lot of writing, do you think you would be able to do it?	0 = Difficulty with writing 1 = Some difficulty with writing 2 = No difficulty with writing	
3.6	Reading If you buy medicine at a shop or a pharmacy, do you have difficulty reading the information leaflet inside the box, or reading the instructions on how to take the medicine? <i>(show image of the medication instructions on a box)</i>	0 = Difficulty with reading 1 = Some difficulty with reading 2 = No difficulty with reading	
Total Score (out of 10) Interpretation 0 - 3: Inadequate functional health literacy 4 - 5: Marginal functional health literacy ≥ 6: Adequate functional health literacy			
Time taken for MFSHL (mins)			



4. HEALTH LITERACY QUESTIONS

			Score
4.1	Are there people who visit your community to talk about health and illness and how to care for yourself?	0=never 1= occasionally 2=frequently	
4.2	If you have TB, feel very weak and need help, and there is no one to care of you at home, is there anyone from the community who will visit you and take care of you?	0=no 1= maybe/unsure 2=Yes	
4.3	If you have an operation, is there a family member who can care for you after you leave the hospital?	0=no 1= sometimes 2=yes	
4.4	When you go and see the doctor/nurse, do you ever ask them questions about a problem with your health?	0=never 1= sometimes 2= often	
4.5	If you don't understand what the nurse/doctor/ pharmacist says, do you usually ask them to give you more information and explain things to you?	0=never 1= sometimes 2=often	
4.6	When you want to find out more about a health problem, do you think your friends and neighbours would give you good information and advice about your problem?	0=yes 1=unsure/maybe 2=no	
4.7	Do you know how to use the internet to answer your health-related questions?	0=no 2=yes	
4.8	Are you always able to get transport to go to the clinic when you need to?	0=no 1= sometimes 2=yes	
4.9	If you feel stressed or worried about a problem, would you require someone who would help you or would you be able to face this yourself?	0= requires help 1= may require help 2=no help required	
4.10	Is it easy for you to understand the instructions for your medication?	0=no 1= sometimes 2=yes	
4.11	How often do you have problems learning about your medical conditions because it is difficult to understand written information?	0= always/ often 1=occasionally/sometimes 2=never	
4.12	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist? <i>(show image of the information leaflet)</i>	0= always/ often 1=occasionally/sometimes 2=never	
4.13	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be? <i>Correct answer: 21st of March</i>	0=incorrect 2=correct	
4.14	Next winter 4 out of 20 people have a chance of getting a cold. What is the percentage (%) chance of getting a cold? <i>Correct answer: 20%</i>	0=incorrect 2=correct	
4.15	You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one? <i>Correct answer: 3pm</i>	0=incorrect 2=correct	
4.16	You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to. <i>(show image of the syringe)</i>	0=incorrect 2=correct	
4.17	Choose which plate of food you think is healthier: Plate 1:	0=incorrect	

	chicken stew, rice and spinach; Plate 2: fried chicken and chips. <i>Correct answer: Plate 1: chicken stew, rice and spinach</i>	2=correct	
4.18	After you have seen the nurse/doctor at the clinic, is it acceptable for the nurse/doctor to discuss your health issue with other people who are not health colleagues? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.19	Do you think that health information from the internet is always good information that you can trust? <i>Correct answer: No</i>	0=yes 2=no	
4.20	What is a normal body temperature? <i>Correct answer: 36-37.5°C</i>	0=incorrect 2=correct	
4.21	Can you explain what diabetes is? <i>Correct answer: Any mention of high levels of sugar in the blood</i>	0=incorrect 2=correct	
4.22	Certain people have a higher risk of developing diabetes. Is a thin person more likely to develop diabetes than an overweight person? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.23	If your blood pressure reading is 160/100, what does that mean? <i>Correct answer: blood pressure is high</i>	0=incorrect 2=correct	
4.24	Can HIV/AIDS be cured? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.25	Can you get TB if you use the same toilet as someone with TB? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.26	Is someone with HIV/AIDS at a high or low risk of getting TB? <i>Correct answer: High risk of getting TB</i>	0=incorrect 2=correct	
4.27	Do you make the time to exercise (walk, play sport for about 30 minutes) at least three times every week?	0=no 1= sometimes 2=yes	
4.28	When taking antibiotics, you are told to finish the course. Can you then stop taking the antibiotics as soon as you start to feel better? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.29	You are given a new medicine at the clinic. At home you have been taking herbal/traditional medicine. What should you do? <i>Correct answer: tell the doctor/nurse/pharmacist, I only take medicines from the clinic or I do not take them at the same time.</i>	0=incorrect 2=correct	
4.30	Herbal/traditional medicines are natural and are from plants. Are they always safe to take? <i>Correct answer: No</i>	0=incorrect 2=correct	
Total Score			
Time taken (mins)			
TOTAL TIME TAKEN FOR ENTIRE INTERVIEW (MINS)			

PATIENT INFORMATION LEAFLET

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S4

NAME, STRENGTH AND DOSAGE FORM:

ASPEN LEVOFLOXACIN 250 mg tablets

ASPEN LEVOFLOXACIN 500 mg tablets

WHAT THIS MEDICINE CONTAINS

Each 250 mg tablet contains Levofloxacin 250 mg as Levofloxacin hemihydrate.
Each 500 mg tablet contains Levofloxacin 500 mg as Levofloxacin hemihydrate.

WHAT THIS MEDICINE IS USED FOR

Levofloxacin is a fluoroquinolone-type antibiotic. It works by killing bacteria or preventing their growth. ASPEN LEVOFLOXACIN is used in adults to treat bacterial infections such as bronchitis, pneumonia, sinusitis, urinary tract infections, skin and soft tissue infections and infections in the abdomen.

BEFORE YOU TAKE THIS MEDICINE

Do not take ASPEN LEVOFLOXACIN:

- If you are hypersensitive (allergic) to levofloxacin, to other quinolone-type antibiotics or to any of the other ingredients of ASPEN LEVOFLOXACIN.
- If you have epilepsy – ASPEN LEVOFLOXACIN may increase the chance of a seizure.
- If you have developed a tendon disorder following the use of another fluoroquinolone-type antibiotic.
- If you are pregnant or breast-feeding.

ASPEN LEVOFLOXACIN should not be used in children under the age of 18 years.

Take special care with ASPEN LEVOFLOXACIN:

- If you have brain or spinal cord disease or a history of seizures - ASPEN LEVOFLOXACIN may increase the chance of a seizure.
- If you are taking inflammation or pain medicine of the NSAID class or if you are taking theophylline – These medicines may increase the chance of a seizure.
- If you have diabetes mellitus (sugar diabetes) – ASPEN LEVOFLOXACIN may cause changes in blood sugar levels.
- If you have kidney disease – The effects of ASPEN LEVOFLOXACIN may be increased because of slower removal from the body.
- If you have porphyria – ASPEN LEVOFLOXACIN may trigger an attack of porphyria.

Taking ASPEN LEVOFLOXACIN with food and drink:

ASPEN LEVOFLOXACIN may be taken with food or on an empty stomach.

Drink plenty of water while you take this medicine.

Pregnancy and breast-feeding:

ASPEN LEVOFLOXACIN should not be used during pregnancy or while breast-feeding.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

ASPEN LEVOFLOXACIN may cause dizziness or drowsiness. Make sure you know how you react to this medicine before you drive or use machines that require you to be alert.

Important information about ASPEN LEVOFLOXACIN:

ASPEN LEVOFLOXACIN may make your skin more sensitive to the sun and ultraviolet light.

Stay out of the direct sun and do not use a sun bed or sunlamp while you take this medicine.

Before you have a tuberculosis test, tell the doctor that you are taking this medicine.

Taking other medicines with ASPEN LEVOFLOXACIN:

ASPEN LEVOFLOXACIN should not be taken together with:

- Antacids (magnesium- or aluminium-containing), sucralate or iron salts – These medicines may reduce the absorption of ASPEN LEVOFLOXACIN by the body. Take ASPEN LEVOFLOXACIN either two hours before or two hours after taking these medicines.
- Theophylline, inflammation or pain medicine from the NSAID class - These medicines may increase the chance of a seizure.
- Warfarin (blood thinner) – The chance of bleeding is increased.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ASPEN LEVOFLOXACIN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE THIS MEDICINE

Always take ASPEN LEVOFLOXACIN exactly as your doctor has instructed you. Take ASPEN LEVOFLOXACIN for the full time of treatment, even if you start to feel better within a few days.

If your symptoms do not improve within a few days or if they get worse, contact your doctor.

Dosage (adults):

The dosage of ASPEN LEVOFLOXACIN depends on the type and the severity of infection. The length of time that you take ASPEN

LEVOFLOXACIN also depends on the nature of the infection. The usual dose range is 250 to 500 mg once or twice daily. The dose of ASPEN LEVOFLOXACIN may need to be reduced if you have kidney problems.

Swallow ASPEN LEVOFLOXACIN tablets whole with a full glass of water. The tablets may be broken along the score-line.

If you have the impression that the effect of ASPEN LEVOFLOXACIN is too strong or too weak, talk to your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

If you take more ASPEN LEVOFLOXACIN than you should:

Dizziness, confusion, loss of consciousness and fits can occur. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ASPEN LEVOFLOXACIN:

This medicine works best when there is a constant amount in the blood. To help keep the amount constant, do not miss any doses.

If you do miss a dose of this medicine, take it as soon as you remember. If you don't remember until the next day, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ASPEN LEVOFLOXACIN is stopped:

After you stop taking this medicine, your body may need some time to adjust. During this time, contact your doctor at once if you develop severe abdominal pain or stomach cramps, diarrhoea (watery and severe and may also be bloody) or fever.

POSSIBLE SIDE-EFFECTS

Like all medicines, ASPEN LEVOFLOXACIN can have side-effects.

If any of the following minor side-effects continue, are severe or bother you, speak to your doctor or pharmacist:

Frequent:

- Nausea, diarrhoea

Less frequent:

- Loss of appetite, vomiting, abdominal pain or discomfort, headache, dizziness, drowsiness, trouble in sleeping, vaginal itching or discharge.

If any of the following side-effects occur, speak to your doctor or pharmacist as soon as possible:

Less frequent or rare:

- Unusual bleeding or bruising, mood or mental changes, low blood sugar in diabetic patients, tremor, fits, numbness, tingling or painful sensations, changes in taste, smell, touch, vision or hearing, fainting, yellowing of the skin or eyes, sun sensitivity, blistering, peeling or loosening of skin, pain, swelling or inflammation in calves, shoulders or hands, joint pain, muscle pain, stiffness or weakness, problems with passing urine.

If any of the following side-effects occur, speak to your doctor immediately:

Rare:

- Skin rash, itching or redness, difficult breathing, tightness of chest, swelling of the eyelids, lips, face or tongue, severe dizziness, hallucinations, psychotic reactions, severe, persistent or bloody diarrhoea, fever.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF THIS MEDICINE

Store in a dry place (below 25 °C). Protect from light.

Keep the tablets in the outer container until required for use.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION

Aspen Levofloxacin 250 mg: 5 tablets are packed into Al-PVC blisters;

Aspen Levofloxacin 500 mg: 5 tablets and 10 tablets are packed into Al-PVC blisters

IDENTIFICATION

ASPEN LEVOFLOXACIN 250 mg:

Pink, oval, film-coated, biconvex 6 x 13 mm, scored on one face with side scores and an engraved "L" on the unscored face, OR with a C03 embossed on one side and a deep bisect line on the other side.

ASPEN LEVOFLOXACIN 500 mg:

Pink, oval, film-coated, biconvex 8 x 16 mm, scored on one face with side scores and an engraved "L" on the unscored face, OR with C04 embossed on one side and a deep bisect line on the other side.

REGISTRATION NUMBER

ASPEN LEVOFLOXACIN 250 mg: 42/20.1.1/0509

ASPEN LEVOFLOXACIN 500 mg: 42/20.1.1/0510

NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMACARE LIMITED

Building 12

Healthcare Park

Woodlands Drive

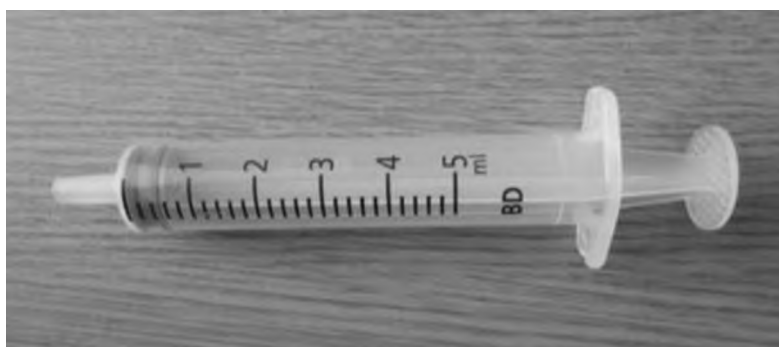
Woodmead

2191

DATE OF PUBLICATION

4 December 2008

1018101-02



APPENDIX E

QUESTIONNAIRE

Development of an item bank of health literacy questions for public sector patients in South Africa
Chipiwa Marimwe: 2015-2016

Date: _____	Interview site: _____
Interviewer: _____	Interpreter: _____
Participant: _____	Participant number: _____
Participant contact number: _____	

1. TIME-TO SIGN (TTS)

	Time
Time taken to sign consent form (secs) <div style="border: 1px solid black; width: 400px; height: 50px; margin: 10px auto; position: relative;"> <div style="position: absolute; bottom: 5px; right: 5px; text-align: right;"> <i>Sign here</i> </div> </div>	

2. DEMOGRAPHICS

We would first like to ask you some questions about yourself			Score
2.1	Gender	1 = Male 2 = Female	
2.2	Age	1 = 18 - 29 2 = 30 - 44 3 = 45 - 59 4 = ≥60 Number of years:	
2.3	Race	1 = Black 2 = White 3 = Coloured 4 = Asian	
2.4	What is your home language?	1 = Xhosa 2 = English 3 = Zulu 4 = Afrikaans 5 = Venda 6 = Ndebele 7 = Tsonga 8 = Swazi 9 = Tswana 10 = Sotho 11 = Northern Sotho	
2.5	Education	1 = Grade 0- 4 2 = Grade 5 - 7 3 = Grade 8- 10 4 = Grade 11 - 12 Grade: Number of years:	
2.6	Are you employed?	1 = Yes 0 = No	
2.7	Type of employment	1 = Not employed 2 = Predominantly manual 3 = Predominantly non-manual	
2.8	Do you receive a government grant?	1 = Yes 0 = No	
2.9	If yes, what type of grant?	1 = child support 2 = foster care 3 = disability 4 = older persons 5 = war veterans 6 = care dependency 7 = social relief of distress 8 = grants in aid 9 = N/A	
2.10	How much do you receive for your grant?		

2.11	Income	1 = < R2000 2 = R2000- R4999 3= R5000- R10000 4 = > R10000 5= N/A						
2.12	How many people are currently living in your house?							
2.13	Self-reported isiXhosa literacy	1 = Listen (verbal understanding) 2 = Listen and respond (but not able to read) 3 = Listen, speak and read						
2.14	Self-reported English literacy	0 = No understanding 1 = Listen (verbal understanding) 2 = Listen and respond (but not able to read) 3 = Listen, speak and read						
2.15	Do you have a long term health condition?	1 = Yes 0 = No						
2.16	If yes, for how many conditions?							
2.17	Chronic condition	1		Hypertension				
		2		Diabetes				
		3		HIV/AIDS				
		4		TB				
		5		Other (Specify)				
		6		None				
2.18	How many prescribed medicines do you take?							
2.19	How would you rate your overall health?	1 = Poor 2 = Fair 3 = Good						
2.20	Where do you obtain most of your health information?	1		Doctors	7		Television	
		2		Nurses	8		Radio	
		3		Pharmacists	9		Newspapers	
		4		Community health worker	10		Family	
		5		Information leaflets	11		Friends/coworkers	
		6		Internet				
2.21	Do you have a computer?	1 = Yes 0 = No						
2.22	Do you know how to use a computer?	1 = Yes 0 = No						
2.23	Do you know how to look for information on a computer?	1 = Yes 0 = No						
2.24	Do you have a cellphone?	1 = Yes 0 = No						
2.25	How often do you use your cellphone?	1= Most of the time (with you most of the time) 2= Sometimes 3=Never 4=N/A						
2.26	Is your cellphone a smartphone?	0 = No 1 = Yes 2 = N/A						
2.27	Can you use your cell phone to look for health information?	0 = No 1 = Yes 2= N/A						

3. MULTIDIMENSIONAL SCREENER OF FUNCTIONAL HEALTH LITERACY (MSFHL)

			Score
3.1	Educational attainment* What grade did you complete at school? <i>*Highest grade completed (in years)</i>	0 = 0 - 3 years 1 = 4 - 7 years 2 = 8 - 11 years 3 = ≥12 years	
3.2	Mother's educational attainment* What grade did your mother complete at school? <i>*Individuals who are unable to give an exact answer should be asked to make an estimation.</i>	0 = 0 - 3 years 0 = 4 - 7 years 1 = 8 - 11 years 1 = ≥12 years	
3.3	Lifetime occupation* What sort of work/job have you done for most of your life? <i>*Manual occupations - do not require intensive training or supervisory elements (e.g. farming, mining, construction, manufacturing, mechanical maintenance, garden maintenance, housekeeping and cleaning). Or never had a paid job.</i>	0 = Predominantly manual 1 = Predominantly non-manual	
3.4	Use of technology* How often do you use a computer? <i>*Desktops, laptops, and tablets should be considered computer</i>	0 = Do not use computers or do it only occasionally 1 = Use computers at least once a week	
3.5	Writing If there was a job that involved a lot of writing, do you think you would be able to do it?	0 = Difficulty with writing 1 = Some difficulty with writing 2 = No difficulty with writing	
3.6	Reading If you buy medicine at a shop or a pharmacy, do you have difficulty reading the information leaflet inside the box, or reading the instructions on how to take the medicine? <i>(show image of the medication instructions on a box)</i>	0 = Difficulty with reading 1 = Some difficulty with reading 2 = No difficulty with reading	
Total Score (out of 10) Interpretation 0 - 3: Inadequate functional health literacy 4 - 5: Marginal functional health literacy ≥ 6: Adequate functional health literacy			
Time taken for MFSHL (mins)			



ENGLISH VERSION

4. HEALTH LITERACY QUESTIONS

			Score
4.1	Are there people who visit your community to talk about health and illness and how to care for yourself?	0=never 1= occasionally 2=frequently	
4.2	If you have TB, feel very weak and need help, and there is no one to care of you at home, is there anyone from the community who will visit you and take care of you?	0=no 1= maybe/unsure 2=Yes	
4.3	If you have an operation, is there a family member who can care for you after you leave the hospital?	0=no 1= sometimes 2=yes	
4.4	When you go and see the doctor/nurse, do you ever ask them questions about a problem with your health?	0=never 1= sometimes 2= often	
4.5	If you don't understand what the nurse/doctor/ pharmacist says, do you usually ask them to give you more information and explain things to you?	0=never 1= sometimes 2=often	
4.6	When you want to find out more about a health problem, do you think your friends and neighbours would give you good information and advice about your problem?	0=yes 1=unsure/maybe 2=no	
4.7	Do you know how to use the internet to answer your health-related questions?	0=no 2=yes	
4.8	Are you always able to get transport to go to the clinic when you need to?	0=no 1= sometimes 2=yes	
4.9	If you feel stressed or worried about a problem, would you require someone who would help you or would you be able to face this yourself?	0= requires help 1= may require help 2=no help required	
4.10	Is it easy for you to understand the instructions for your medication?	0=no 1= sometimes 2=yes	
4.11	How often do you have problems learning about your medical conditions because it is difficult to understand written information?	0= always/ often 1=occasionally/sometimes 2=never	
4.12	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist? <i>(show image of the information leaflet)</i>	0= always/ often 1=occasionally/sometimes 2=never	
4.13	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be? <i>Correct answer: 21st of March</i>	0=incorrect 2=correct	
4.14	Next winter 4 out of 20 people have a chance of getting a cold. What is the percentage (%) chance of getting a cold? <i>Correct answer: 20%</i>	0=incorrect 2=correct	
4.15	You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one? <i>Correct answer: 3pm</i>	0=incorrect 2=correct	
4.16	You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	0=incorrect 2=correct	

	<i>(show image of the syringe)</i>		
4.17	Choose which plate of food you think is healthier: Plate 1: chicken stew, rice and spinach; Plate 2: fried chicken and chips. <i>Correct answer: Plate 1: chicken stew, rice and spinach</i>	0=incorrect 2=correct	
4.18	After you have seen the nurse/doctor at the clinic, is it acceptable for the nurse/doctor to discuss your health issue with other people who are not health colleagues? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.19	Do you think that health information from the internet is always good information that you can trust? <i>Correct answer: No</i>	0=yes 2=no	
4.20	What is a normal body temperature? <i>Correct answer: 36-37.5°C</i>	0=incorrect 2=correct	
4.21	Can you explain what diabetes is? <i>Correct answer: Any mention of high levels of sugar in the blood</i>	0=incorrect 2=correct	
4.22	Certain people have a higher risk of developing diabetes. Is a thin person more likely to develop diabetes than an overweight person? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.23	Which of the three blood pressure readings is closest to a normal blood pressure reading? <i>(show image of the blood pressure reading)</i> <i>Correct answer: 120/80</i>	0=incorrect 2=correct	
4.24	Can HIV/AIDS be cured? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.25	Can you get TB if you use the same toilet as someone with TB? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.26	Is someone with HIV/AIDS at a high or low risk of getting TB? <i>Correct answer: High risk of getting TB</i>	0=incorrect 2=correct	
4.27	Do you make the time to exercise (walk, play sport for about 30 minutes) at least three times every week?	0=no 1= sometimes 2=yes	
4.28	When taking antibiotics, you are told to finish the course. Can you then stop taking the antibiotics as soon as you start to feel better? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.29	You are given a new medicine at the clinic. At home you have been taking herbal/traditional medicine. What should you do? <i>Correct answer: tell the doctor/nurse/pharmacist, I only take medicines from the clinic or I do not take them at the same time.</i>	0=incorrect 2=correct	
4.30	Herbal/traditional medicines are natural and are from plants. Are they always safe to take? <i>Correct answer: No</i>	0=incorrect 2=correct	
Total Score			
Time taken (mins)			
TOTAL TIME TAKEN FOR ENTIRE INTERVIEW (MINS)			

ISIXHOSA VERSION

4. HEALTH LITERACY QUESTIONS

			Inqaku
4.1	Bakhona abantu abezayo kwindawo ohlala kuyo ukuza kuthetha ngempilo nangokugula, nangendlela yokuzinakekela?	0= zange 1= ngamamaxesha athile 2= rhoqo	
4.2	Ukuba une-TB, uzive utyhafile kakhulu yaye udinga uncedo, kube kungekho mntu wokukunakekela ekhayeni lakho, ngaba ukhona umntu endaweni ohlala kuyo ongakuhambela, akunakekele?	0=hayi 1= akaqinisekanga 2=ewe	
4.3	Ukuba uthe wenziwa utyando, ngaba ukhona umntu efemelini yakho oza kukunakekela xa uphumileyo esibhedlele?	0= hayi 1= ngamanye amaxesha 2=ewe	
4.4	Xa uthe waya kubona ugqirha/unesi ukhe umbuze imibuzo ngengxaki malunga nempilo yakho?	0= zange 1= ngamanye amaxesha 2= kaninzi	
4.5	Ukuba awuyiqondi into ethetha ngunesi/ngugqirha/ngusokhemesti, ngaba uyamcela akunike ulwazi olungaphezulu, akucacisele izinot ongaziqondiyo?	0= zange 1= ngamanye amaxesha 2= kaninzi	
4.6	Xa ufuna ukwazi nangakumbi ngengxaki ethile malunga nengxaki yempilo, ucinga ukuba abahlobo bakho nabamelwane bakho bangakunika ulwazi neengcebiso ezilungileyo malunga nengxaki leyo?	0=ewe 1= akaqinisekanga/ mhlawumbi 2=hayi	
4.7	Ngaba uyakwazi ukusebenzisa i-intanethi ekukuncedeni ukuphendula imibuzo enxulumene nempilo yakho?	0=hayi 1= 2=ewe	
4.8	Ngaba uyakwazi ngalo lonke ixesha ukufumana isithuthi sokukusa ekliniki xa ufunayo?	0=hayi 1=ngamanye amaxesha 2=ewe	
4.9	Xa uziva unxunguphele okanye unenxalabo ngengxaki ethile, ngaba udinga umntu onokukunceda okanye uzibona unako ukujongana nayo le nto ngokwakho?	0=hayi 1=mhlawumbi 2=ewe	
4.10	Ingaba kulula kuwe ukuyiqonda imiyalelo yamayeza akho?	0=hayi 1=ngamanye amaxesha 2=ewe	
4.11	Kukangaphi apho ube neengxaki ngokufunda ngezigulo zakho kuba kunzima ukuqonda iinkcukacha ezibhaliweyo?	0= lonke ixesha/kaninzi 1= ngamanye 2maxesha/ngamaxesha athile 2= zange	
4.12	Kukangaphi apho kufuneka kubekho umntu omakakuncede xa ufunda imiyalelo, amaphetshana nezinye izinto ezibhaliweyo ezivela kugqirha wakho/unesi nosokhemesti?	0= lonke ixesha/kaninzi 1= ngamanye amaxesha/ngamaxesha athile 2= zange	
4.13	Ukuba uye ekliniki ngomhla wesi-7 kuMatshi, ze kuthiwe uze ubuyele ekliniki emva kweeveki ezimbini, iya kube ingumhla wesingaphi le mini kufuneka ubuyele ngayo? <i>21st of march</i>	0= ayichanekanga 2=ichanekile	
4.14	Ebusika kunyaka ozayo ba-4 kubantu abangama-20 abanethuba lokugula ngengqele. Mangakanani amathuba, ngokwepesenti (%) okuba ungagula yingqele? <i>20%</i>	0= ayichanekanga 2=ichanekile	
4.15	Uxelelwa ukuba uthathe ipilisi enye (1) kathathu (3) ngemini, qho emva kweeyure ezisibhozo. Ukuba uthatha	0= ayichanekanga 2=ichanekile	

	ipilisi yakho yokuqala yonke imihla ngo-7 kusasa, kufanele uyithathe nini elandelayo? ngo-3 emva kwemini		
4.16	Uxelelwa ukuba unike umntwana umlinganiselo oyi-2 ml yeyeza ngesirinji. Ndicela undibonise kwisirinji ukuba uza kuwenza ubengakanani lo mlinganiselo.	0= ayichanekanga 2=ichanekile	
4.17	Khetha eyona pleyiti ucinga ukuba inesidlo esifanelekileyo ngokwempilo. Ipleyiti 1: isityu senkuku, irayisi, isipinatshi; Ipleyiti 2: Inkuku efrayishiweyo neetshipshi ? <i>Isityu senyama yenkuku, irayisi nesipinatshi</i>	0= ayichanekanga 2=ichanekile	
4.18	Emva kokuba ubonene nonesi/nogqirha ekliniki, ngaba kwamkelekile ukuba unesi/ugqirha athethe ngempilo yakho nabanye abantu abangengabo oonesi noogqirha <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.19	Ucinga ukuba iinkcukacha nolwazi olufumaneka kwi-intanethi ngezempilo lulwazi olulungileyo ongaluthemba? <i>Hayi</i>	0=ewe 2=hayi	
4.20	Lithini iqondo lobushushu (ithempitsha) lesiqhelo lomzimba? <i>36-37.5°C</i>	0= ayichanekanga 2=ichanekile	
4.21	Ungacacisa uthi yintoni na isifo seswekile? Ukuba nje kukhankanywe nantoni na emalunga nezinga eliphezulu leswekile egazini	0= ayichanekanga 2=ichanekile	
4.22	Ngabantu abathile abasemngciphekweni wokufumana isifo seswekile. Ngaba umntu obhityileyo unelona nethuba liphezulu lokufumana isifo seswekile kunomntu otyebileyo? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.23	Sesiphi kwezi ziphumo zintathu <i>zeblood pressure</i> esisondeleyo kwisiphumo esamkelekileyo? <i>120/180</i>	0= ayichanekanga 2=ichanekile	
4.24	Ngaba i-HIV/AIDS inganyangeka? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.25	Ungayifumana iTB ngokusebenzisa ithoyilethi esetyenziswa ngumntu oneTB? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.26	Ngaba umntu oneHIV/AIDS usemngciphekweni ophezulu okanye ophantsi wokufumana iTB? <i>Usemngciphekweni ophezulu</i>	0= ayichanekanga 2=ichanekile	
4.27	Uyalenza na ixesha lokwenza imithambo yomzimba (ukuhamba-hamba, ukwenza ezemidlalo imizuzu emalunga nama-30) ubuncinane kathathu qho ngeveki?	0=hayi 1=ngamanye amaxesha 2=ewe	
4.28	Xa uthatha ii-antibiotics uye exelelwe ukuba uzigqibe ezimiselweyo. Ngaba oku kuthetha ukuba ungayeka ukuzisela ii-antibiotics wakuba uziva bhetele? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.29	Unikwa amayeza amatsha ekliniki. Ekhaya ubusebenzisa amayeza nemithi ubuyifumene egqirheni. Wenza ntoni? <i>Xelela ugqirha/unesi/usokhemesti</i>	0=ayichanekanga 2=ichanekile	
4.30	Amayeza enziwe ngezityalo/egqirha akaxutywanga namachiza. Ngaba kusoloko kukhuselekile ukuwasebenzisa? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
Total Score			
Time taken (mins)			
TOTAL TIME TAKEN FOR ENTIRE INTERVIEW (MINS)			

PATIENT INFORMATION LEAFLET

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS: S4

NAME, STRENGTH AND DOSAGE FORM:

ASPEN LEVOFLOXACIN 250 mg tablets ASPEN LEVOFLOXACIN 500 mg tablets

WHAT THIS MEDICINE CONTAINS

Each 250 mg tablet contains Levofloxacin 250 mg as Levofloxacin hemihydrate.
Each 500 mg tablet contains Levofloxacin 500 mg as Levofloxacin hemihydrate.

WHAT THIS MEDICINE IS USED FOR

Levofloxacin is a fluoroquinolone-type antibiotic. It works by killing bacteria or preventing their growth. ASPEN LEVOFLOXACIN is used in adults to treat bacterial infections such as bronchitis, pneumonia, sinusitis, urinary tract infections, skin and soft tissue infections and infections in the abdomen.

BEFORE YOU TAKE THIS MEDICINE

Do not take ASPEN LEVOFLOXACIN:

- If you are hypersensitive (allergic) to levofloxacin, to other quinolone-type antibiotics or to any of the other ingredients of ASPEN LEVOFLOXACIN.
- If you have epilepsy – ASPEN LEVOFLOXACIN may increase the chance of a seizure.
- If you developed a tendon disorder following the use of another fluoroquinolone-type antibiotic.
- If you are pregnant or breast-feeding.

ASPEN LEVOFLOXACIN should not be used in children under the age of 18 years.

Take special care with ASPEN LEVOFLOXACIN:

- If you have brain or spinal cord disease or a history of seizures - ASPEN LEVOFLOXACIN may increase the chance of a seizure.
- If you are taking inflammation or pain medicine of the NSAID class or if you are taking theophylline – These medicines may increase the chance of a seizure.
- If you have diabetes mellitus (sugar diabetes) – ASPEN LEVOFLOXACIN may cause changes in blood sugar levels.
- If you have kidney disease – The effects of ASPEN LEVOFLOXACIN may be increased because of slower removal from the body.
- If you have porphyria – ASPEN LEVOFLOXACIN may trigger an attack of porphyria.

Taking ASPEN LEVOFLOXACIN with food and drink:

ASPEN LEVOFLOXACIN may be taken with food or on an empty stomach.

Drink plenty of water while you take this medicine.

Pregnancy and breast-feeding:

ASPEN LEVOFLOXACIN should not be used during pregnancy or while breast-feeding.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

ASPEN LEVOFLOXACIN may cause dizziness or drowsiness. Make sure you know how you react to this medicine before you drive or use machines that require you to be alert.

Important information about ASPEN LEVOFLOXACIN:

ASPEN LEVOFLOXACIN may make your skin more sensitive to the sun and ultraviolet light. Stay out of the direct sun and do not use a sun bed or sunlamp while you take this medicine.

Before you have a tuberculosis test, tell the doctor that you are taking this medicine.

Taking other medicines with ASPEN LEVOFLOXACIN:

ASPEN LEVOFLOXACIN should not be taken together with:

- Antacids (magnesium- or aluminium-containing), sucralate or iron salts – These medicines may reduce the absorption of ASPEN LEVOFLOXACIN by the body. Take ASPEN LEVOFLOXACIN either two hours before or two hours after taking these medicines.
- Theophylline, inflammation or pain medicine from the NSAID class - These medicines may increase the chance of a seizure.
- Warfarin (blood thinner) – The chance of bleeding is increased.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ASPEN LEVOFLOXACIN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE THIS MEDICINE

Always take ASPEN LEVOFLOXACIN exactly as your doctor has instructed you. Take ASPEN LEVOFLOXACIN for the full time of treatment, even if you start to feel better within a few days.

If your symptoms do not improve within a few days or if they get worse, contact your doctor.

Dosage (adults):

The dosage of ASPEN LEVOFLOXACIN depends on the type and the severity of infection. The length of time that you take ASPEN

LEVOFLOXACIN also depends on the nature of the infection. The usual dose range is 250 to 500 mg once or twice daily. The dose of ASPEN LEVOFLOXACIN may need to be reduced if you have kidney problems.

Swallow ASPEN LEVOFLOXACIN tablets whole with a full glass of water. The tablets may be broken along the score-line.

If you have the impression that the effect of ASPEN LEVOFLOXACIN is too strong or too weak, talk to your doctor or pharmacist. Do not share medicines prescribed for you with any other person.

If you take more ASPEN LEVOFLOXACIN than you should:

Dizziness, confusion, loss of consciousness and fits can occur. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ASPEN LEVOFLOXACIN:

This medicine works best when there is a constant amount in the blood. To help keep the amount constant, do not miss any doses.

If you do miss a dose of this medicine, take it as soon as you remember. If you don't remember until the next day, skip the missed dose and go back to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ASPEN LEVOFLOXACIN is stopped:

After you stop taking this medicine, your body may need some time to adjust. During this time, contact your doctor at once if you develop severe abdominal pain or stomach cramps, diarrhoea (watery and severe and may also be bloody) or fever.

POSSIBLE SIDE-EFFECTS

Like all medicines, ASPEN LEVOFLOXACIN can have side-effects.

If any of the following minor side-effects continue, are severe or bother you, speak to your doctor or pharmacist:

Frequent:

- Nausea, diarrhoea
- Less frequent:
 - Loss of appetite, vomiting, abdominal pain or discomfort, headache, dizziness, drowsiness, trouble in sleeping, vaginal itching or discharge.

If any of the following side-effects occur, speak to your doctor or pharmacist as soon as possible:

Less frequent or rare:

- Unusual bleeding or bruising, mood or mental changes, low blood sugar in diabetic patients, tremor, fits, numbness, tingling or painful sensations, changes in taste, smell, touch, vision or hearing, fainting, yellowing of the skin or eyes, sun sensitivity, blistering, peeling or loosening of skin, pain, swelling or inflammation in calves, shoulders or hands, joint pain, muscle pain, stiffness or weakness, problems with passing urine.

If any of the following side-effects occur, speak to your doctor immediately:

Rare:

- Skin rash, itching or redness, difficult breathing, tightness of chest, swelling of the eyelids, lips, face or tongue, severe dizziness, hallucinations, psychotic reactions, severe, persistent or bloody diarrhoea, fever.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF THIS MEDICINE

Store in a dry place (below 25 °C). Protect from light.

Keep the tablets in the outer container until required for use.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION

Aspen Levofloxacin 250 mg: 5 tablets are packed into Al-PVC blisters;

Aspen Levofloxacin 500 mg: 5 tablets and 10 tablets are packed into Al-PVC blisters

IDENTIFICATION

ASPEN LEVOFLOXACIN 250 mg:

Pink, oval, film-coated, biconvex 6 x 13 mm, scored on one face with side scores and an engraved "L" on the unscored face, OR with a C03 embossed on one side and a deep bisect line on the other side.

ASPEN LEVOFLOXACIN 500 mg:

Pink, oval, film-coated, biconvex 8 x 16 mm, scored on one face with side scores and an engraved "L" on the unscored face, OR with C04 embossed on one side and a deep bisect line on the other side.

REGISTRATION NUMBER

ASPEN LEVOFLOXACIN 250 mg: 42/20.1.1/0509

ASPEN LEVOFLOXACIN 500 mg: 42/20.1.1/0510

NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMACARE LIMITED

Building 12

Healthcare Park

Woodlands Drive

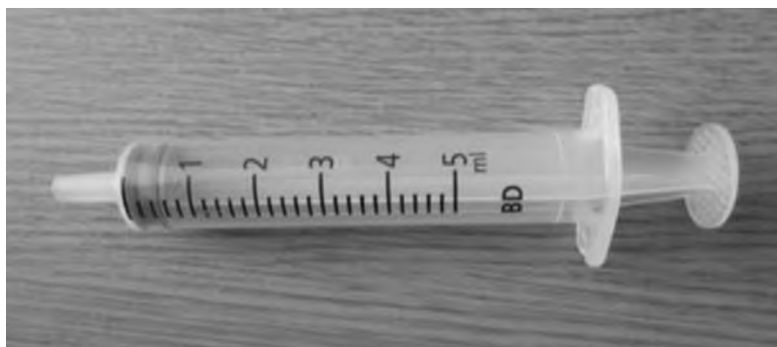
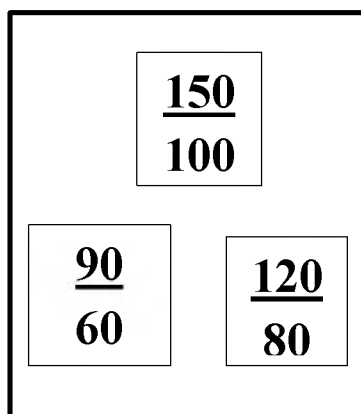
Woodmead

2191

DATE OF PUBLICATION

4 December 2008

1018101-02



APPENDIX F

QUESTIONNAIRE

Validation of a health literacy measure appropriate for public sector patients in South Africa
Chipiwa Marimwe: 2017

Date: _____	Interview site: _____
Interviewer: _____	Interpreter: _____
Participant: _____	Participant number: _____
Participant contact number: _____	

1. TIME-TO SIGN (TTS)

	Time
Time taken to sign consent form (secs) <div style="border: 1px solid black; width: 400px; height: 50px; margin: 10px auto; position: relative;"> <div style="position: absolute; bottom: 5px; right: 10px;"> <i>Sign here</i> </div> </div>	

2. DEMOGRAPHICS

We would first like to ask you some questions about yourself			Score
2.1	Gender	1 = Male 2 = Female	
2.2	Age	1 = 18 - 29 2 = 30 - 44 3 = 45 - 59 4 = ≥60 Number of years:	
2.3	Race	1 = Black 2 = White 3 = Coloured 4 = Asian	
2.4	What is your home language?	1 = Xhosa 2 = English 3 = Zulu 4 = Afrikaans 5 = Venda 6 = Ndebele 7 = Tsonga 8 = Swazi 9 = Tswana 10 = Sotho 11 = Northern Sotho	
2.5	Education	1 = Grade 0- 4 2 = Grade 5 - 7 3 = Grade 8- 10 4 = Grade 11 - 12 Grade: Number of years:	
2.6	Are you employed?	1 = Yes 0 = No	
2.7	Type of employment	1 = Not employed 2 = Predominantly manual 3 = Predominantly non-manual	
2.8	Do you receive a government grant?	1 = Yes 0 = No	
2.9	If yes, what type of grant?	1 = child support 2 = foster care 3 = disability 4 = older persons 5 = war veterans 6 = care dependency 7 = social relief of distress 8 = grants in aid 9 = N/A	

2.10	How much do you receive for your grant?						
2.11	Income	1 = < R2000 2 = R2000- R4999 3= R5000- R10000 4 = > R10000 5= N/A					
2.12	How many people are currently living in your house?						
2.13	Self-reported isiXhosa literacy	1 = Listen (verbal understanding) 2 = Listen and respond (but not able to read) 3 = Listen, speak and read					
2.14	Self-reported English literacy	0 = No understanding 1 = Listen (verbal understanding) 2 = Listen and respond (but not able to read) 3 = Listen, speak and read					
2.15	Do you have a long term health condition?	1 = Yes 0 = No					
2.16	If yes, for how many conditions?						
2.17	Chronic condition	1		Hypertension			
		2		Diabetes			
		3		HIV/AIDS			
		4		TB			
		5		Other (Specify)			
		6		None			
2.18	How many prescribed medicines do you take?						
2.19	How would you rate your overall health?	1 = Poor 2 = Fair 3 = Good					
2.20	Where do you obtain most of your health information?	1		Doctors	7		Television
		2		Nurses	8		Radio
		3		Pharmacists	9		Newspapers
		4		Community health worker	10		Family
		5		Information leaflets	11		Friends/coworkers
		6		Internet			
2.21	Do you have a computer?	1 = Yes 0 = No					
2.22	Do you know how to use a computer?	1 = Yes 0 = No					
2.23	Do you know how to look for information on a computer?	1 = Yes 0 = No					
2.24	Do you have a cellphone?	1 = Yes 0 = No					
2.25	How often do you use your cellphone?	1= Most of the time (with you most of the time) 2= Sometimes 3=Never 4=N/A					
2.26	Is your cellphone a smartphone?	0 = No 1 = Yes 2 = N/A					
2.27	Can you use your cell phone to look for health information?	0 = No 1 = Yes 2= N/A					

3. MULTIDIMENSIONAL SCREENER OF FUNCTIONAL HEALTH LITERACY (MSFHL)

			Score
3.1	Educational attainment* What grade did you complete at school? <i>*Highest grade completed (in years)</i>	0 = 0 - 3 years 1 = 4 - 7 years 2 = 8 - 11 years 3 = ≥12 years	
3.2	Mother's educational attainment* What grade did your mother complete at school? <i>*Individuals who are unable to give an exact answer should be asked to make an estimation.</i>	0 = 0 - 3 years 0 = 4 - 7 years 1 = 8 - 11 years 1 = ≥12 years	
3.3	Lifetime occupation* What sort of work/job have you done for most of your life? <i>*Manual occupations - do not require intensive training or supervisory elements (e.g. farming, mining, construction, manufacturing, mechanical maintenance, garden maintenance, housekeeping and cleaning). Or never had a paid job.</i>	0 = Predominantly manual 1 = Predominantly non-manual	
3.4	Use of technology* How often do you use a computer? <i>*Desktops, laptops, and tablets should be considered computer</i>	0 = Do not use computers or do it only occasionally 1 = Use computers at least once a week	
3.5	Writing If there was a job that involved a lot of writing, do you think you would be able to do it?	0 = Difficulty with writing 1 = Some difficulty with writing 2 = No difficulty with writing	
3.6	Reading If you buy medicine at a shop or a pharmacy, do you have difficulty reading the information leaflet inside the box, or reading the instructions on how to take the medicine? <i>(show image of the medication instructions on a box)</i>	0 = Difficulty with reading 1 = Some difficulty with reading 2 = No difficulty with reading	
Total Score (out of 10) Interpretation 0 - 3: Inadequate functional health literacy 4 - 5: Marginal functional health literacy ≥ 6: Adequate functional health literacy			
Time taken for MFSHL (mins)			



ENGLISH VERSION

4. HEALTH LITERACY TEST - LIMITED LITERACY (HELT-LL)

			Score
4.1	If you don't understand what the nurse/doctor/ pharmacist says, do you usually ask them to give you more information and explain things to you?	0=never 1= sometimes 2=often	
4.2	Do you know how to use a computer or cellphone to answer your health-related questions?	0=no 2=yes	
4.3	If you are worried about a health problem do you usually ask your friends and neighbours first for information and advice before going to the clinic?	0=yes 1=sometimes 2=no	
4.4	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be? <i>Correct answer: 21st of March</i>	0=incorrect 2=correct	
4.5	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist? <i>(show image of the information leaflet)</i>	0= always/ often 1=occasionally/sometimes 2=never	
4.6	You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one? <i>Correct answer: 3pm</i>	0=incorrect 2=correct	
4.7	You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	0=incorrect 2=correct	
4.8	Do you think that health information from the internet on your cellphone or computer is always good information that you can trust? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.9	Which of the three blood pressure readings is closest to a normal blood pressure reading? <i>(show image of the blood pressure reading)</i> <i>Correct answer: 120/80.</i>	0=incorrect 2=correct	
4.10	Can HIV/AIDS be cured? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.11	Can you get TB if you use the same toilet as someone with TB? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.12	Herbal/traditional medicines are natural and are from plants. Are they always safe to take? <i>Correct answer: No</i>	0=incorrect 2=correct	
Total Score			
Time taken (mins)			

ISIXHOSA VERSION

4. HEALTH LITERACY TEST - LIMITED LITERACY (HELT-LL)

			Inqaku
4.1	Ukuba akuyiqondi into ethethwa ngumongikazi/ugqirha/ifamasist/ akuxelela yona ngesimo sakho sempilo, uyakwazi ukuthi ubabuze, bakunike ulwazi oluthe vetshe ngokuthi bakucacisele ngokuphangaleleyo?	0= zange 1=ngamanye amaxesha/ngamaxesha athile 2= lonke ixesha/kaninzi	
4.2	Uyakwazi ukusebenzisa ikhompuyutha okanye iCellphone ukuphendula imibuzo engqamene nempilo yakho?	0=ewe 2=hayi	
4.3	Ukuba unexhala ngesimo sempilo yakho, uye wenze njani, ingaba ubuza abahlobo bakho okanye umakhelwane wakho ukuba akucacisele phambi kokuba uye ekliniki?	0=ewe 1= akaqinisekanga/ mhlawumbi 2=hayi	
4.4	Ukuba uye ekliniki ngomhla wesi-7 kuMatshi, ze kuthiwe uze ubuyele ekliniki emva kweeveki ezimbini, iya kube ingumhla wesingaphi le mini kufuneka ubuyele ngayo? <i>21st of march</i>	0= ayichanekanga 2=ichanekile	
4.5	Kukangaphi apho kufuneka kubekho umntu omakakuncede xa ufunda imiyalelo, amaphetshana nezinye izinto ezibhaliweyo ezivela kugqirha wakho/unesi nosokhemesti?	0= lonke ixesha/kaninzi 1= ngamanye amaxesha/ngamaxesha athile 2= zange	
4.6	Uxelelwa ukuba uthathe ipilisi enye (1) kathathu (3) ngemini, qho emva kweeyure ezisibhozo. Ukuba uthatha ipilisi yakho yokuqala yonke imihla ngo-7 kusasa, kufanele uyithathe nini elandelayo? <i>ngo-3 emva kwemini</i>	0= ayichanekanga 2=ichanekile	
4.7	Uxelelwa ukuba unike umntwana umlinganiselo oyi-2 ml yeyeza ngesirinji. . Ndicela undibonise kwisirinji ukuba uza kuwenza ubengakanani lo mlinganiselo.	0= ayichanekanga 2=ichanekile	
4.8	Ucinga ukuba ulwazi olufumanayo ngezempilo kwiInternet ekwiCellphone yakho okanye kwiKhompuyutha yakho lelona lwazi onokulithemba? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.9	Sesiphi kwezi ziphumo zintathu <i>zeblood pressure</i> esisondeleyo kwisiphumo esamkelekileyo? <i>120/180</i>	0= ayichanekanga 2=ichanekile	
4.10	Ngaba i-HIV/AIDS inganyangeka? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.11	Ungayifumana iTB ngokusebenzisa ithoyilethi esetyenziswa ngumntu oneTB? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
4.12	Amayeza enziwe ngezityalo/egqirha akaxutywanga namachiza. Ngaba kusoloko kukhuselekile ukuwasebenzisa? <i>Hayi</i>	0= ayichanekanga 2=ichanekile	
Total Score			
Time taken (mins)			

5. NEWEST VITAL SIGN – SOUTH AFRICA (NVS-SA)

Show prompt card (image of tin of pilchards) and read: Do you know what this is? Have you and your family ever eaten this food before and if so do you like it? There is a label on the tin that is quite small, so we have made the label bigger so that it is easier to read. Please could you read the label			Score
5.1	Are the pilchards (the fish) plain or is there a flavour that has been added? <i>The pilchards are in a tomato sauce</i>	0 = Incorrect 1 = Correct	
5.2	If you eat 200g from this tin, how much of the tin will you eat? <i>Half the tin</i>	0 = Incorrect 1 = Correct	
5.3	If 3 slices of bread contains about 6g of protein, which will give you more protein: eating the 3 slices of bread or eating some pilchards? <i>Pilchards has 17g protein/100 g (i.e. in ¼ tin) and this is much more than the 6g of protein in the 3 slices of bread (Subject must indicate label info of 17g protein/100g. Subject not required to specify the amount of pilchards eaten)</i>	0 = Incorrect 1 = Correct	
5.4	Pretend that you are allergic to the following substances: penicillin, milk and gluten. Is it safe for you to eat this food? <i>Yes</i>	0 = Incorrect 1 = Correct	
5.5	If you eat the whole can of pilchards, how many grams of carbohydrate will you eat? <i>2 x 4 = 8 g</i>	0 = Incorrect 1 = Correct	
5.6	Pretend that you have a problem with your blood pressure or heart. According to the label how would you know if this food is good for you <i>Because it is approved as part of the Heart and Stroke Foundation eating plan (subject must indicate text and image)</i>	0 = Incorrect 1 = Correct	
Total Score (out of 6) Interpretation 0 - 2: Inadequate health literacy 3 - 4: Marginal health literacy 5 - 6: Adequate health literacy			
Time taken for NVS-SA (mins)			

Total time taken for entire interview (mins)	
----------------------------------------------	--

END OF BASELINE INTERVIEW


4. HEALTH LITERACY TEST - LIMITED LITERACY (HELT-LL)

4.1	If you don't understand what the nurse/doctor/ pharmacist says, do you usually ask them to give you more information and explain things to you?	0=never 1= sometimes 2=often	
4.2	Do you know how to use a computer or cellphone to answer your health-related questions?	0=no 2=yes	
4.3	If you are worried about a health problem do you usually ask your friends and neighbours first for information and advice before going to the clinic?	0=yes 1=sometimes 2=no	
4.4	If you go to the clinic on the 7 th of March and you are asked to return to the clinic two weeks later, what will the date be? <i>Correct answer: 21st of March</i>	0=incorrect 2=correct	
4.5	How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor/nurse/pharmacist? <i>(show image of the information leaflet)</i>	0= always/ often 1=occasionally/sometimes 2=never	
4.6	You are told to take one (1) tablet three (3) times a day, every 8 hours. If you take your first tablet each day at 7 am, when should you take the next one? <i>Correct answer: 3pm</i>	0=incorrect 2=correct	
4.7	You are told to give a child 2 ml of a liquid medicine. On the syringe, please show me where you will fill the syringe up to.	0=incorrect 2=correct	
4.8	Do you think that health information from the internet on your cellphone or computer is always good information that you can trust? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.9	Which of the three blood pressure readings is closest to a normal blood pressure reading? <i>(show image of the blood pressure reading)</i> <i>Correct answer: 120/80.</i>	0=incorrect 2=correct	
4.10	Can HIV/AIDS be cured? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.11	Can you get TB if you use the same toilet as someone with TB? <i>Correct answer: No</i>	0=incorrect 2=correct	
4.12	Herbal/traditional medicines are natural and are from plants. Are they always safe to take? <i>Correct answer: No</i>	0=incorrect 1= unsure 2=correct	
Total Score			
Time taken (mins)			

END OF FOLLOW-UP INTERVIEW


APPENDIX G

NVS-SA NUTRITIONAL LABEL (ENGLISH)

INGREDIENTS	
Pilchards (fish), water, tomato paste, salt, maize starch, guar gum	
NUTRITIONAL INFORMATION	
Per 100 g serving	
Energy	438 kj
Protein	17 g
Carbohydrate	2 g
- total sugar is	1 g
Total fat	5.1 g
Cholesterol	68 mg
Dietary fibre	2.3 g
Sodium	270 mg
Calcium	267 mg
ALLERGY INFORMATION	
Free from: gluten	
Contains: fish	
Contents: 400 g	
 APPROVED AS PART OF THE HEART AND STROKE FOUNDATION EATING PLAN	

APPENDIX H

NVS-SA NUTRITIONAL LABEL (ISIXHOSA)

IZITHAKO	
Ipilchards (intlazi), amanzi, itumato ecujiweyo, ityuwa, istatchi sombona, iguar gum	
IINKCUKACHA ZESONDLO	
Kumlinganiselo ngamnye we-100 g	
Amandla	438 kj
Iproteni	17 g
Ikhobhohayidrethi	2 g
- iswekile xa iphelele yenza	1 g
Amafutha xa ewonke	68 mg
Icholesterol	68 mg
Ifibre ekukutya	2.3 g
Isodium (ityuwa)	270 mg
Icalcium	267 mg
IZINTO EZINOKUNGAVUMELANI NOMZIMBA WAKHO	
Aynayo: igluten	
Inayo: intlazi	
Isiqulatho: 400 g	
 IVUNYIWE NJENGENXENYE YENDLELA YOKUTYA YEHEART AND STROKE FOUNDATION	

APPENDIX I



RHODES UNIVERSITY

Validation of a health literacy measure appropriate for public sector patients in South Africa

My name is **Chipiwa Marimwe** and I am Doctoral student from the Faculty of Pharmacy at Rhodes University. I would like to invite you to take part in this research study. We have developed a measure that will tell us about your health literacy (how well you can read and understand things to do with your health, visiting the clinic and taking medicines). Once you have read and understood the information in this form, you can ask me or the interpreter any questions. I will then ask you to sign the consent form on the next page if you agree to take part.

Why are we doing this research?

The purpose of this research is to see how good our health literacy test is for patients like you who visit clinics. This will help us to measure how much you understand about looking after your health, what to do if you get sick and what you should know about taking medicines.

I am looking for people visiting the clinic who are isiXhosa-speaking and are over the age of 18. You should be able to read at least a little bit of isiXhosa.

What will you do if you take part in this study?

I will interview you with an interpreter so that you can speak in isiXhosa. I may see you before you see the doctor or nurse and get your medicines, or after you have done that. The interview will last about 20 minutes. In the interview I will ask you questions about yourself. I will then ask you to read some sentences and ask you questions about the information. You will be given a voucher from Shoprite to thank you for your time and for helping us.

How will this study help patients like me?

Your answers will help us find out which patients find it difficult to understand the information they are told at the clinic, how to take their medicines and how to stay healthy. Those patients can then be helped by the doctor or nurse to understand more about taking care of their health

Confidentiality

All the personal details you give me will be confidential. The only people who will know your name will be myself, the interpreter and my supervisor. We will not tell anyone about anything you say or the answers you give.

Do you have the right to refuse or leave the interview?

You can choose whether to take part in this study. You have the right to refuse. If you decide not to take part in this study or if you want to end the interview at any time, you are free to do that.

Now that you have read the information and have asked questions, and if you have decided that you would like to part in the study, could you please sign this Consent Form. If you have decided not to take part, thank you for reading this and I wish you well.

Contact details:

Ms Chipiwa Marimwe (researcher): 078 2356859

Prof Ros Dowse (supervisor): 046 6038071



RHODES UNIVERSITY

CONSENT FORM

TITLE OF PROJECT: Validation of a health literacy measure appropriate for public sector patients in South Africa

PARTICIPANT:

I, would like to take part in this research study.
I give permission to **Chipiwa Marimwe** (researcher) and
(interpreter) to ask the necessary questions.

I understand that all information gathered from this research study will be kept confidential.

Signature:

Witness:

Date:

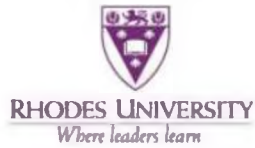
RESEARCHER AND INTERPRETER:

I, **Chipiwa Marimwe** (researcher) and (interpreter),
swear that all the information obtained during this research study will remain strictly confidential.

Signature:(researcher)

Signature:(interpreter)

APPENDIX J



Faculty of Pharmacy
Artillery Road, Grahamstown, 6139, South Africa
PO Box 94, Grahamstown, 6140, South Africa
t: +27 (0) 46 603 8381
f: +27 (0) 46 603 7506
e: dean.pharmacy@ru.ac.za
www.ru.ac.za

Grahamstown 16th March 2017

From:
Dr. Roman Tandlich
Faculty of Pharmacy
Rhodes University
P.O. Box 94
Grahamstown 6140
South Africa
e-mail: r.tandlich@ru.ac.za

To:
Dr. Professor Dowse and Ms. Marimwe

Re: Approval of the Faculty of Pharmacy Ethics Committee Application PHARM-2017-03.

Dear Dr. Professor Dowse and Ms. Marimwe,

Thank for your application for ethical approval entitled: "Development and validation of a health literacy measure appropriate for public sector patients in South Africa". This application was considered by the Faculty of Pharmacy Ethics Committee under the tracking number: PHARM-2017-03. I am pleased to inform you that after review of your application, the Faculty of Pharmacy Ethics Committee grants ethical approval for your study.


You can proceed to obtain any necessary institutional approval(s). Please ensure that the Faculty of Pharmacy Ethics Committee is notified should any substantive changes(s) be made, for whatever reason, during the research process.

Yours sincerely,

Roman Tandlich, PhD

CHAIRPERSON: FACULTY OF PHARMACY ETHICS COMMITTEE

APPENDIX K




The National Health Research Database

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RESEARCH PROPOSAL DETAILS: EC_2015RP40_351

Research Committee

EASTERN CAPE HEALTH RESEARCH COMMITTEE

APPLICATION DETAILS

Title of Research Project

Development of a health literacy measure appropriate for public sector patients in South Africa

Status of Application

Approved

Status of Project

On-Going

Proposal Submission Date

2015/08/19

Comments

You will find a list of all comments made on the selected research application. The list below displays comments visible to both the Applicant and Research Committee

Comment	Comment Date	Comment By
---------	--------------	------------

Research Staff assigned to Project/Proposal

Title	Name	Surname	Role	Institution	E-Mail	Telephone No.	Mobile No.	CV/Resume
MS	Chipiwa	Marimwe	Student	Rhodes University	g11m0629@campus.ru.ac.za	+27466038071	+27782356859	Download CV
PROF	Ros	Dowse	Supervisor	Rhodes University	r.dowse@ru.ac.za	+27466038071	+27835569796	Download CV