The design and evaluation of targeted patient-centred health information to improve knowledge and behavioural outcomes in tuberculosis patients with limited literacy

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SONAL PATEL

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Rhodes University

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ABSTRACT

South Africa carries a significant TB burden as evidenced in the 2013 statistics which report 450 000 new active TB cases and 890 000 TB-related mortalities. For successful treatment outcomes, 90% adherence is necessary, but many patients prematurely discontinue treatment due to poor knowledge and understanding of their complex TB medicines. Patient education is pivotal in improving knowledge, health literacy and behavioural outcomes such as health information seeking, self-efficacy and adherence. In the under-resourced South African healthcare system, time and capacity to adequately counsel patients are limited.

The value of written medicine information (WMI) to supplement the verbal information provided by healthcare professionals (HCPs) has been widely investigated but minimal South African research is available. Current WMI distributed in South Africa is mainly generated by pharmaceutical manufacturers and is complex, incomprehensible and undesirable to patients. TB-related WMI focuses mainly on the disease, with little information relating to TB medicines and their use. The overall aim of this project was to improve patient knowledge about their TB medicines through the use of a simple illustrated patient information leaflet (PIL). Objectives to achieve this aim included: investigation of the medicine information seeking behaviour (MISB) of long term patients attending public health sector facilities; the development and validation of a medicine literacy test (MLT) to identify patients with limited health literacy requiring additional support and counselling; the development and evaluation of a patient-centred illustrated PIL for first-line TB treatment; the assessment of self-efficacy and adherence using modified versions of the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES) and Morisky 8-item Medicine Adherence Scale (MMAS-8), respectively, and the investigation of the impact of the PIL on patient knowledge and these health-related behaviours.

Six focus group discussions (FGDs) conducted in 34 isiXhosa-speaking patients with limited formal education taking long-term treatment explored themes related to information needs, information-seeking practices and awareness of and ability to utilize information sources. Codes were analysed and potential themes and subthemes were identified and refined. The findings of this study reflected a passive, disempowered patient due to both patient-related and systemic healthcare factors. Poor awareness of information sources, lack of health-related knowledge, stigma and lack of awareness of the importance of appropriate medicine-related

knowledge contributed to a lack of information-seeking practice. Patients neither asked questions nor were encouraged to do so. All expressed an unmet need for information and a desire for receiving relevant, appropriate, written medicine-related information. Feedback from this phase of the study was used to inform the development of the targeted patient-centred PIL.

A double-sided A4 PIL containing information about TB medicines was designed giving careful consideration to content, format and layout features. Twenty five pictograms were designed through a rigorous, iterative design process and were included in the PIL that was evaluated in a randomised control trial (RCT) conducted amongst 120 TB patients attending a high burden TB clinic in South Africa. Interviews were conducted in either isiXhosa or Afrikaans via a trained interpreter. Patients were randomly allocated to either a control (standard care) or an experimental group (standard care plus brief counselling using the PIL). Two interviews were conducted using a prepared questionnaire; one at baseline followed by a 4-week follow-up. Baseline data included demographics, medicine literacy test, health information sources, knowledge of TB medicines, self-reported adherence and self-efficacy. Data collected at the 4-week follow-up interview included TB knowledge, self-reported adherence, self-efficacy, opinion of TB medicine information and interpretation of pictograms. Data were analysed using t-test, correlations, chi-square and ANOVA tests at a 0.05 level of significance.

The PIL was successful in improving patient knowledge of the disease, TB medicine-taking, side effects, drug-resistant TB and HIV and TB co-infection. At baseline, there was no significant difference in the overall mean percentage knowledge score between the control and experimental groups ($p=0.074$). At follow-up, the percentage knowledge score for the experimental group increased significantly from 59.0% to 84.6% ($p<0.001$) and showed a significantly higher score than the control group ($p<0.001$), displaying evidence of the impact of the PIL as a counselling tool on patient knowledge. The PIL generated a highly positive response in the experimental group who indicated that they had referred to the leaflet over the last month and that it had played an important role in improving their TB medicine-related knowledge. This was reflected in the experimental group knowledge score of greater than 80% for almost three quarters of the patients whereas only 14% in the control group achieved this score. Patients appreciated the inclusion of pictograms and strongly felt that they helped them to recall and understand the textual PIL content. The study found that patients want side

effect information and, interestingly, did not perceive the presentation of side effects in pictorial form to constitute a risk factor for nonadherence.

Use of the illustrated PIL (experimental group) resulted in a significant improvement in patient self-efficacy ($p=0.002$), but showed no effect on self-reported adherence ($p=0.563$). Neither self-efficacy nor adherence was influenced by gender, age or education. An education effect on knowledge was only observed in the control group at baseline. The newly developed MLT was shown to be a valid and reliable tool and a moderate, positive and significant correlation was noted between the MLT score and baseline TB medicine-related knowledge in both the control and experimental groups.

As there is a paucity of studies investigating the influence of take-home written leaflets on TB medicine knowledge and on patient behaviour, this study represents a significant knowledge contribution. It is the first study to report the development and evaluation of a patient-centred PIL to address the dearth of available TB medicine information. The use of targeted user-friendly, illustrated information leaflets can be a valuable counselling aid to improve patient knowledge and self-efficacy, particularly among patients with limited literacy. However, careful consideration of the design and content, with input from the end-users at all stages of the process, will optimise its effectiveness. The proposed framework for the development and implementation of patient-centred health and medicines information in a developing country context presented in this thesis could be used as a theoretical basis for informing the development of effective information materials targeting other disease states.

Local patients taking TB medicines identified nurses, WMI and media as their current sources of information but they expressed a strong desire to know more about their treatment. Targeted public health interventions that focus on medicine-taking information and behaviours and encourage patients to adopt a more active, questioning role in health consultations could improve health literacy and empower patients in their medicine-taking practices.

I would like to dedicate this dissertation to…

my beloved parents
Mr Pravin Chandra Patel and Mrs Pushpaben Patel

and

to all those patients who have encountered tuberculosis in their lifetime.

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LIST OF ACRONYMS

ANOVA	Analysis of Variance
ANSI	American National Standards Institute
ARVs	Antiretrovirals
BCG	Bacille Calmette Guérin
CHW(s)	Community Health Worker(s)
DNA	Deoxyribonucleic acid
DoH	Department of Health
DOTS	Directly Observed Treatment Short-course
ELF	Evaluative Linguistic Framework
FDCs	Fixed Dose Combinations
FGDs	Focus Group Discussions
HCP(s)	Healthcare Professional(s)
HISB	Health Information Seeking Behaviour
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HIV-ASES	HIV Treatment Adherence Self-Efficacy Scale
IPT	Isoniazid Prophylaxis Therapy
MDGs	Millennium Development Goals
MDR-TB	Multidrug-resistant Tuberculosis
MISB	Medicine Information Seeking Behaviour
MLT	Medicine Literacy Test
MMAS-8	Morisky 8-item Medicine Adherence Scale
MSFHL	Multidimensional Screener of Functional Health Literacy
NGOs	Non-governmental Organisations
NVS	Newest Vital Sign
NVS-SA	Newest Vital Sign-South Africa
PEMAT	Patient Education Materials Assessment Tool
PIL(s)	Patient Information Leaflet(s)
RCT	Randomised Controlled Trial
REALM	Rapid Estimate of Adult Literacy in Medicine
REALM-R	Rapid Estimate of Adult Literacy in Medicine, shortened version
SAM	Suitability Assessment of Materials
SILS	Single Item Literacy Screener
SMOG	Simplified Measure of Gobbledygook
StatsSA	Statistics South Africa
S-TOFHLA	Test of Functional Health Literacy in Adults, shortened version
TB	Tuberculosis
TB-ASES	TB Treatment Adherence Self-Efficacy Scale
TDR-TB	Totally drug-resistant Tuberculosis
TOFHLA	Test of Functional Health Literacy in Adults
TST	Tuberculin Skin Test
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UK	United Kingdom
URC	University Research Co., LLC
USA	United States of America
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organisation
WMI	Written Medicine Information
XDR-TB	Extensively Drug-resistant Tuberculosis

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CHAPTER 1
INTRODUCTION

1.1 Background to research

TB is a global public health problem that has existed for thousands of years and continues to affect millions of people worldwide, particularly those in developing countries [1]. South Africa has a long history of TB and is amongst the top three countries with a high TB burden [2]. In 2013, the estimated incidence was 450 000 active cases and just over one third had both Human Immunodeficiency Virus (HIV) and TB [1]. To successfully treat TB, more than 90% adherence is necessary [3]; however, many patients prematurely discontinue their treatment resulting in drug-resistant strains of TB which has escalated to a major problem in South Africa [2].

Treatment for TB is complex as it involves taking large fixed-dose combination (FDC) tablets for approximately six months [4], with the combination of four medicines (rifampicin, isoniazid, pyrazinamide and ethambutol) being associated with both mild and fatal side effects [5]. Schaberg *et al.* [6] found that side effects such as hepatitis, dyspepsia, exanthema and arthralgia were responsible for termination of treatment in 23% of patients in the initial intensive phase of treatment. Educating patients about their TB treatment can promote treatment completion although this is highly dependent on the nature of the intervention as well as the healthcare setting [7].

To many patients the healthcare system is like being in a foreign country with its own language and culture, and in order to negotiate their way through the system, patients require health literacy skills [8]. Unfortunately, health literacy appears to be low worldwide, even in developed countries [9]. In the United States of America (USA), the Institute of Medicine reported that approximately 50% of adults have some difficulties with understanding and acting upon health information. Health literacy is even worse in developing countries and is often linked to high levels of illiteracy and limited education prevalent amongst the population [10,11]. Numerous definitions of health literacy have evolved along with various health literacy measurement tools and, despite the difficulties encountered by many South African patients when navigating the health system, the concept has not been defined and there are no formal tools to measure health literacy within this population. Limited health

literacy is associated with poor health status, high mortality rates, increased health costs and hospitalizations, misunderstanding medicines instructions and nonadherence [12]. Individuals with limited health literacy often encounter difficulty understanding health information, following medicine instructions, interacting with HCPs and seeking appropriate timely healthcare. Thus it is important to identify these patients and, in an effort to improve health literacy, offer them resources such as appropriate targeted health information to assist them in navigating the healthcare system [13].

Improving accessibility to and provision of information can empower patients to make more informed choices about their health whereby informed patients are more likely to seek treatment at an earlier stage, involve themselves in decision-making regarding their health and adhere to their treatment plan [14-16]. Patients who understand their medicines tend to have a greater perceived self-efficacy and are more likely to be adherent [17]. Self-efficacy, defined as "a belief in one's ability to perform a specific behaviour in order to meet a goal" [18], has shown to improve positive engagement with healthy behaviours [19,20] and, in the case of medicine-taking practices, can potentially influence patient choice to take medicines, the effort expended to ensure correct use and persistence with prescribed treatment. Understanding self-efficacy in relation to patient knowledge about their medicines may assist in understanding why patients with limited literacy often do not adhere to their treatment [21].

In South Africa, two major, common barriers to effective interaction between HCPs and patients are language and limited literacy [22], making verbal communication of medicine information difficult. The use of targeted written information incorporating pictograms and simple text can serve as a useful tool to facilitate the communication of medicine information [23,24]. WMI has shown to be beneficial in improving patient understanding, knowledge and adherence to medicines, enhancing the recall of medicine information, reducing medication errors and bridging the information gap between HCPs and patients [14,25,26]. However, there is limited reader-friendly medicine information available in South Africa to guide patients in their medicine-taking practices. Most available information for TB patients focuses on the disease and is written at a higher reading level than that understood by the average patient.

The success of WMI lies in the effective design and evaluation process which ensures that the materials developed are of a high standard and cater to the needs of the target audience [27,28]. The importance of including patients in the design and evaluation of materials has become increasingly recognised. Lack of patient input in the development of WMI has been identified as one of the major reasons for the poor use of currently available materials as they do not cater to patients' information needs, expectations and priorities [15]. Understanding the medicine information seeking behaviour (MISB) and information needs of the target population, could inform the development and dissemination of appropriate materials that are consistent with patient needs and preferences. However, limited research has been conducted on the MISB and information needs of populations in developing countries, including South Africa [29].

Patient information leaflets (PILs) containing well-designed pictograms have been acknowledged as a useful tool to communicate medicine information to local patients [30-33]. Although South African regulations state that each medicine package should contain a PIL [34], currently available PILs are sub-standard and patients often express dissatisfaction with many aspects of this information due to the use of complex terminology and small font size [35]. There is often a lack of theoretical understanding about the overall design and evaluation process that should inform developers when producing patient-centred information leaflets. The more attention paid to these theoretical underpinnings of information design, the more likely it will be that the developed information will result in successful knowledge transfer and improvement in health skills in clinical practice.

1.2 Aim and objectives

The overall aim of this project was to improve patient TB medicine-related knowledge by developing and evaluating a patient-centred illustrated TB medicine PIL for first-line TB treatment.

Objectives

- To investigate the medicine information needs and MISB in long-term patients with limited literacy skills
- To develop and validate a medicine literacy test to measure health literacy skills

- To assess self-efficacy and adherence in local patients by modifying existing research tools
- To design and develop a simple, user-friendly and attractive illustrated patient-centred information leaflet for limited literacy patients taking standard first-line TB treatment
- To design culturally appropriate pictograms that are well comprehended for inclusion in the PIL
- To evaluate the impact of the experimental PIL on patient knowledge, self-efficacy and adherence by conducting a RCT
- To assess patient opinion of acceptability and usefulness of the TB medicine information PIL
- To investigate the association of selected variables (gender, age, education) with knowledge, self-efficacy, adherence and medicine literacy
- To compare inter- and intra-group knowledge, self-efficacy, adherence and medicine literacy at baseline and at the one month follow-up
- To develop a framework that describes the theoretical underpinning for the development of effective health and medicine information materials for limited literacy patients

1.3 Significance of research and theoretical framework

There is limited WMI to support patients taking complex TB medicines in South Africa. Through this study, we anticipated developing an effective patient-centred illustrated leaflet that would assist HCPs in communicating key information about TB medicines to their patients and hopefully increase patient knowledge and medicine-taking behaviours.

Consistent with moving towards a more patient-centred approach to healthcare, the study initially aims to understand the information needs and MISB of local patients and, based on the findings, to develop applicable information materials that address patient needs and preferences. As no other similar study has been conducted in the South African setting, my study should contribute to a better understanding of the medicine information needs and MISB in local patients taking long-term medicines.

This study intends to consolidate aspects of the various developmental stages into a framework that describes the design and implementation process for effective patient-centred medicine information leaflets targeted at South African patients with limited literacy. It is anticipated that this framework will provide HCPs, pharmaceutical manufacturers and other organisations involved in the design of medicine information intended for patients with a deeper understanding about the theoretical principles and the stages that should be considered when developing information materials.

In order to understand and evaluate patient behaviour, certain disease-specific tools are presented in literature. However, many of these originate from developed countries which consist of more literate educated populations and there are few tools available to investigate patient behaviour in patients with limited literacy skills who are served by under-resourced health systems [36,37]. In South Africa, healthcare services are offered within either the private or public sectors. The under-resourced public sector provides services to approximately 80% of the population but roughly 70% of all doctors and most specialists work only in the private sector [38]. Diseases such as HIV/AIDS and TB have also placed an additional burden on the public sector and efforts to understand and promote patient behaviour in the context of these two high burden diseases is urgently needed [36]. Locally applicable research tools to evaluate other health-related behaviours such as adherence and self-efficacy are neither readily available nor appropriate for patients taking TB treatment. Effective tools to do so could deepen the understanding of these important behaviours, particularly their relationship with patient knowledge.

Patients attending public sector healthcare facilities are likely to encounter problems navigating the health system due to their limited education, limited health literacy and lack of adequate access to healthcare and technology. The need to identify such patients and provide healthcare services that are sensitive to their limited health literacy could result in better health outcomes as well as reduced hospitalization and healthcare costs [13]. However, there is a paucity of health literacy measurement tools that are applicable to local South African patients who are served by the public health sector. The need to develop and validate a quick health literacy tool, that could differentiate patients with adequate or inadequate health literacy, was apparent and this led to the development of the MLT.

A theoretical framework for a study consists of theories, principles and research findings that are closely related to the research being undertaken [39]. For this study, the framework proposed by Graham *et al.* [40] that maps the process of knowledge to action, was considered appropriate as it provided a well-supported rationale for the study and supported the main goal of the study which was the development of a targeted illustrated PIL aimed at improving patient knowledge and behaviour. This framework originated from the field of continuous education for HCPs and was developed to better understand and influence change in clinical practice. The framework is divided into two concepts illustrated in Figure 1.1; knowledge synthesis (shaded funnel in the centre) and action (stages shown in the outer cycle).

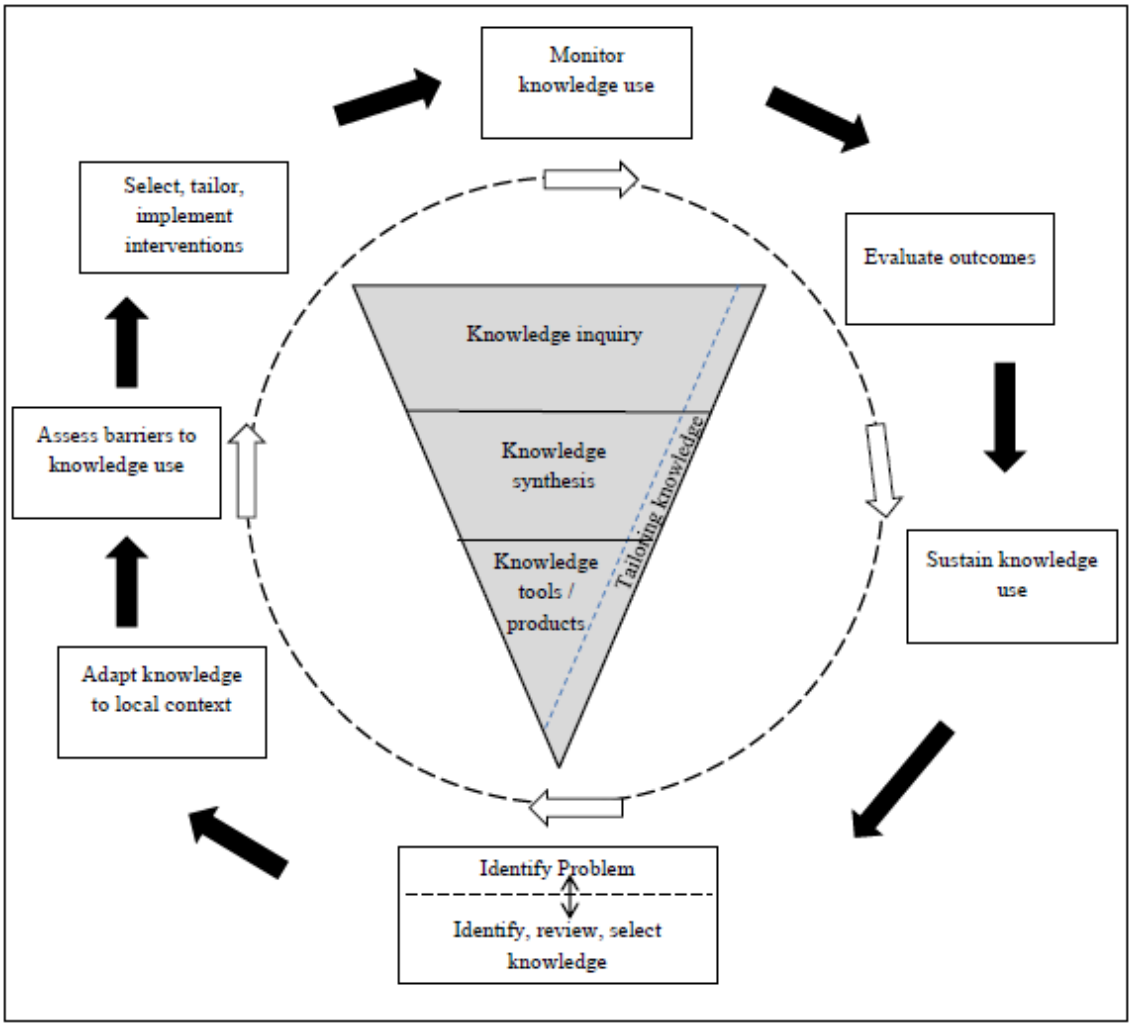


Figure 1.1: Conceptual framework for knowledge to action (Graham *et al.* [40])

Based on the model, knowledge is created through evidence and experiences and this can be separated into three generations; knowledge inquiry, knowledge synthesis and knowledge tools/products. Each of these generations of knowledge creation can be tailored to the needs of the target group and, when moving from the first to the last generation, knowledge synthesised is more refined and useful. For my study, the knowledge synthesis component is the comprehensive literature review that identifies gaps in the literature and guides better understanding of the needs of patients in developing countries such as South Africa.

The action cycle describes the stages involved in applying the synthesised knowledge and this cycle is derived from planned action theories, models and frameworks that are intended to either increase or decrease the likelihood of change. Graham *et al.* [40] identified 60 studies that utilized planned action theories and identified certain commonalities which contributed to the action cycle shown in Figure 1.1. This action cycle forms the theoretical basis for the development of the targeted patient-centred TB medicine PIL aimed at improving patient knowledge and behavioural outcomes amongst local patients. There are no other studies that have been conducted in Sub-Saharan Africa that have described the application of a conceptual framework in the development of medicine information materials.

1.4 Dissertation outline

The following chapter is a detailed literature review that begins by describing TB and its treatment, specifically looking at the history, epidemiology, disease characteristics, prevention and complexity of treatment. The definitions and conceptualisation of literacy and health literacy are then presented along with details on measurement of health literacy using tools identified from literature. The link between health literacy and empowerment is also conceptualised with specific reference to a model of external influences on information use and empowerment proposed by Edwards *et al.* [41]. Three patient behaviours (Health Information Seeking Behaviour (HISB), self-efficacy and adherence) are explained along with information about approaches taken to measure these patient behaviours in a healthcare setting. The final section of this chapter focuses on WMI, specifically PILs along with the use of pictograms in pharmacy.

Chapter three describes the research undertaken to investigate the MISB and information needs of local patients with limited literacy. Part of this chapter has been prepared as a journal article and is currently in press [29].

Chapter four provides comprehensive details about the development of the illustrated TB medicine information PIL, pictograms and research instruments to be used in the RCT, including the development and validation of the MLT and modification of tools used to measure patient behaviour (HIV-ASES and MMAS-8).

Chapter five describes the methodology used for the RCT to determine the impact of the experimental leaflet on patient knowledge and behaviour. This includes details about the study site, study population, data collection tools and study design.

Chapter six reports the findings of the RCT focusing on patient characteristics, medicine literacy, impact of the experimental PIL on knowledge, self-efficacy and adherence, and correlations between knowledge and various parameters. This chapter also highlights in detail the acceptability and usefulness of the PIL as well as the influence of pictograms in the PIL.

Chapter seven discusses the findings of the study based on critical analysis of the results and divides the discussion into eight key areas: health and medicine information for TB patients; availability, use and format of medicine information; inclusion of pictograms into WMI; information needs and HISB of patients in developing countries; applicability of existing tools for evaluating self-efficacy and adherence; proposed framework for the development and implementation of patient-centred health and medicine information; measuring limited health literacy in South Africa and; approaches to understanding and improving health literacy in South Africa. The limitations of the study are detailed at the end of this chapter.

Chapter 8 addresses 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 TB and its treatment

2.1.1 Brief history of TB

Tuberculosis, previously referred to as "consumption" and "white plague", has been around for centuries [42,43]. Evidence of the disease has been found in human remains dating back to 6000 years ago and in the spines of 3000 year old Egyptian mummies [42,43]. The history of TB was dramatically changed in March 1882, when Dr. Robert Koch announced the discovery of *Mycobacterium tuberculosis (M. tuberculosis)*, the bacteria that causes TB [43]. This important milestone lead to several advances in TB diagnostics and treatment, including the discovery of the vaccine Bacille Calmette Guérin (BCG) [42]. With this knowledge and understanding of the disease state, one would expect that the disease would be under control, however, in the 21st century TB is still a major global threat [42,43].

In 1993, the World Health Organisation (WHO) declared TB a worldwide public health emergency and in its efforts to improve TB control at both a national and international level, came up with a strategy known as Directly Observed Treatment Short-course (DOTS) consisting of five key components [44]:

1. government commitment
2. standardised short-course chemotherapy to all smear positive patients
3. regular supply of treatment
4. diagnosis using smear microscopy
5. monitoring system for programme supervision and evaluation

This strategy was well adopted by many countries worldwide and led to considerable progress towards the targets set for 2005: detection of 70% of the estimated number of smear positive pulmonary TB cases and successful treatment of 85% of these cases [44].

However, despite the implementation of the DOTS strategy, TB still continued to kill millions of people around the world, particularly in developing countries [44]. Consequently, the DOTS strategy was followed by the implementation of the first Global Plan - the Stop TB

Strategy [44]. This strategy was developed in line with the global targets set for 2015 as part of the Millennium Development Goals (MDGs) and by the Stop TB Partnership [44]. MDG 6, Target 8 is aimed at ensuring a decrease in TB incidence with a 50% decrease in prevalence and death rates in comparison to previous statistics obtained in 1990 [44]. Meeting these targets requires a well-implemented cohesive approach and, as for the DOTS strategy, the Stop TB Strategy comprised of various components [44]:

- DOTS expansion and enhancement
- Address TB and HIV/AIDS co-infection, drug-resistant TB and other challenges
- Contribute to health system strengthening
- Engage all care providers
- Empower patients with TB and communities
- Enable and promote research

The Patients' Charter for Tuberculosis Care was developed by the WHO in 2006 with input from both patients and HCPs and highlights the rights and responsibilities of patients, including the importance of access to information about health and medicine [45]. One of the key objectives of the Charter is to provide a patient-centred approach to TB care aimed at empowering patients and encouraging them to engage with HCPs [45]. The Charter also promotes the principle of greater involvement of people with TB in the battle against the disease and supports the claim that empowerment is a potential catalyst for effective collaboration between patients and HCPs [45,46].

With the implementation of the DOTS Strategy, current global Stop TB Strategy and development of the Patients' Charter for Tuberculosis Care, great progress has been made with approximately 22 million lives being saved since 1995 and a 45% decrease in TB deaths since 1990 [44]. Nevertheless, even with this progress over the last two decades, the burden of TB continues to affect millions of people, particularly in developing countries like South Africa. Therefore, the following question arises - 'Is this progress enough?'

2.1.2 Global epidemiology and burden of TB

Despite being a curable disease, TB kills approximately 3800 people every day with 95% of these deaths occurring in developing countries [47]. In 2013, there were approximately nine

million new cases of TB and 1.5 million people died of the disease, including 360 000 deaths among HIV/AIDS patients [1].

Over the past two decades there has been a 45% reduction in the global TB mortality rate hence the world is on track to achieve MDG 6; a 50% reduction in mortality between 1990 and 2015 [48]. However, this global progress conceals regional variations as the African and European regions are still not on track to halve 1990 levels of TB-related mortality [1,44,48]. Furthermore, the African continent accounts for the highest rate of TB deaths relative to the population [48].

The global incidence of new cases of TB has decreased over the last decade but at 2% per annum, the rate of decline remains slow [48]. In 2013, the majority of TB cases were in the regions of South-East Asia and Western Pacific (56%), with a further quarter of cases reported in the Africa Region [1]. Figure 2.1 shows the estimated number of new TB cases per 100 000 people per year [48]. In South Africa, Swaziland, Lesotho, Namibia, Mozambique and Zimbabwe the burden of TB is substantial with more than 500 TB cases per 100 000 people. In contrast, in some parts of the Americas, several countries in western Europe, Japan, Australia and New Zealand, there are fewer than 10 TB cases per 100 000 [48].

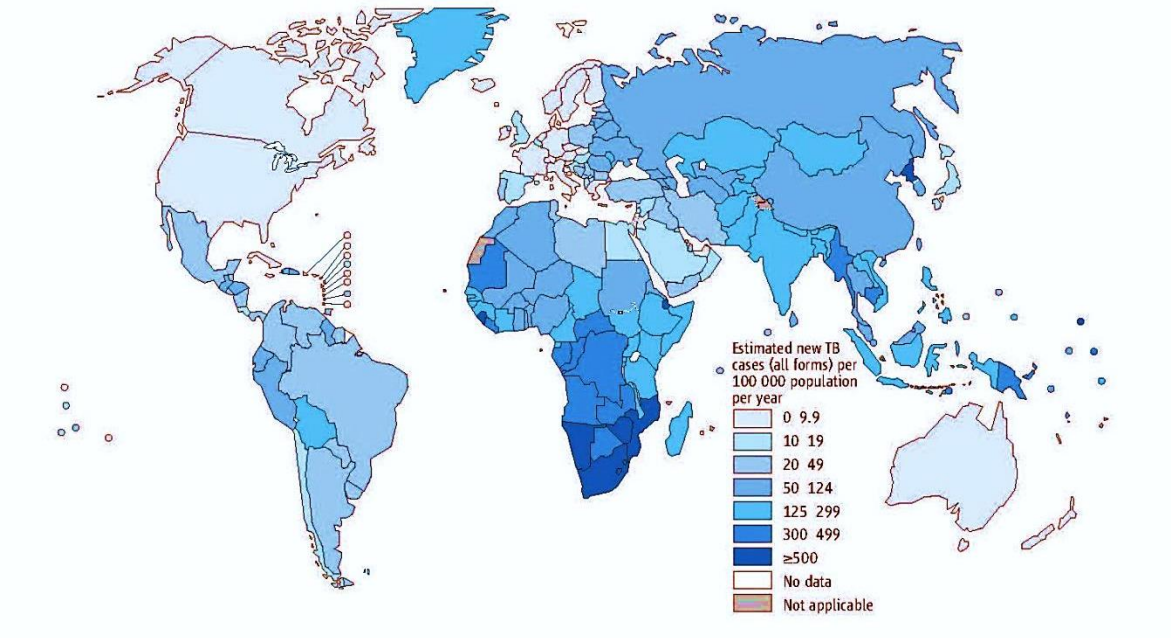


Figure 2.1: Estimated Global TB incidence rates, 2012

Source: http://www.stoptb.org/assets/images/countries/GTBCR2013_incidence.jpg

The emergence of drug-resistant strains of TB has been significant. Multidrug-resistant TB (MDR-TB) is caused by an organism that is resistant to at least isoniazid and rifampicin, the two most potent TB drugs. Worldwide, 3.5% of new cases and 20.5% of retreatment cases were estimated to have MDR-TB [1]. India, China, the Russian Federation and South Africa have almost 60% of the world's cases of MDR-TB [48]. In the 2013 global cohort of diagnosed MDR patients, only 48% were successfully treated, reflecting the extremely high mortality rate and number of patients lost at follow-up visits. Extensively drug-resistant TB, or XDR-TB, is a type of MDR-TB that is resistant to isoniazid and rifampicin, plus any fluoroquinolone and at least one of three injectable second-line drugs (amikacin, kanamycin, or capreomycin). XDR-TB was reported by 100 countries at the end of 2013 and the average proportion of MDR-TB cases with XDR-TB is approximately 9% [1].

Several cases of "totally drug-resistant TB" (TDR-TB) have been identified in India [49]. This strain of TB is said to be resistant to all first- and second-line TB treatment [49]. The WHO has not formally classified "TDR-TB" as not many drug susceptibility studies have been conducted to characterise this strain of TB, but research along these lines is currently being pursued [50].

2.1.3 TB epidemic in South Africa

South Africa has a long history of TB and is amongst the top three countries with a high TB burden. The WHO statistics for South Africa indicate an estimated incidence of 450 000 cases of active TB in 2013. Of these, it is estimated that about 330 000 people (66%) have both HIV and TB infection [1]. Since 2003, case detection rate in South Africa has remained above target, however treatment success has remained low, with a very high number of treatment defaulters and escalating mortality rates indicating failure to control the deepening TB crisis [44].

Of the nine provinces of South Africa, KwaZulu-Natal has the worst TB cure rate in the country (40%), followed closely by the Eastern Cape (41%). The Eastern Cape is a province characterised by high levels of poverty, unemployment and widespread TB with the 41% cure rate lagging far behind the 85% cure rate recommended by the WHO [51].

The 2014 WHO Global Tuberculosis Report indicates that South Africa, in addition to other African countries, is unlikely to meet the MDG 6 targets set for 2015 [1]. Numerous factors that include both patient-related and systemic factors have contributed to the widespread TB burden and failure to reach the specified targets. The latter includes poor TB management programmes consisting of a delay in diagnosis, poor case detection or tracking, out of stock medicines and poor patient education. Patient-related factors include poor adherence to medicines prescribed, alcohol and drug abuse, stigma, poor health seeking practices, development of resistance, HIV and TB co-infection and of particular relevance to the typical South African public sector patient is the influence of inadequate knowledge and awareness about TB and its complex treatment [2,52-54].

The poor TB-related knowledge is reflected in the quote by Theo Smart who wrote: "Like TB infection, poor knowledge about TB is endemic" [55]. In a survey of 85 people with TB in the Eastern Cape, despite 86.9% feeling that they were informed on TB, most believed that TB was caused by exposure to cold (42.4%), smoking (24.7%) or alcohol abuse (20%) [56].

Limited knowledge of the disease and its treatment often leads to treatment failure and development of resistance and is associated with a delay in seeking treatment and poor adherence to treatment [55-60]. This highlights the need to inform and educate patients about their condition, its signs and symptoms, the dosing and possible adverse reactions of the medication and the importance of adherence. Informed patients are more likely to seek treatment at an earlier stage, involve themselves in decision-making regarding their health and adhere to their treatment plan [61,62].

2.1.4 TB as a disease

TB is caused by the bacterial organism *M. tuberculosis* [63,64]. There are eight closely related mycobacterial species (*M. tuberculosis, M. bovis, M. africanum, M. microti, M. caprae, M. pinnipedii, M. canetti and M. mungi*) but the majority of cases of TB infection can be attributed to *M. tuberculosis*. In South Africa, 99% of all TB infections in humans are caused by *M. tuberculosis*, with a small number of infections due to *M. bovis* [65].

M. tuberculosis is carried in airborne particles of 1-5μm in diameter, called droplet nuclei [66]. These infectious droplet nuclei enter the air when an individual who has pulmonary or

laryngeal TB coughs, sneezes or shouts and expels the droplet nuclei containing *M. tuberculosis* into the air [64-66]. These particles can remain suspended in the air for several hours [66]. Transmission occurs when another individual inhales the infected droplet nuclei via the nose or mouth and these then travel to the alveoli of the lungs. The bacteria usually attack the lungs resulting in pulmonary TB, but can also enter the blood stream and spread to other parts of the body such as the kidney, spine and brain [64-66]. Pulmonary TB is the most common type of TB, however, extra-pulmonary TB does occur in more than 20% of immunocompetent patients and the risk increases further with immunocompromised individuals. The most serious form of extra-pulmonary TB is infection of the nervous system, where infection can result in TB meningitis. Patients with TB meningitis should be diagnosed promptly as untreated cases can result in mortality [64].

The focus of this study is pulmonary TB due to its infectious nature that contributes to the extremely high global TB burden. There are a range of diagnostic tests that are used to detect if an individual's lungs have been infected with the TB bacterium. These include sputum smear microscopy test, chest radiography, Tuberculin Skin Test (TST), Inferon Gamma Release Assay (blood test) and GeneXpert (a rapid, fully automated nucleic acid amplification test).

GeneXpert, the latest diagnostic test, has revolutionised TB diagnosis and South Africa has invested a great deal into its introduction and roll-out in an effort to increase case detection and decrease the laboratory turn-over time [67]. The machine is the size of a microwave and detects the presence of deoxyribonucleic acid (DNA) specific to the *M. tuberculosis* bacterium and replicates it through a technique called polymerase chain reaction. GeneXpert is able to produce a result in less than two hours enabling patients to receive their test results on the same day. The machine can also ascertain if there are any changes in the DNA structure thus indicating the possibility of resistance to TB treatment. The other major advantage is the high sensitivity (up to 98%) in comparison to other TB diagnostic tools. This is extremely important in the case of HIV positive patients who often show a false-negative result when tested for TB. Major disadvantages of GeneXpert are the cost which is significantly higher than the standard sputum-smear tests, plus it requires a computer and an uninterrupted supply of electricity to function [68]. Therefore, it is essential that clinics and hospitals where GeneXpert is utilized have reliable and proper infrastructure in place to sustain the equipment.

2.1.5 Strategies to prevent the spread of TB

In order to attain the Global Target of elimination of TB by 2050, besides early diagnosis and treatment it is also important to consider strategies to prevent the spread of tuberculosis [44]. A vaccine that could prevent active TB disease is considered to be the most cost-effective approach to global control of TB. In South Africa, a single shot of the BCG vaccine is administered to infants at birth in an attempt to immunise them against TB. Unfortunately, this vaccine does not provide protection against primary TB infection which results in active pulmonary TB and is ineffective against preventing the reactivation of latent TB infection [69]. However, the vaccine does provide protection against the development of milliary and meningeal TB in early childhood years [70]. The development of a successful new TB vaccine is much needed to avoid many of the limitations of current diagnostic and treatment practices. The main factors contributing to the delay in development of new TB vaccines is their complex nature as well as the financial implications involved with its development and testing [69].

TB is one of the leading causes of death amongst patients with a compromised immune system, particularly HIV positive patients. The risk of TB infection is approximately 20-30% greater in people living with HIV than in HIV-naïve patients. In response to the dual HIV/TB epidemic, the WHO has recommended targeted interventions including the timely provision of Antiretrovirals (ARVs) and the Three I's for HIV/TB co-infected cases: Intensified case-finding, Isoniazid Prophylaxis Therapy (IPT) and Infection control [71]. Early initiation of ARVs is strongly advocated in HIV positive patients that are at risk of TB infection [2,72]. Suthar *et al.* [72] conducted a meta-analysis of studies that analysed the impact of ARVs on the incidence of TB in adults with HIV infection. The results revealed that initiation of ARVs at an early stage can result in a 65% reduction in TB incidence amongst HIV positive patients irrespective of their CD4 count.

IPT is another strategy that has been recommended by the WHO to prevent the spread of TB amongst HIV positive patients [71]. Clinical trials have proven that administering IPT to HIV-infected patients can reduce the risk of TB infection [73]. Meta-analysis indicates that IPT reduces TB incidence by 42% overall, or by 60% among individuals who have positive Tuberculin skin tests [74]. The WHO and the Joint United Nations Programme on HIV/AIDS recommended that IPT be implemented globally however this has not been adopted by the

vast majority of countries due to economic and operational barriers [71]. In 2007, only 30 000 (0.1%) HIV and TB co-infected patients were on IPT [75]. This slow uptake was attributed to the inability to perform the TST in resource limited settings along with the controversy about the development of isoniazid resistance [71]. In 2008, the guidelines were modified to remove TST as a prerequisite to initiation of IPT and this resulted in a radical increase in uptake of IPT [71]. This was evident in South Africa where more than 37 500 HIV positive patients were initiated on IPT between 2011 and 2012 [2]. However, IPT guidelines were again modified in 2013 and TST diagnostic tool was re-introduced [2]. Modified IPT guidelines state that at least 36 months of IPT must be prescribed to TST positive patients or 6 months IPT if TST was unknown. The re-introduction of TST could prove to be a problem, especially in areas that do not have access to performing this diagnostic test.

Infection control is important in reducing the transmission of TB among individuals attending healthcare facilities and involves a combination of measures that should be stringently followed. These measures can be classified according to a 3-level hierarchy of control namely: administrative or work practice, environmental controls, and respiratory protection. Non-compliance to all three can have detrimental effects with the most prominent feature being increased transmission of TB amongst staff and patients [76].

In an effort to prevent the spread of TB, it is also important to educate and raise awareness about TB amongst patients and the community. Studies have shown that better public awareness of TB can promote patient detection, decreased delay in diagnosis as well as successful treatment completion [77,78]. HCPs should ensure that all patients initiated on TB treatment receive the necessary advice and counselling to motivate them to adhere to their treatment. A study by Morisky *et al.* [79] showed that provision of information to TB patients had a positive effect on patient adherence to their prescribed TB medicines. All patients on TB treatment should have a basic understanding of their treatment in order to exercise good medicine-taking practices.

2.1.6 Complex nature of TB treatment

TB treatment is complex and long-term, generally extending over six months but, if required, treatment may be taken for nine months or longer [80]. Standard TB treatment is typically

divided into two phases: phase one is an intensive phase in which a four anti-tuberculosis drug combination (rifampicin, isoniazid, ethambutol and pyrazinamide) is taken for approximately two months and phase two is the continuation phase in which only isoniazid and rifampicin are given for four months [80]. TB can be cured in almost all cases by taking the medicines for the full course of treatment. However, up to half of patients do not complete their TB medication regimen. In many cases patients no longer feel sick and decide to discontinue taking their TB medication [81]. This behaviour is one of the biggest problems in TB control and can lead to serious consequences like increased resistance, cost of treatment, re-infection and mortality [82].

The need for multi-drug therapy to treat TB means that a large number of tablets should be taken daily. To resolve this problem, the WHO and the International Union Against Tuberculosis and Lung Disease has recommended that countries make use of FDCs [83] as their use is associated with several advantages such as decreased prescription errors and number of tablets to administer as a result promoting adherence [4]. Table 2.1 provides examples of the FDC tablets available to TB patients in South Africa.

Table 2.1: Fixed dose combination tablets currently available at public healthcare facilities in Eastern Cape Province of South Africa

PHASE 1 **Intensive Phase**	**PHASE 2** **Continuation Phase**	
RHZE (150, 75, 400, 275 mg)[a]	RH (300, 150mg)[a]	RH (150, 75mg)[a]
		

[a]R - rifampicin; H - isoniazid; Z - pyrazinamide; E - ethambutol

One of the major disadvantages of these FDC TB medications is that patients often find it difficult to swallow the tablets and report that the tablets are “too big” and “too sour” [4]. This issue can be addressed by communicating with patients and educating them about ways to obviate these problems, such as correctly crushing the tablets and taking them with food [84]. Very few TB medications are available in liquid or chewable form for patients who have difficulty swallowing. Isoniazid and rifampicin are the only TB medications available in a commercially prepared liquid form [84].

The side effects associated with TB medicines have an influence on adherence to treatment [3,85], and have resulted in termination of therapy in up to 23% of patients [3]. Table 2.2 shows some of the side effects associated with the TB medicines and the symptomatic approach to manage them.

Table 2.2: Symptom-based approach to the management of side effects [4]

Minor Symptoms	**Drug(s) responsible**	**Management**
Anorexia, nausea, abdominal pain	Rifampicin	Continue TB drugs. Give tablets last thing at night
Joint pains	Pyrazinamide	Continue TB drugs Aspirin
Peripheral neuropathy	Isoniazid	Continue TB drugs Pyridoxine 25mg daily
Orange / red urine	Rifampicin	Continue TB drugs, reassurance
Major Symptoms		
Skin itching / rash (anaphylactic reaction)	Streptomycin	Stop streptomycin. Treat as for hypersensitivity reaction
Deafness (no wax on auroscopy)	Streptomycin	Stop streptomycin
Dizziness (vertigo and nystamus)	Streptomycin	Stop streptomycin if severe
Jaundice (other causes excluded)	Most TB drugs	Stop TB drugs until jaundice resolves, then re-introduce one by one
Vomiting and confusion (suspected drug-induced pre-icteric hepatitis)	Most TB drugs	Stop TB drugs, urgent liver function tests
Visual impairment	Ethambutol	Stop Ethambutol
Generalised reaction, including shock and purpura	Rifampicin	Stop Rifampicin

The side effect profile is intensified when a patient is co-infected with HIV and/or has a history of hepatitis. In patients taking second-line TB medicines, approximately 86% may develop side effects. In order to minimise the adverse effects, HCPs should offer patients the necessary counselling and advice regarding possible side effects. It is crucial that HCPs themselves know the side effects and are able to offer advice on how to manage them.

Drug interactions are also a common occurrence with some of the medicines used to treat TB, particularly rifampicin. This medicine is an enzyme inducer, whereby it stimulates liver enzymes (Cytochrome P450) which are responsible for metabolizing drugs [86]. Another cause for concern is the interaction of ARVs and TB treatment. The most prominent drug-drug interaction in the treatment of HIV-TB co-infection is between rifampicin and efavirenz/nevirapine. Rifampicin reduces the levels of efavirenz/nevirapine due to its enzyme inducing property. Other drugs which interact with rifampicin include the oral anti-coagulants

(warfarin), oral anti-diabetic drugs, digoxin, phenobarbitone, other anti-epileptics and oral contraceptives [86]. In addition, substance abuse, for example smoking cigarettes and drinking alcohol can impact on the performance of drugs and adherence to treatment [85,87].

Due to the complex nature of TB treatment, patients are more likely to encounter medicine-related problems and should be counselled adequately to ensure the safe and effective use of medicines, particularly those patients with limited health literacy skills.

2.2 Literacy and health literacy

2.2.1 Concepts and definitions

Literacy is a complex but important concept that affects an individual's ability to perform certain daily activities or tasks [88]. Kirsch [89] describes literacy as a set of reading, writing, basic numeracy, speech, and speech comprehension skills needed by an individual to increase their knowledge and function in society. Poor literacy skills are common amongst populations in developed countries and the figures are even higher in developing countries [13]. Low literacy is often indirectly associated with poor socio-economic conditions and lack of access to formal education [13]. Although education can be used as a rough surrogate measure of literacy, this should be done with caution. This was illustrated in a study conducted by Jackson *et al.* [90] that tested the relationship between patient reading ability and the last grade completed, where they found that the majority of patients had reading abilities far below their last grade completed. HCPs often assume that if a patient has completed a certain grade at school they are able to read at that level [90]. A survey conducted among young adults in Malawi found that despite individuals having similar education attainment, many had varying levels of basic literacy [91]. The study also found that 59% of the young adults with a secondary education experienced difficulty reading.

Improved literacy can have several beneficial effects including economic growth, reduced poverty, reduced crime, increase in civic engagement, promoting democracy and improved health [92]. Quality of life can improve significantly and individuals are likely to have increased self-esteem, self-confidence and empowerment [92]. The concept of literacy as a tool to empower and liberate an individual is captured aptly by Kassam [93]:

"To be literate is to become liberated from the constraints of dependency. To be literate is to gain a voice and to participate meaningfully and assertively in decisions that affect one's life. To be literate is to gain self-confidence. To be literate is to become self-assertive. To be literate is to become politically conscious and critically aware, and to demystify social reality. Literacy enables people to read their own world and to write their own history. Literacy makes people aware of their basic human rights and enables them to fight for and protect their rights. Literacy enables people to have a greater degree of control over their own lives. Literacy helps people to become self-reliant and resist exploitation and oppression. Literacy provides access to written knowledge - and knowledge is power. In a nutshell, literacy empowers."

In the early 1990s, numerous studies reported a trend between patients with inadequate literacy and poor health outcomes [94]. De Walt *et al.* [95] conducted a systematic review to investigate the relationship between literacy and health outcomes in which they reviewed a total of 3015 titles and abstracts and identified 684 articles for full review, with 44 meeting the inclusion criteria. The findings revealed that patients with limited literacy had poorer health outcomes, including poor disease-related knowledge, increased costs and hospitalisations, poor adherence to therapy, increased likelihood of smoking and drug abuse, greater risk of depression and poor management of chronic conditions such as asthma, diabetes, hypertension and HIV/AIDS [95]. Effective school education and adult literacy interventions are needed to alleviate the prevalence of inadequate literacy amongst communities [88].

As researchers delved further into the field of literacy, it became apparent that the concept of literacy is context-specific and as a result the concept of various specialised forms of 'literacies' emerged such as financial literacy and computer literacy [88]. In the healthcare setting, literacy provides individuals with the skills that enable them to access, understand and use health information. A visual framework proposed in a report by the Institute of Medicine (Figure 2.2) recognises literacy as the foundation for health literacy and describes health literacy as being the active mediator between individuals and health contexts, with this association influencing health outcomes and costs [9].

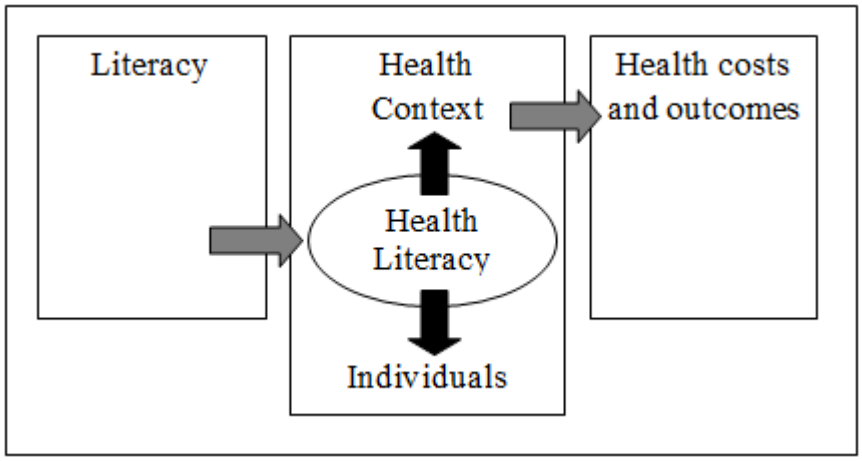


Figure 2.2: Health literacy framework [9]

Individuals with similar educational attainment can differ in their abilities to read and write and, despite the same number of years of formal schooling, they may not have the same level of health literacy [9]. Ability to read and write forms the foundation of health literacy skills. However, the concept and understanding of heath literacy has evolved considerably over the last few decades and has resulted in expansion of the concept to include a constellation of skills and abilities including communication, listening, having adequate background knowledge, accessing health information and making informed health-related decisions [9].

Increasing interest in this area led to several attempts to conceptualise health literacy and resulted in a range of definitions that have been identified and summarised by Berkman *et al.* [96] and are presented in Table 2.3. The authors group the definitions of health literacy into two defined areas including focus on either the individual or the broader community, and health literacy as being static or dynamic (can change through personal experiences, changes in healthcare/society and exposure to technology). These important differentiations impact on both the definition as well as the way in which health literacy is measured.

Table 2.3: Definitions of health literacy identified from literature (Adapted and modified from Berkman *et al.* [96])

Definition	Origin
Individual static definitions	
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) [97]
The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.	Ratzan & Parker (2000) [98] Institute of Medicine (2004) [9] Healthy People 2010- DHHS (2000) [99]
The capacity of individuals to obtain, process, and understand the basic information and services needed to make appropriate health decisions.	Lee, Arozullah, & Cho (2004) [100]
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) [101] Ratzan (2001) [102]
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 changed attitudes and motivations in relation to health behaviour, as well as improved self-efficacy in relation to defined tasks.	Nutbeam (2006) [103]
An individual-level construct composed of a combination of attributes that can explain and predict one's ability to access, understand, and apply health information in a manner necessary to successfully function in daily life and within the health care system.	Schwartzberg *et al.* (2005) [104]
Individual dynamic definition	
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 (2005) [105]
Individual/system definition	
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) [106]

Dependent on individual and systemic factors, including communication skills of lay persons and professionals, lay and professional knowledge of health topics, culture, the demands of the healthcare and public health systems, and the demands of the situation/context	Healthy People 2010- DHHS (2000) [99]
Medical literacy is the type of health literacy that focuses on knowledge and skills relating primarily to health care settings, and which takes various forms such as: basic reading and numerical skills that allow a person to function in the health care environment.	Peerson & Saunders (2009) [107]
Public health definition 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 *et al.* (2009) [108]

Early definitions of health literacy focus mainly on the ability of individuals to apply basic reading and numeracy skills in the context of health [96]. However, more recent and widely used definitions focus on an array of skills, including the ability to "obtain, process, and understand basic health information and services needed to make appropriate health decisions". These definitions include not only reading ability and numeracy but also effective communication (listening, speaking and writing), the ability to use technology such as the internet, cognitive skills, social skills and self-efficacy [9]. Freedman *et al.* [108] propose a definition of 'public health literacy' and this places emphasis on not just the benefits of health literacy among individuals but the community at large. Based on this, public health literacy is defined as "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".

Nutbeam [101] examined the concept of health literacy and identified three distinct levels:

a) Functional health literacy - adequate reading and writing skills that allow individuals to function in their day-to-day lives.
b) Interactive health literacy - involves advanced cognitive, social and literacy skills that are required to actively participate in daily activities. Additionally, these skills allow an individual to derive meaning through communication and to apply new information to situations they may encounter.
c) Critical health literacy - involves more advanced cognitive and social skills that can be used to critically analyse information and to use the information to make more informed choices and exert greater control over life situations.

Classification of health literacy into these three levels highlights how individuals can progress from having the basic ability to read and write to a level of health literacy that demands greater cognitive skills, allowing for patient autonomy and empowerment [101]. Functional health literacy forms the foundation on which an individual can develop other more advanced abilities. The progression from one level to the next is not only based on an increase in an individual's cognitive abilities but also from exposure to various health materials, interactions with HCPs and through the media, suggesting that health literacy is a dynamic concept which changes over time [101]. By improving patient access to health information and their capacity to use it, HCPs can influence patients' health literacy skills and enable them to navigate more easily through the healthcare system. Therefore, patients

are not solely responsible for improving their own health literacy; it should essentially be a shared responsibility whereby the HCP also promotes health literacy during their interactions with patients.

2.2.2 Literacy and health literacy statistics

Literacy is recognised as a basic human right and this is implicit in the importance placed on the provision of formal education to all youth and adults worldwide [92]. According to the United Nations Educational, Scientific and Cultural Organisation (UNESCO) statistics, literacy rates for both adults and youth have increased over the past decade [92]. More than half of the countries with data have reported youth literacy rates of 95% or higher [92]. However, the accuracy of these figures is questionable as the estimated literacy rates are calculated by assuming that adults with more than 5 years of schooling can read [91]. Despite an increase in global literacy, 774 million adults (15 years and older) still cannot read or write, of which two thirds are female [92]. Additionally, 98% of the illiterate population live in developing countries, with the African continent having an average literacy rate less than 60% [92].

According to the 2012 General Household Survey conducted by Statistics South Africa (StatsSA), the adult literacy rate in 2012 was 92.9% [109]. This figure is exceptionally high and it could be as a result of the way in which literacy was defined and measured, which was by self-reported measures that ascertained an individual's ability to write their name, read, fill in a form, write a letter, calculate monetary change and read road signs. Additionally, all respondents who had an education level above Grade 7 were assumed to have adequate literacy and were not questioned further on their ability to read and write short sentences [110]. Thus a total of 83% of respondents were categorised as having adequate literacy based on their educational qualification being above Grade 7 [110]. The 2011 Census conducted in South Africa revealed that 74.6% of the population had an educational attainment above Grade 7. Therefore, according to the measures used by StatsSA in the General Household Survey, if we were to assess the health literacy of the South African population, only 25.4% of the population will be evaluated for inadequate health literacy [109]. As highlighted earlier, using education as a measure of literacy can be problematic especially as many individuals who have completed Grade 7, may face difficulties with basic reading, writing and numeracy skills [90].

In the context of health, many patients lack the necessary 'language' and literacy skills to function within the healthcare system and thus encounter difficulties navigating and engaging within the system. In the USA, approximately 50% of adults have some difficulty accessing and acting upon health-related information [9]. In developing countries, the situation is even worse and is linked to the high levels of illiteracy and the lack of formal education amongst the population.

There is a dearth of information available on health literacy activities in developing countries, including South Africa. In an attempt to understand and acknowledge health literacy accomplishments globally, Pleasant [111] put together a commissioned paper titled "Health literacy around the world". One aspect of the paper focussed on determining the penetration of the concept of health literacy throughout the world and for this he conducted a review of literature and mapped the number of peer-reviewed journal articles on health literacy by country of origin of the first author. The results obtained are presented in Table 2.4. It is evident that literature on health literacy predominately originates from USA, Australia and the United Kingdom (UK).

Table 2.4: Peer-reviewed journal articles on health literacy by nation of first author in 2011 (Pleasant [111])

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		

Pleasant [111] also approached expert participants from all over the world and asked them for their input on several health literacy-related aspects in the context of their country. This included how health literacy is defined, government policies, health literacy initiatives and educational interventions targeting health professionals. The snowball sampling strategy was used and involved sending email invitations to individuals who worked in the field of health literacy. These individuals were requested to suggest other participants who may be able to provide insight.

In the South African context, the participants reported the following:

- health literacy affects the majority of the population (as opposed to minority populations in developed countries)
- health literacy was not formally defined as a public policy issue and participants were unaware of any government policies and programmes that explicitly focussed on health literacy
- health literacy is not a commonly utilized term and there are no formal health literacy tests that have been developed and validated in the South African context and most of the existing tools in literature are inadequate or non-applicable to the population

From these responses, it is evident that there is a lot of scope for research in this field and interventions targeted at identifying and improving patient health literacy throughout the country are needed.

2.2.3 Measurement of health literacy

Limited health literacy is a major barrier to receiving adequate healthcare [112]. Many patients do not understand appointment slips, medicine labels, directions for self-care, informed consent forms, medical forms as well as health education materials [112]. Often these health-related resources are written at a reading level higher than that understood by an average patient and contain complex terminology and medical jargon that many patients are unfamiliar with [30]. Patients often encounter difficulties reading health-related materials but in fear of embarrassment and shame many do not ask for an explanation or clarification [113]. HCPs need to recognise patients with limited literacy and provide them with appropriate targeted information and counselling.

Patients often exhibit certain behavioural traits which are indicative of inadequate health literacy and these can be used as an informal way of determining if a patient has limited health literacy namely [114]:

- filling out forms inappropriately
- not taking the medicines as instructed
- inability to specify the name of medicines or what they are for
- missing scheduled appointments
- bringing a friend/family member to fill out forms or do the reading
- avoiding having to read by indicating that "I forgot my glasses", "I'll read later" or "let me take this home to read"
- being quiet or passive
- becoming angry, frustrated or demanding

However, it is not always possible to identify patients with limited health literacy through informal techniques and as a result researchers have developed screening tools and instruments to determine an individual's health literacy [114]. Zumbo *et al.* [115] conducted a review of literature to identify these various health literacy tools and these are summarised in Table 2.5 in chronological order according to date of publication.

The various tools and instruments identified from literature can be classified as either word recognition tests, comprehension tests or self-reported measures [115] and are used to assess an individual's health literacy level. Each of these tools has its own purpose, time to complete, versions, procedures, scoring system, reliability, validity, strengths and weaknesses. The first instrument that was identified in literature was developed in the USA in 1961 by Samora *et al.* [116]. The purpose was to obtain a measure of the extent to which patients understand 50 frequently used medical words. The instrument is administered by an interviewer who reads out an illustrative sentence for each medical word to the participant and then asks for his/her interpretation of the key word [116]. The strength of the instrument lies in the ability to measure comprehension through listening and oral skills, however, it does not take into account reading skills and is quite time consuming to administer [115].

Table 2.5: Health literacy tools and instruments identified from literature (Adapted and modified from Zumbo *et al.* [115])

Year	Authors	Instrument	Abbreviation
1961	Samora *et al.*[116]	Comprehension of fifty medical terms (instrument was not named)	-
1991	Davis *et al.* [117]	Rapid Estimate of Adult Literacy in Medicine	REALM
1995	Parker *et al.* [118]	Test of Functional Health Literacy in Adults	TOFHLA
1997	Hanson-Divers [119]	Medical Achievement Reading Test	MART
1999	Baker *et al.* [120]	Test of Functional Health Literacy in Adults, shortened version	S-TOFHLA
2001	Nath *et al.* [121]	Literacy Assessment for Diabetes	LAD
2003	Bass *et al.* [122]	Rapid Estimate of Adult Literacy in Medicine, shortened version	REALM-R
2003	National Center for Education Statistics (NCES) in the U.S.	Health Literacy Component of the National Assessment of Adult Literacy (NAAL)	HLC
2004	Rudd *et al.* [123]	Health Activities Literacy Scale using data from the National Adult Literacy Survey (NALS)	HALS
2004	Chew *et al.* [124]	Three screening questions (the set of questions was not named)	-
2005	Weiss *et al.* [125]	Newest Vital Sign	NVS
2006	Agre *et al.* [126]	Stieglitz Informal Reading Assessment of Cancer Text	SIRACT
2006	Lee *et al.* [127]	Short Assessment of Health Literacy for Spanish-speaking Adults (Spanish instrument)	SAHLSA
2006	Morris *et al.* [128]	Single Item Literacy Screener	SILS
2013	Apolinario *et al.* [129]	Multidimensional Screener of Functional Health Literacy	MSFHL

REALM is another widely used screening tool developed in the USA and can give an indication of estimated reading level of an individual [117]. It consists of a 66-word recognition test with a high number of items at lower literacy levels thus increasing the discriminatory power to screen patients with limited literacy [117]. It does not take long to administer the test and minimal training is required for its administration [117]. In 2003, the REALM was modified to REALM-R, a shortened version of the original test [122]. REALM-R consists of 8 words (osteoporosis, allergic, jaundice, anaemia, fatigue, directed, colitis, and constipation) and takes less than 2 minutes to administer [122]. However, a major limitation of the REALM and REALM-R is that they only measures the ability to pronounce words and do not measure understanding or comprehension [115].

To measure the ability to perform health-related tasks that require reading, numeracy and appraisal skills (i.e functional health literacy), an instrument called TOFHLA was developed in the USA which is a 50-item reading comprehension and 17-item numerical ability test. [118]. The instrument is available in English and in Spanish (TOFHLA-S) [118]. The major limitation of the test is that it takes a long period to administer, with a time limit of 22 minutes, and as a result it is more useful as a research tool than as a screening tool used in practice. A shortened version (S-TOFHLA) has been developed to address the time factor, however it still takes up to a maximum of 12 minutes to administer [115]. Additionally, the prompt cards used when administering TOFHLA and S-TOFHLA are based on scenarios that are commonly encountered amongst the population in developed countries such as USA and are not really applicable to populations in developing countries such as South Africa [115]. For example, one of the scenarios is based on a medical aid scheme that is found in USA and this would be unfamiliar to a patient attending a public healthcare facility in South Africa.

This raises an important concern about the need to ensure that instruments that are used to measure health literacy are context specific and take into consideration the cultural, social and economic characteristics of the target population. Dowse *et al.* [130] conducted a study in South Africa to investigate health literacy levels in an English second language population using REALM. The findings revealed that the REALM instrument was inapplicable for an average of four out of 10 words and was deemed unsuitable for assessing health literacy of the study population [30]. The authors highlighted the need to avoid assuming universal applicability of health literacy tests and emphasised the need to take into consideration the local language, culture and healthcare setting prior to use of the instruments in practice [30].

A recent study conducted in Brazil focused on developing and evaluating a screening tool called the Multidimensional Screener of Functional Health Literacy (MSFHL) [129]. The tool was based on three demographic variables and three simple questions which have the potential to provide an accurate prediction of an individual's health literacy level. The three demographic variables include educational attainment, mother's educational attainment and major lifetime occupation (either manual or non-manual) [129]. The three simple questions focused on 'frequency of use of computers', 'difficulty reading and the resulting interference with getting a better job' and 'difficulty reading subtitles when watching a foreign film'. The score obtained for the MSFHL provided an accurate prediction of an individual's level of

functional health literacy and scores obtained significantly correlated with the scores attained for S-TOFHLA [129].

It is important to note that limited data are available on the prevalence of health literacy in developing countries [129]. In developed countries, several studies have been conducted amongst the general adult population and have used TOFHLA or S-TOFHLA with the percentage of the study population with limited literacy ranging from 6.8% in Australia [131] to 19.7% in Switzerland [132]. According to the Brazilian study, the proportion of individuals with limited functional health literacy is 31.7% and this is indicative of the greater prevalence of limited health literacy amongst populations in developing countries [129].

In 2004, Chew *et al.* [124] proposed three screening questions to identify patients in a clinical setting with inadequate or marginal literacy skills. The screening questions are quick, and like the MSFHL, they do not directly assess health literacy through reading or comprehension tests and as a result are less likely to cause anxiety and shame [115]. However, the limitations of this tool include its limited testing in different countries and the fact that it only addresses written health information [115]. In 2006, Morris *et al.* [128] formulated a Single Item Literacy Screener (SILS) which consisted of one question: "How often do you need to have someone help you when you read instructions, pamphlets, or written material from your doctor or pharmacy?" When the test was validated, it performed moderately well and was able to successfully identify patients who require assistance with reading health-related information materials. The authors recommend the validation of the SILs in other populations to determine its applicability and usefulness [128].

A more recent literacy screening instrument called the Newest Vital Sign (NVS) consists of a nutritional label with six accompanying questions to assess reading skills, numeracy skills and document literacy [125]. Advantages of this test include its short administration time of three minutes, it allows assessment of literacy and numeracy, is available in both English and Spanish and uses a commonly encountered text, viz. nutritional labels [125]. However, the test is based on an ice-cream label and requires calculation of caloric intake. In developing countries, ice-cream is unlikely to be found in a fair proportion of homes and individuals may have no knowledge of the concept of food intake as measured by calories.

Being a developing country, South Africa is likely to have a high proportion of the population with inadequate health literacy skills [115]. At present, there are no health literacy tools or instruments that have been developed for use in the context of South Africa. Apart from the study conducted by Dowse *et al.* [130], no other study has looked at the validation or applicability of existing health literacy tools for use in this country. As a significant proportion of patients attending South African public healthcare facilities are likely to encounter difficulties navigating within the healthcare system, there is an urgent need to develop a tool that can be used in clinical settings to quickly and accurately identify patients with limited health literacy in order to support their care with appropriate advice and counselling.

2.2.4 Health literacy models

Health literacy itself is a complicated construct that can be improved through multiple strategies including changes in both individual capacity as well as changes in the healthcare system [106]. Nutbeam [13] identified two approaches to understanding and improving health literacy; the first approach originates from clinical care and views health literacy as a "risk" and the second originates from the public health and health promotion field where health literacy is viewed as an "asset".

Health literacy as a "risk" draws attention from policy-makers and health service providers who aim to mitigate the negative effects of poor health literacy including nonadherence, poor treatment outcomes, hospitalisations and increased health costs. The process of identifying and managing health literacy as a risk factor is conceptualised by Nutbeam [13] in a six component model (Figure 2.3) and each components is outlined as follows: (1) assessment of prior knowledge and health literacy using various applicable tools; (2) improved organisation and service delivery whereby HCPs and the health system are sensitive to the needs of patients with limited health literacy and are equipped with measures to facilitate communication with these patients; (3) measures could include improved access to healthcare and productive engagement with HCPs; (4) HCPs are in a better position to tailoring health information, communication and education to meet the needs of patients with limited literacy; (5) implementation of components 1-4 result in improved self-efficacy, self-management and increased compliance and; (6) this in turn results in enhanced clinical outcomes.

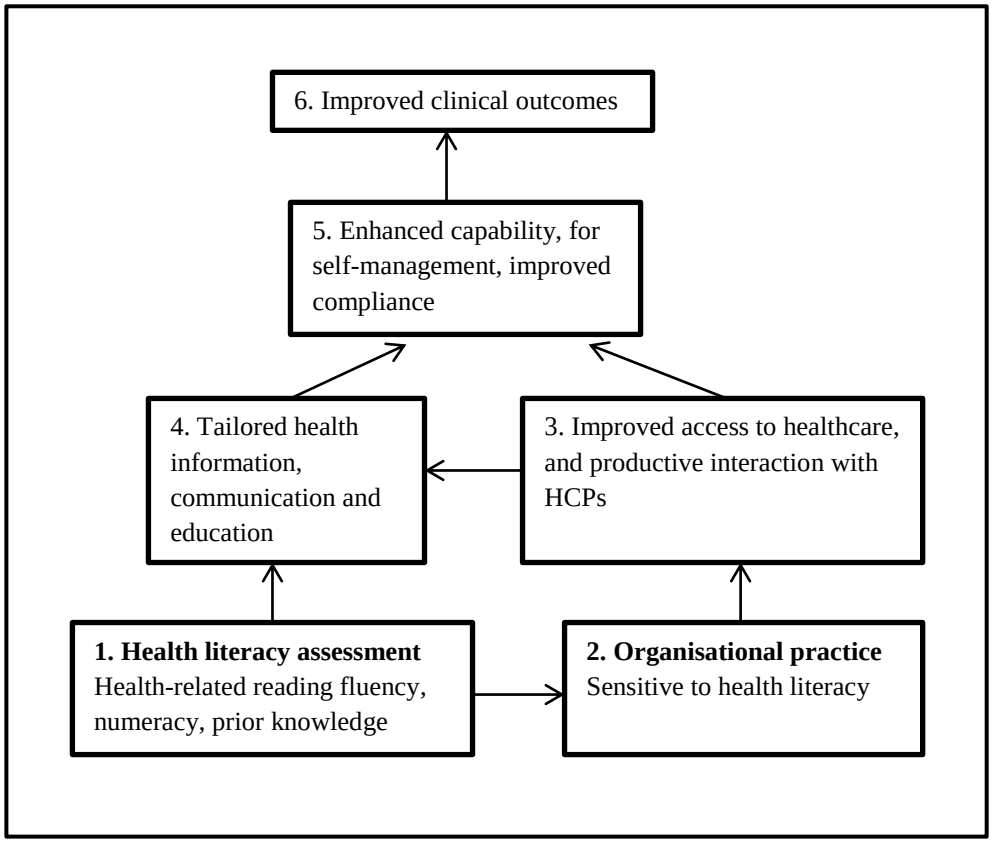


Figure 2.3: Conceptual model of health literacy as a risk (Nutbeam [13])

When viewed as an "asset" in the second model, improved health literacy facilitates greater patient autonomy and participation in health decisions. The outcome of this model is an empowered patient who engages with the healthcare system. According to the model, this is achieved through health education that not only focuses on providing information about medicines and health but also incorporates education on self-management of disease, development of skills to promote HCP-patient interactions and abilities to navigate the healthcare system. It involves a different method of educating patients that involves patient participation, interaction, personal experiences and critical analysis. The model proposed for this approach builds on the conceptual model of health literacy as a "risk" and is presented in Figure 2.4.

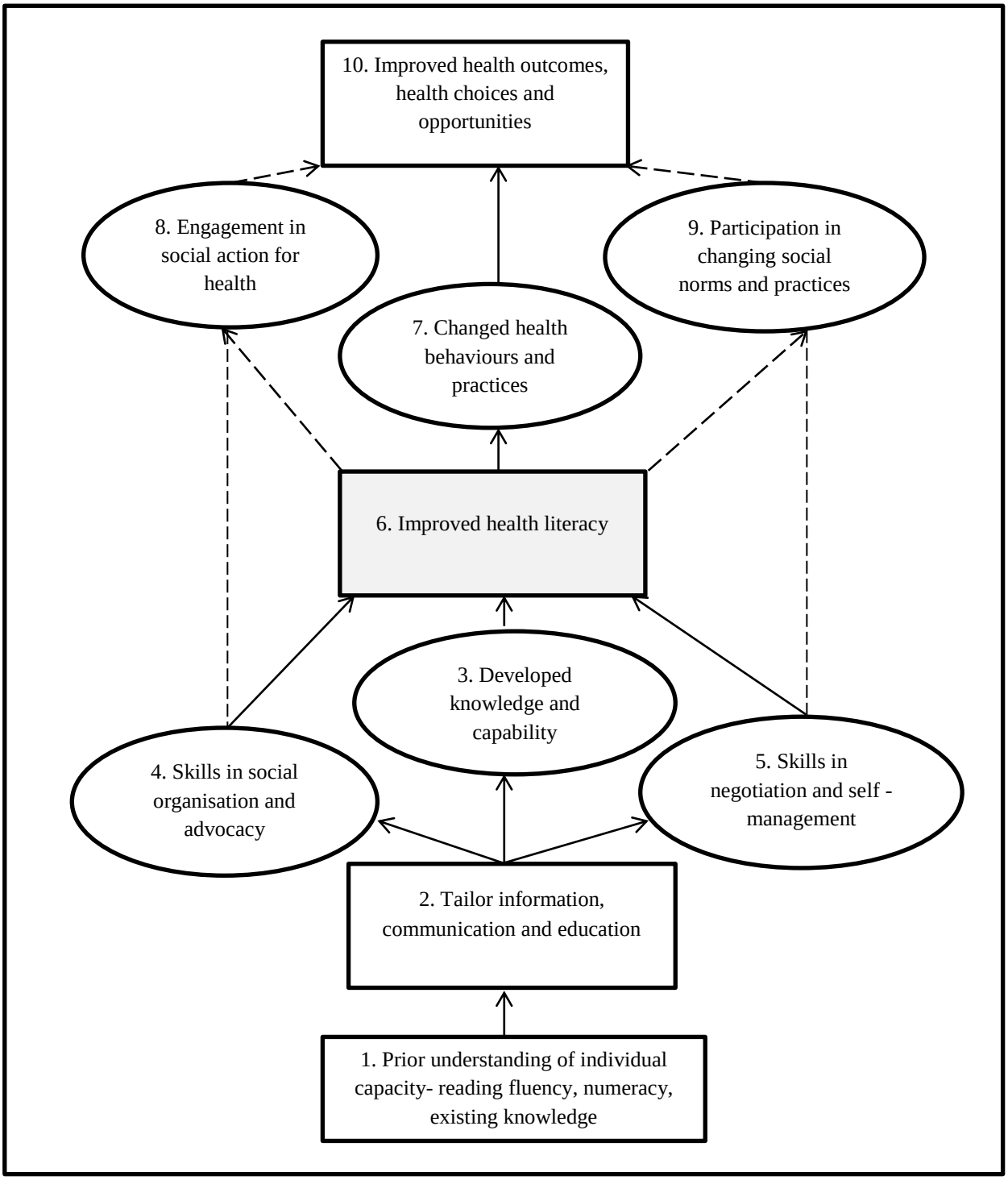


Figure 2.4: Conceptual model of health literacy as an asset (Nutbeam [13])

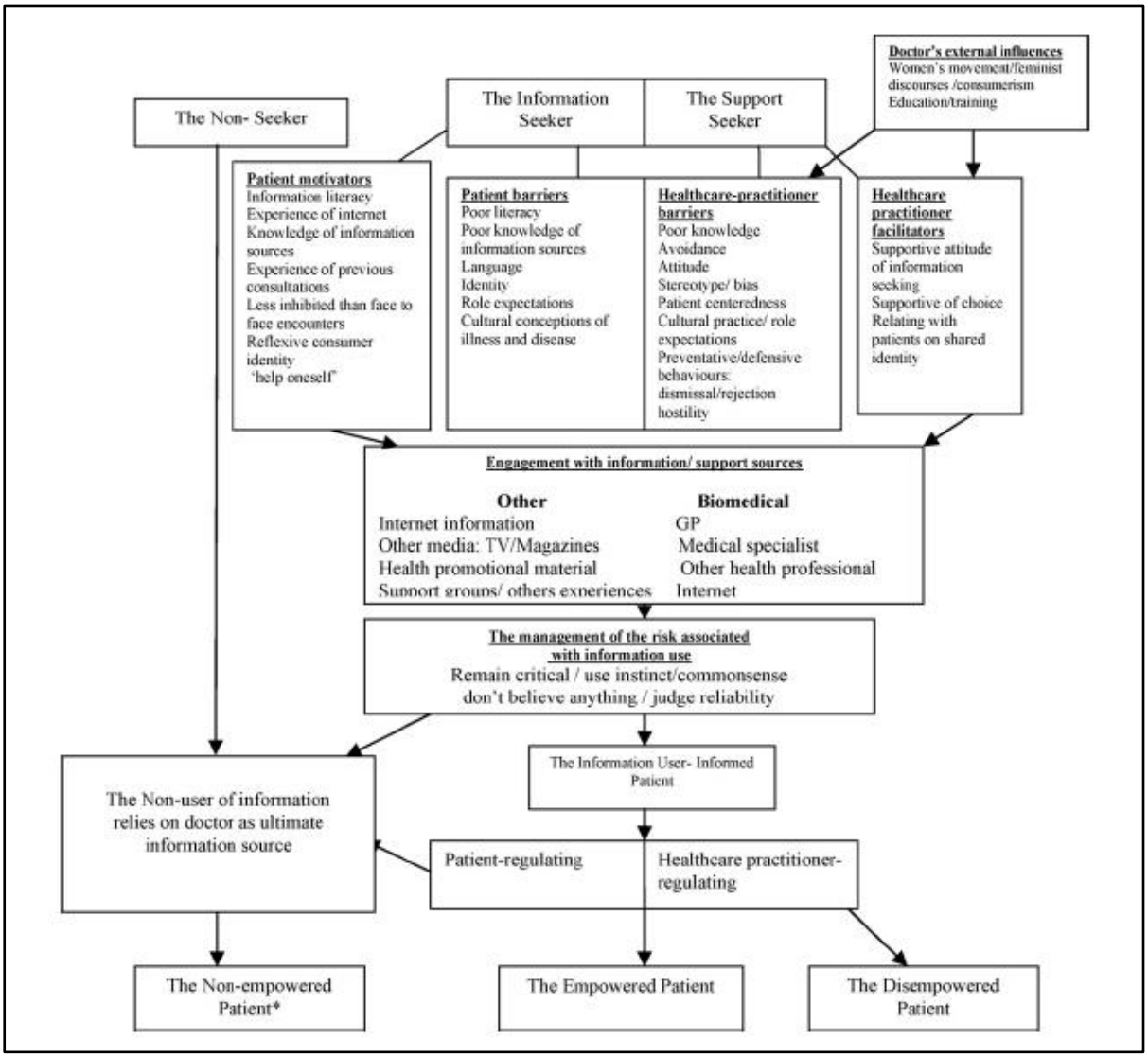
The first two components (1 and 2) of this model (Figure 2.4) are similar to the previous, however, after this point the models vary significantly with the inclusion of component (3), (4) and (5) which bring in health education aspects and developing patient skills and capabilities to navigate the healthcare system resulting in improved health literacy (6) which then translates into changes in behaviour (7), social engagement (8) and participation in social change to norms and practices (9). This all ultimately culminates in improved health outcomes, heath choice and greater opportunities (10).

Both these conceptual models assist in understanding health literacy and its place in the process of health communication and improved outcomes [13].

2.2.5 Health literacy and patient empowerment

Effective communication of health information to patients is critical to empowerment [133,134]. The definition of patient empowerment is not well-articulated and numerous attempts to conceptualise patient empowerment have been documented in literature. Most of the definitions available primarily focus on patient empowerment as an individual's capacity to make health-related decisions and to take control of aspects of their lives that relate to health [134]. Some of the common assumptions that are made about empowered patients include their ability to make more rational health-related decisions and a decreased dependence on health services, resulting in more cost-effective use of health resources. Further research is needed to prove these various assumptions. Some researchers suggest that empowerment may be context and population specific and therefore a universal definition may not apply [135].

In countries with a high prevalence of limited health literacy, patients often have limited knowledge and understanding of their health and medicines and this reduces their autonomy in both self-care and decision-making [136]. Additionally, HCPs who attend to patients with limited health literacy tend to use an authoritative approach during consultations and this ultimately results in disempowered patients who do not even attempt to engage with their HCPs. A meta-analysis conducted by Edwards *et al.* [41] found that health literacy is a key mediator of information exchange, shared decision-making and empowerment. Based on the findings the authors propose a model that describes information use and its relationship to patient empowerment (Figure 2.5).



*patient choosing not to act as an empowered patient

Figure 2.5: Model of external influences on information use and patient empowerment (Edwards *et al.* [41])

This model demonstrates five key principles:

1. How the use of information and support can be hindered and facilitated by both patient and HCP characteristics.
2. How information is managed in terms of its risk of providing misinformation.
3. How people either become an 'informed patient or user of information ' or a 'non-user of information'
4. How patients and HCPs 'regulate' information input in consultations.
5. The relationship between information use and exchange and empowerment, and how patients can be viewed as 'non-empowered', 'empowered' and 'disempowered'.

Health literacy was highlighted as the concept that underpins the processes in this model with the principal underlying message being that the more health literate patients are, the greater the likelihood of empowerment through health information use and exchange both inside and outside of consultations. Research suggests that improvements in patient health literacy can have a positive impact on patient knowledge, experiences, health service utilisation, patient behaviours and health status [137].

2.3 Patient behaviours

2.3.1 Information needs and Health Information Seeking Behaviour (HISB)

2.3.1.1 Concepts and definitions

Patients require information to empower them in their medicine-taking practices [14-16]. An increasing demand for information relating to health, medicines and disease states has been reported, with informed patients being more likely to seek treatment at an earlier stage, involve themselves in decision-making regarding their treatment and adhere to their treatment plan [15,16,62,138].

Case [139] defined patient information needs as "...a recognition that your knowledge is inadequate to satisfy a goal that you have, within the context/situation that you find yourself at a specific point in time". Studies indicate that if information given matches the information needs of patients, positive outcomes result including increased self-care, self-management and adherence to treatment [140,141] as well as decreased dependency on health services [142,143].

Theories of HISB describing the behavioural process of seeking information have gained increasing attention over the past few decades, but despite this focus there is no apparent principal definition of HISB [144]. From a broad perspective, HISB is simply "…the way in which individuals go about obtaining health information in order to promote and reduce the risks associated with their illness or condition" [144].

The literature on HISB emanates mainly from developed countries with their largely literate, educated patient populations who are aware of the various sources of health information

(including the internet) and are able to actively seek the necessary information [15,145-148]. Many of the patients are fairly well acquainted with their disease state and medicines and are able to engage in some form of decision-making with their HCPs [145-150]. Conversely, studies targeting patients with limited literacy skills residing in developed countries indicate that patients may have difficulty accessing and understanding health information [151-153]. In developing countries this may be further exacerbated by factors such as poverty, limited education, limited health literacy, stigma and lack of access to healthcare and technology. There are few studies from developing countries that specifically aimed to investigate HISB. Two studies from Iran, one in patients and the other in library users, described the HISB as a passive process, with the most common source of information as family and friends, followed by television for the library users [149,154]. There are currently no studies in South Africa that have investigated patient information needs and HISB. Further investigation into the application of this concept in the South African context is needed.

2.3.1.2 HISB models and frameworks

A number of models describing HISB have been developed [144,155-162], with some models representing the various steps involved in seeking information and highlighting the underlying factors that may influence information seeking [146,163,164]. Models describing HISB contribute to conceptualising the process of seeking health-related information and provide a theoretical underpinning with which to understand, analyse and interpret data on how patients look for information [160]. A literature search revealed a number of frequently used models related to HISB [144,155-162]. Lazarus and Folkman's theory [158] and Miller's framework [162] are the most frequently referenced and primarily focus on an individual's response to stress, highlighting coping strategies employed by individuals when faced with a dilemma in the context of health [157]. However, they do not expand on the actual process of heath information seeking.

The other models are essentially frameworks representing the various steps involved in seeking information and they highlight the underlying factors that may influence information seeking [144,157]. The Expanded Longo Model takes into consideration the fact that not only do patients/consumers actively look for information but may also passively encounter information during their daily activities [160]. The model also focuses on patients' ability to understand and make use of information, ultimately culminating in outcomes such as

improved satisfaction, health outcomes, empowerment and locus of control [160]. Anker, Reinhart and Feely [144] conducted a review of several studies on HISB and integrated their findings into a framework. This framework demonstrates the basic process of health information seeking as a linear one and considers the association of predisposing characteristics (e.g. age, education, race, gender, health literacy) with engagement in health information seeking and related health outcomes (e.g. adherence).

These models and frameworks provide a foundation to better understand patients' desire for information [157,160] and can inform the subsequent process of developing appropriate, user-friendly information materials [160].

2.3.2 Self-efficacy

2.3.2.1 Concepts and definition

Bandura [18] defined self-efficacy as "people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives". Perceived self-efficacy has an influence on an individual's choice of activity and behavioural settings, how much effort they put in and how long they will persevere when challenged. It is believed that the stronger the perceived self-efficacy, the greater ability and motivation to succeed when faced with adverse experiences [165]. Bandura describes four sources of information that influence self-efficacy: performance mastery, vicarious experience, verbal persuasion, and physiological symptoms [166]. Performance mastery refers to the knowledge and skills gained through experience and perseverance. Vicarious experience involves observing others completing a task successfully and this imparts a sense of self-efficacy. Verbal persuasion, reported to be the most popular method of influencing self-efficacy and it is used by HCPs to convince patients that they have the ability to attain the necessary health outcome. Finally, physiological symptoms can inform a person's self-efficacy whereby a person's physical reaction to difficult situations can influence how prepared that person feels to effectively handle the situation [166].

Self-efficacy and self-esteem are two related concepts but are often incorrectly used interchangeably. Self-efficacy is defined simply as an individual's perception of their ability to reach a goal, whereas self-esteem relates to an individual's personal sense of self-worth

[18,167]. Bandura highlights the difference between the two concepts by pointing out that a person can have high self-efficacy for a task but they do not necessarily derive any self-pride from doing it (e.g. being able to brush one's teeth well). He also noted that people often tend to develop self-efficacy in activities that give them self-worth and this overlap accounts for the incorrect use of the terms [18,167].

2.3.2.2 Importance of patient self-efficacy in health

Perceived self-efficacy has been shown to have an effect on health behaviours and medicine-taking practices [168,169]. A review conducted by Strecher *et al.* [168] that investigated the concept of self-efficacy and its relationship with certain health practices (cigarette smoking, weight control, contraception, alcohol abuse and exercise) found that there is a strong relationship between the two. The authors suggest that altering self-efficacy can potentially enhance positive health behaviour. Self-efficacy is an important element of many theories related to health including the Health Action Process Approach [170], the Theory of Planned Behaviour [171] and the Health Belief Model [172]. The latter model is widely used in understanding health-related behaviour and in 1988, self-efficacy was added to four other components of this model (perceived susceptibility, seriousness, benefits and barriers) in an attempt to better comprehend confidence in one's ability to effect change in health behavioural outcomes [172].

2.3.2.3 Measurement of self-efficacy

Reliable and valid measurement tools are essential in assessing self-efficacy. Various context-specific tools to measure self-efficacy have been developed, for example in chronic diseases, assessment tools are available for conditions such as HIV, diabetes, asthma, arthritis and chronic obstructive pulmonary disorder [173]. Self-efficacy amongst patients taking ARVs is crucial as adherence of more than 95% is needed for treatment success. The HIV-ASES is a valid and reliable measurement tool that has been used in HIV treatment adherence research and has shown potential for use in clinical practice to address patient adherence-related problems [174]. The HIV-ASES consists of 12 items that address adherence to HIV treatment particularly focusing on side effects, complexity and beliefs about treatment, stigma, general health, dietary changes, visits to healthcare facilities and other individual's beliefs about ARVs. These aspects are considered important in adherence to HIV treatment.

For each of the 12 items, patients are asked to comment on their level of confidence using a scale from 1 (cannot do it at all) to 10 (certain can do it). Johnson *et al.* [174] recommend that the HIV-ASES could be adapted for adherence in other disease management contexts. Limited research has been conducted on the role of self-efficacy in patients with TB and how this health-related behaviour can possibly be improved through effective HCP-patient counselling. Morisky *et al.* [175] conducted a study to investigate the effects of innovative behavioural interventions on adolescents taking treatment for latent TB at two clinics in Los Angeles, USA. In comparison to the usual care control group, adolescents assigned to the peer-counselling groups (peer counsellors were adolescents who had completed their latent TB treatment) demonstrated significantly greater improvements in self-efficacy. These results are consistent with a Namibian study that reports that TB treatment-related counselling incorporating patient success stories (vicarious experiences) has a greater impact on patient motivation and self-efficacy as opposed to conventional counselling (verbal persuasion) [176]. Further investigation into improving self-efficacy through effective patient counselling about their TB medicines is warranted.

2.3.3 Adherence

Adherence to therapy is a global health problem [177]. Literature indicates that poor adherence to treatment is prevalent across various health conditions, treatments and ages [178]. Only 50% of patients in developed countries adhere to their chronic therapy, with the situation in developing countries being even worse due to the paucity of health resources and staff [80]. A meta-analysis of literature on nonadherence to chronic therapy by elderly outpatients reported that up to 59% do not take their medicines as prescribed. A vast amount of research has been conducted to understand patient medicine-taking behaviour and reasons for nonadherence to treatment [177,179].

2.3.3.1 Definitions

The intense interest in adherence has resulted in the emergence of various terminologies describing this behaviour, namely compliance, adherence and concordance. These terms are sometimes used interchangeably but essentially have major differences in their meanings [177,179].

Compliance. This term was first used in medical literature in the 1950s and originated based on a physician-led approach to prescribing treatment [179]. Haynes, Taylor and Sackett defined compliance as "the extent to which the patient's behaviour matches the prescriber's recommendations" [180]. However, this term was criticised due to the negative inference it placed on the HCP-patient relationship whereby the HCP plays an authoritative role, simply giving the patient instructions to follow, with the patient playing a passive role with no involvement in decisions about their own health. Due to the negative connotations attached to this word alternative terms were sought [177,179].

Adherence. This term is often used interchangeably with compliance, but in actual fact it develops the definition of compliance to include the fact that there is some form of an agreement between the patient and the HCP. Based on the information and instructions provided by the HCP, the patient is free to decide whether to take the treatment or not [177,179]. Additionally, adherence to treatment is the responsibility of both the patient and the HCP. Adherence is defined by the 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" [80]. Failure to adhere to treatment is a common problem and patients often discontinue their treatment without telling their HCP, especially in the case of chronic therapies.

Concordance. This is a more recent term used predominately in the UK [177] and has not yet been widely adopted in South Africa. Both patients and HCPs have their individual set of beliefs, expectations and preferences. In the case of compliance, the HCP's beliefs and preferences are considered with little or no consideration to that of the patient [177,181]. In contrast, concordance is defined as "an agreement between the patient and HCP, reached after negotiation that respects the beliefs and wishes of the patient in determining whether, when and how their medicine is taken, and (in which) the primacy of the patient's decision (is recognized)" [182]. However, there is some controversy surrounding the use of this term with some researchers suggesting that HCPs may coerce a patient by providing them with only selected information thereby influencing their decision [181]. They also suggest that patient involvement in health decisions may vary from person to person as some may be better informed and ask questions whereas others will rely solely on the information provided by their HCP [181]. Additionally, concordance is much more complex and less clearly defined with some authors suggesting that there is no such thing as patient concordance, but rather

that a consultation should be concordant [177]. They describe the term concordance as being focused more on the two-way communication process that takes place during a consultation [181]. More research is needed to enhance understanding in order to adopt the term concordance in clinical practice and research studies [177].

For the purposes of this thesis, the term adherence was selected to describe the extent to which a patient follows the instructions recommended by the HCP based on an agreement made by both stakeholders.

2.3.3.2 Patient nonadherence to medicines

Poor adherence to prescribed medicines is a continuous and complex problem and has shown to have a significant impact on health outcomes [183]. A landmark review of the field over the last 40 years was published by Haynes and Sackett [184] which explored the various factors affecting adherence to medicines. The authors highlighted that when all determinants are considered, there is no single or simple explanation for behaviours associated with poor adherence. However, several predominant factors have been identified and are categorised into five broad categories that have been summarised in Table 2.6.

Table 2.6: Predominant factors associated with nonadherence to medicines [184]

Category	Specific factors associated with nonadherence
Disease	Psychiatric diagnosis
Treatment	Complexity Degree of behavioural change Duration
Healthcare system	Inefficient and inconvenient clinics
Healthcare professional-patient interaction	Inadequate supervision by HCPs Patient dissatisfaction with interactions
Patient	Inappropriate health beliefs Past or present nonadherence to medicines Family instability

Another comprehensive review of literature on patient adherence over the last three decades found similar findings and reported that there are almost 200 different doctor-, patient- and encounter-related variables that influence adherence. None of them are proven to fully predict

adherence, although several significant but weak correlations have been noted [183]. The complexity of the treatment and poor HCP-patient interactions are often mentioned as common determinants of nonadherence, especially amongst those with poor or impaired cognitive ability [185]. Another salient factor affecting adherence is patient beliefs about their medicines and about medicine in general [183]. Patient knowledge, ideas and experiences, as well as that of their family members and friends, have shown to have an association with adherence to treatment. It is possible that each disease state has different factors that influence patient adherence.

2.3.3.3 Factors influencing adherence to complex TB treatment

TB treatment is complex and adherence of more than 90% is necessary for cure [3]. In South Africa, adherence to TB treatment is extremely low and this adversely affects quality of health, treatment outcomes and leads to the development of resistant strains of TB [186]. Treatment of resistant strains is more expensive, less effective and has a greater side effect profile than standard first-line drugs [186].

Nonadherence is a complex phenomenon, with a wide range of factors contributing to the medicine-taking behaviour of patients [80]. Factors contributing to nonadherence to TB medicines are often interlinked; however they can be grouped into five categories as described in Table 2.7. These categories are similar to those identified by Haynes and Sackett [184] in their landmark review that characterised predominant factors associated with patient nonadherence to medicines (Table 2.6).

Table 2.7: Factors affecting adherence to TB treatment

Categories	Examples from literature
Socio-economic	▪ Lack of effective social support systems and poor living conditions [187,188] ▪ Social factors such as poverty, poor education, unemployment and migration leading to development of informal settlements with poor living conditions [87] ▪ High cost of medication [87] ▪ High cost of transport [87,189] ▪ Stigmatization by family and community members [85,189] ▪ Lack of food security in household [85,87,188,189]
Patient-related	▪ Cultural beliefs about TB and TB treatment [87,189,190] ▪ Perception of the illness and treatment [85]

	▪ Inadequate knowledge about TB and consequences of nonadherence [85,87] ▪ Patients' risk perception of the disease [80] ▪ Ethnicity, gender and age [191] ▪ Mental disorders such as drug abuse, alcohol abuse, smoking and depression [85,87] ▪ Denial and difficulty accepting diagnosis [85] ▪ Poor understanding of medicine instructions and health education due to low literacy level [189,192,193] ▪ Forgetfulness [193] ▪ Concern about dependence on the medication [193] ▪ Patient discontinues medicines due to feeling better [189]
Health services and health provider-related	▪ Poorly developed health services and lack of resources to effectively manage and deliver healthcare [188,193] ▪ Poor relationship between health care worker and patient [85,87] ▪ Lack of empathy shown by the healthcare workers to TB patients [87] ▪ Healthcare workers who are overworked, untrained, inadequately supervised and lack expertise [87,188] resulting in weakening control initiatives like health education and counselling [188] ▪ Lack of access to services and staff [85,87,188] ▪ Long waiting hours, queues, lack of privacy and poor conditions of clinic waiting areas [85,87,188] ▪ Failure to adhere to a uniform policy [188] resulting in confusion amongst patients in terms of TB treatment
Disease-related	▪ Rate and progression of symptoms [80] ▪ Absence of symptoms (patient asymptomatic) [192] ▪ TB and HIV co-infection [188] ▪ Co-morbidities [80]
Treatment-related	▪ Complex treatment regime (long-term treatment involving a number of drugs) [85,87] ▪ Side effects or adverse drug reactions to medication [85,87,194] ▪ Difficulty administering the medication

2.3.3.4 Measurement of adherence

It is important to measure patient adherence accurately in order to recommend efficacious interventions that address the barriers to adherence [80]. There are a variety of strategies to measure adherence and these can be divided into three broad categories: subjective, objective and biochemical measurements.

***Subjective measurements*.** These are obtained by asking patients, family members, caregivers and HCPs about a patient's medicine-taking practices. This can be done through verbal assessment or through the use of questionnaires. This form of measurement can be problematic as many patients tend to overestimate their level of adherence [80]. In some

cases, the 'white coat effect' results in overestimation of adherence [195]. Patients often tell their HCP exactly what they want to hear for fear of getting reprimanded for not following instructions. Conversely, some studies have shown that self-reported adherence can adequately predict a patient's level of adherence to medication [196,197]. Morisky *et al.* [197] developed a four-item scale that has been widely used to assess patient adherence. More recently, an 8-item scale has been developed called the Morisky Medicine Adherence Scale (MMAS-8), and it has shown to be beneficial in evaluating patient adherence [198,199].

Objective measurement. This can be done through pill count, examining refill records, or using Medication Event Monitoring System [80]. At first glance, objective strategies may appear to be an improvement over subjective approaches; however, each strategy has its own drawbacks. Pill count can be conducted in clinical practice but it is time consuming for HCPs who have a large patient load. Additionally, inaccuracies in counting may lead to over- or under-estimation of adherence [200]. This method does not take into account important information about medicine administration including the time of dosing and patterns of missed doses [80].

Examining refill records is another method of objectively assessing patient adherence. The drawback of this method is that patients may collect medication refills on the stated date but may not actually be taking the medication at home. Additionally, some patients may visit different pharmacies thus invalidating the use of this method [80]. A recent innovative way to objectively measure patient adherence is through the use of the Medication Event Monitoring System, which involves a microelectronic chip being inserted on the medicine container that registers the date and time of every opening. This date and time log can be downloaded and the data can be used to determine patient adherence. The major disadvantages with use of this method are the cost of the device that precludes widespread use and the fact that a patient may open the container but not necessarily to take a dose [80].

Biochemical measurement. This method involves attaching a biomarker to a medicine and determining the presence of this biomarker in blood or urine. If the patient has taken the medication, the biomarker will present in the sample of blood or urine analysed. However, a major drawback with this technique is that the detection of the biomarker can be influenced by a variety of individual factors including diet, absorption and rate of excretion [201].

Additionally, the cost of using biochemical measurement techniques serves as a major-draw back for its use in determining patient adherence.

In summary, there is no correct or right way of measuring adherence to treatment. Many considerations should be taken when choosing a method to assess adherence, with cost-effectiveness and applicability to the target group being key issues to consider.

2.3.3.5 Implications of nonadherence to TB medicines

Poor adherence to therapy results in increased expenditure on health and medicines, higher transmission and increased morbidity [80]. Patients who are co-infected with HIV and TB may develop other severe opportunistic infections and as a result require hospitalisation. Additionally, many patients who do not adhere to their first-line TB medicines develop resistant strains of TB which are more expensive to treat, and the medicines are less effective and have a greater side effect profile than standard first-line drugs [186]. A study conducted by Pooran *et al.* [202] analysed the cost (in US$) of diagnosis and treatment of drug-sensitive TB, MDR-TB and XDR-TB and found that, assuming adherence to the National South African TB guidelines, the per patient cost of XDR-TB was US$26392, four times greater than MDR-TB (US$6772), and 103 times greater than drug-sensitive TB (US$257). The extra cost of treating drug-resistant TB puts a financial strain on the government and subsequently impacts on the quality of healthcare provided to patients. Another national concern related to poor adherence to TB medicines is the impact it has on population health statistics, as it results in increased likelihood of mortality [80], especially amongst young adults and children.

Patients who do not adhere to their treatment can have positive sputum for several months and can infect others in the community. The majority of family members, friends and people in the community do not associate themselves with TB treatment defaulters. Cramm *et al.* [203] conducted a study to investigate the influence of knowledge, perceptions of access to TB treatment and adherence to treatment amongst the local Grahamstown community. The researchers found that 90% of the participants believed that patients who do not take their treatment are to blame for the spread of TB in the community. Additionally, 74% believed (incorrectly) that people who acquire TB through drinking or smoking get what they deserve, and 51% felt that if you have TB, people do not respect you. The study highlighted the fact

that nonadherence to treatment increases the stigma associated with the disease, with the majority (95%) reporting that people with TB tend to hide their TB status for fear of what others in the community might say. It is important to ensure that strategies are implemented to prevent the spread of TB and address nonadherence at a national, community and individual level.

2.3.3.6 Strategies to improve adherence to TB treatment

Numerous interventions have been implemented in practice to improve patient adherence to complex TB treatment and are summarised below [80]:

- Staff training and management methods aimed at improving the way in which HCPs care for patients with TB.
- Giving patients scheduled appointment dates and appropriate action is taken if the patient fails to keep the appointment.
- Routine reminders or prompts ensuring that patients keep pre-arranged appointments.
- Incentives or reimbursement for returning to the healthcare facility or increased attractiveness or appeal to return to the healthcare facility.
- Written or verbal agreements to return for an appointment or re-fill.
- Using social groups and peer motivation to encourage patients to come to the healthcare facility for treatment.
- Using DOTS for which an identified, trained and supervised individual (healthcare worker, volunteer or family member) directly monitors a patient taking their TB medicines.
- Health education through the provision of information about TB and the importance of adherence.

There is no single strategy or intervention that has shown to have a clear advantage in comparison to others. Literature indicates that a comprehensive strategy should ideally include cognitive, behavioural and affective components and this can be achieved through the combined use of several intervention strategies described above [204]. Additionally, when developing interventions it is crucial to take into consideration the target population and allow them to provide their input into the design of the intervention. This patient-centred

approach can result in interventions that take into consideration patient experiences resulting in interventions that are appropriate, reliable and address patient needs [205,206].

2.3.3.7 Education and counselling interventions to promote TB treatment adherence

Provision of information to patients empowers them to make more informed choices about their health and well-being [14-16]. There are numerous ways in which health information is communicated to patients and these include verbal, written information (leaflets, posters and labels), group education, mass media, mobile technology and the internet. Pharmacists have a crucial role to play in ensuring that patients are educated and counselled adequately to allow for the safe and effective use of medicines.

Patient education is defined as "the process of improving knowledge and skills in order to influence the attitudes and behaviour required to maintain or improve health" [207]. Providing information to patients, particularly health and medicine information can alleviate fears, promote realistic expectations, promote health outcomes, increased satisfaction and can also strengthen the relationship between the HCP and the patient [208]. Patient counselling involves the provision of advice and information (verbal and non-verbal) by a HCP aimed at educating, empowering and supporting a patient [209].

Health education strategies aimed at improving adherence can be divided into three broad categories: educational, behavioural, or a combination of the two [180]. The main objective of the educational methods is to increase patient knowledge. They focus on provision of information about a disease and its treatment and can be presented in a motivational format. Behavioural methods focus mainly on behaviours involved in treatment adherence and attempt to reward or reinforce appropriate behaviour along with reducing barriers to adherence. A study comparing various adherence interventions concluded that combined strategies including both behavioural and educational strategies achieved a higher degree of success in comparison to educational strategies alone [180].

M'Imunya *et al.* [7] conducted a review of literature to evaluate the effects of patient education or counselling, or both, on treatment completion in patients taking treatment for latent TB. The authors identified three RCTs, with a total of 1437 participants and found that

two of the three studies demonstrated a beneficial effect of education and counselling interventions. The authors concluded that patient education and counselling could potentially improve treatment outcomes, but highlighted that the magnitude of success depends on the setting, the nature of intervention and the barriers to nonadherence [7].

In the context of a developing country, patient education and counselling can be challenging due to the shortage of trained HCPs, lack of healthcare infrastructure and services and limited literacy levels [210]. The first documented attempt in South Africa to assess the impact of a health education intervention on TB treatment adherence was conducted by Dick and Lombard [211] in 1997 at two clinics in Cape Town. The study was a controlled intervention study with 60 patients in each of the control and intervention groups. The control group received standard care whereas the intervention group received a combination of a patient-centred interview process and a health education booklet. The health education strategy showed a positive influence on patient adherence but due to the fact that the intervention consisted of both a patient-centred interview with trained and enthusiastic nurses in addition to the health educational booklet, it was not possible to deduce exactly which of these two methods had a greater impact on patient adherence. However, this study did highlight the importance of both establishing a relationship between the HCP and the patient as well as providing information to patients. This is the only documented South African study that focuses specifically on a health education and counselling through the provision of WMI for TB patients.

2.4 Written medicine information (WMI)

2.4.1 Introduction

Patients should have a basic understanding of their dispensed medicines including the name, how to take them, beneficial effects, food or drug interactions and possible side effects. Although it is common practice to educate patients verbally, WMI such as PILs, posters, charts and labels are considered to be valuable tools utilized by HCPs [30]. Many patients tend to forget half the information they are told within five minutes of a consultation and retain only 20% of the information given, whereas when provided with WMI to supplement verbal information there is an increase in information retention [212]. The use of WMI has shown to be both cost-effective and time-effective when communicating health information

to patients [213]. An additional benefit is that patients are able to take these educational materials home and refer to them at a later stage [214]. However, it is important that these educational materials are well-designed, user-friendly and attractive to the target population.

Most WMI is presented in a format that is too complex for many patients and this has an impact on the safe and effective use of medicines [215]. A study conducted by Williams *et al.* [94] found that a large proportion of patients were unable to read and understand very basic medicine instructions, with 42% being unable to comprehend directions for use of a medicine on an empty stomach, 33% unable to interpret correct dosage instructions and 13% being unable to understand instructions to take their medicines four times a day. To improve patient understanding and adherence, it is important to ensure that the information is communicated in a format that is simple, relevant and serves patients' needs and preferences [216].

A systematic review on the role and effectiveness of various forms of WMI revealed that many patients do not value the information accompanying their medicines, partly due to the poor design and the higher than average readability level of the information provided [14,16,30,217]. Nevertheless, studies have established that patients want information and appreciate well-designed user-friendly WMI [16,23,62,217]. Raynor *et al.* [217] conducted a systematic review of both quantitative and qualitative research studies to ascertain the role and effectiveness of WMI available to patients about individual medicines. The authors found that there is a gap between the materials that are currently available to patients and the information that patients feel is important to inform their medicine-taking practices. To improve the quality of WMI, they suggested that developers should involve patients at all stages of the development process thus enabling patient information needs to be better reflected. Further research needs to be carried out to determine how patient input can be better integrated into medicine information research.

2.4.2 Patient information leaflets (PILs)

A package insert is a form of WMI and it is compiled by the pharmaceutical company or manufacturer who has patent rights on the product, and it is regarded as a legal document guiding the safe and effective use of the medicine. Initially, package inserts were used as referral documents intended for HCPs, however in the 1970s, package inserts were included in medicine packaging to improve patient knowledge about their prescription medicine. Most

patients find these package inserts difficult to read and apply and this is largely due to the poor aesthetic appeal, small font size and complex medical terminology included in the leaflet. Due to the problems encountered by patients with package inserts, a more patient-oriented form of the package insert evolved in the 1980s and this is commonly referred to as a PIL.

In developed countries, many HCPs use PILs as a tool to facilitate the communication of health and medicine information that may be difficult for patients to understand [218] and is not found on the medicine label. Evidence shows that the use of PILs can improve adherence to therapy, satisfy patient information needs and inform patients on the correct use of medicines [218,219]. However, the effectiveness of these PILs depends on the design features which should be considered during the development of the materials. Bernardini *et al.* [220] conducted a study to determine the comprehensibility of patient-oriented package inserts (PILs) among 1004 Italian patients at 36 pharmacies in Italy. Results showed that despite the majority of patients reading these, just over half (53.3%) found they were not easy to understand and 46.9% could not find the required information readily. Studies conducted in the USA and in Australia have found similar results whereby the information contained in PILs is considered too difficult to read and understand by a vast number of patients [221].

In 2003, new regulations were published in South Africa as part of the terms of the Medicines and Related Substances Act, 101 of 1965 (as amended) and these stated that all new registered medicines should be accompanied by a package insert and a PIL [34]. Details that should be included in both documents are clearly stipulated in Regulation 9 (1) of Act 101 of 1965 (as amended) and are summarised in Table 2.8.

In South Africa, many companies develop PILs as part of the package insert; however several problems have been identified with use of these information materials by local patients. These problems are similar to those identified for package inserts and include the use of complex terminology and medical jargon, small print size, limited white space and general overload of information [30].

Table 2.8: Details that should be included in a package insert and patient information leaflet for medicines registered for use in South Africa [34]

Package insert	Patient Information leaflet
▪ Scheduling status ▪ Proprietary name and dosage form ▪ Composition ▪ Pharmacological classification ▪ Pharmacological action ▪ Indications ▪ Contra-indications ▪ Warnings ▪ Interactions ▪ Pregnancy and lactation ▪ Dosage and directions for use ▪ Side effects and special precautions ▪ Known symptoms of over dosage and particulars of its treatments ▪ Identification ▪ Presentation ▪ Storage instructions ▪ Registration number ▪ Name and business address of the holder of the certificate of registration ▪ Date of publication of package insert	▪ Scheduling status ▪ Proprietary name and dosage form ▪ Composition ▪ Approved indications and use ▪ Instructions before taking the medicine, which include: - Contra-indications - Precautions - Warnings - Interactions - General statement (consult doctor, nurse or pharmacist if you encounter any side effects and if pregnant or breast feeding) ▪ Instructions on how to take medicine (including general statements about avoiding sharing medicines and to contact a doctor or pharmacist in the case of an overdose) ▪ Side effects ▪ Storage and disposal (including statement about storing medicines out of reach of children) ▪ Identification ▪ Registration number ▪ Name, business address and telephone number of the holder of the certificate of registration ▪ Date of publication of patient information leaflet

2.4.2.1 Format and design of PILs

It is important that patients are able to read, understand, believe and remember the written information given to them [222]. When designing PILs, there are various design features that need to be considered so as to maximise the effectiveness of the materials in improving patient knowledge and comprehension. These include readability, content, language, format, layout, legibility, colour and illustrations [223].

Readability is simply the ease of reading a specific text or material [224]. Studies have shown that individuals prefer simple information materials irrespective of their literacy levels [224,225], despite the common misconception that patients with higher literacy skills are insulted by information materials that are simplified. Various reading ease formulae can be applied to PILs and are used to predict the reading ability necessary to understand a certain text (details of these tools provided in the next section). Examples of commonly used

readability formulae identified from literature include the Flesch Reading Ease formula [226], Gunning-Fox Index [227] and the Simplified Measure of Gobbledygook (SMOG) Grading [228]. These formulae have been designed to calculate one or more of the following items: average length of a sentence in words or syllables, proportion of words used, and the proportion of words that are monosyllabic or contain multiple syllables. Readability assessment of WMI using these formulae indicate that many materials are written at a higher reading level than that understood by the target audience [229,230]. Boyd [231] recommends that information materials should be written two to four grades below the average reading ability of the target group.

Content included in PILs should be simple, easily understood, concise and applicable to the target audience [223] and the purpose of the PIL should be apparent to the reader [224]. Another important aspect to consider is the choice of language. Complex terminology and medical jargon that would be unfamiliar to the patient should be avoided [27] and the PIL should be written in a language that is familiar to the target population [30]. The use of the active voice has been shown to increase patient interest and understanding [223,224].
Information in leaflets should be regularly updated to ensure that the materials comply with current practice, and the date of publication should appear on the document. It is important to place key information at the beginning or in the early part of the leaflet as this tends to gain more interest amongst patients [223]. The use of illustrations has been shown to facilitate the comprehension of information, especially amongst patients with limited literacy skills. These illustrations should not be used in isolation but should be combined with simple text. The inclusion of authorship details allows patients to establish the credentials and accuracy of the information [224].

The format and layout of PILs should allow for easy navigation through the various sections [223]. The use of a question-answer strategy has been beneficial whereby a section heading or sub-heading is formatted as a question followed below by the corresponding answer [231]. This assists patients in understanding why a particular aspect has been highlighted and provides answers to common questions they may encounter. The use of bullet points is useful in communicating key information points to patients. It is also crucial that there is an adequate amount of white space between paragraphs and illustrations included in PILs in order to promote understanding and reduce eye fatigue [223]. This can be achieved through

appropriate line spacing that avoids cramping text, optimising space and ensuring consistency of information.

Legibility of information is facilitated by having the font size as large as possible. Boyd [231] suggests that a 12 point font size should be used with not more than 50-70 characters per line. In the case of elderly and visually impaired patients, a larger font size may be necessary [224]. Not more than six different font sizes should be used to keep the information simple and legible [232]. Use of italics and capitals should be avoided as these lettering styles make it difficult for readers to follow [218]. However, the use of bold print has shown to be effective in emphasizing key points or messages.

There is some controversy around the use of colour as some researchers have found that it is beneficial in emphasizing messages and it can effectively link information to a particular colour that is perceived to elucidate a certain emotional response [233]. On the other hand, Bernardini *et al.* [234] found that most patients do not like the use of colour in PILs and it is interesting to note that this dislike increases with a decrease in educational level. However, one major factor to consider in resource-limited settings is the cost of printing a leaflet in colour.

Materials should be culturally relevant and applicable to the target audience [27,223]. It is important to take into consideration both HCP and patient input at all stages of the design process. Patient involvement in the development process will ensure that the resultant materials cater to patient needs while HCPs involvement will strengthen their support and use of the materials when educating patient in practice.

2.4.2.2 Evaluation of the readability and design of PILs

Information materials must be evaluated to ensure that they meet the necessary design and readability criteria [143]. Luk and Aslani [235] reviewed the various instruments used to directly or indirectly evaluate written health and medicine information from both a document and user perspective, and they identified a number of evaluation tools (Table 2.9) which originated mainly from the UK, USA and Australia. These evaluation tools primarily focused on assessing the various features of WMIs, in particular their readability, presentation and layout.

Table 2.9: Instruments used for direct and indirect evaluation of written health/medicine information from both a document and user perspective, including country of origin and some studies that have utilized the instruments (Adapted and modified from Luk and Aslani [235])

Instruments	Country of origin of instrument	Examples of some studies that have used the instruments
Flesch Kincaid Grade Level Score (FKGL)	USA	Aleligay *et al.* [236]; Dollahite *et al.* [237]; Foster and Rhoney [238]; Freda [239]; Galloway *et al.* [240]; Hendrickson *et al.* [241]; Kondilis *et al.* [242]; Lee *et al.* [61]; Trifiletti *et al.* [243]; Weintraub *et al.* [244]
Flesch Reading Ease Score (FRE)	USA	Arnold *et al.* [245]; Baker [246]; Clement and Wales [247]; Dollahite *et al.* [237]; Foster and Rhoney [238]; Hendrickson *et al.* [241]; Rees *et al.* [248]; Wallace *et al.* [249]; Williams *et al.* [250]; Zwaenepoel and Laekeman [251]
Fry graph	USA	Aleligay *et al.* [236]; Dollahite *et al.* [237]; Kondilis *et al.* [242]; Roskos *et al.* [252]; Wallace *et al.* [249];Wallace *et al.* [253]; Weintraub *et al.* [244]
Gunning Fog test	USA	Galloway *et al.* [240]; Glanz and Rudd [254]; Petterson [255]; Svarstad *et al.* [256]
Lexile Score	USA	Lennon *et al.* [257]; Wolf *et al.* [258]
Rate Index (RIX) Formula	Australia	Anderson [259]; Eames *et al.* [260]
Simplified Measure of Gobbledygook (SMOG)	USA	Aleligay *et al.* [236]; Clement and Wales [247]; Estrada *et al.* [261]; Freda [239]; Friedman and Hoffman-Goetz [262]; Glanz and Rudd [254]; Hendrickson *et al.* [241]; Hoffmann and McKenna [263]; Kondilis *et al.* [242]; Rolland [264]; Shieh and Hosei [265]; Vallance *et al.* [266]
Baker Able Leaflet Design (BALD)	Australia	Baker [246]; Krass *et al.* [267]
Medication Information Design Assessment Scale (MIDAS)	Australia	Krass *et al.* [267]; Boundouki *et al.*[268]

Suitability Assessment of Materials (SAM)	USA	Chesson *et al.* [269]; Eames *et al.* [260]; Galloway *et al.* [240]; Rees *et al.* [248]; Hoffmann and McKenna [263]; Shieh and Hosei [265]; Smith and Cason [270]; Trifiletti *et al.* [243]; Weintraub *et al.* [244]; Wilson [271]; Wolf *et al.* [258]; Vallance *et al.* [266]
Readability Assessment Instrument (RAIN)	USA	Kirkpatrick and Mohler [272]; King *et al.* [273]
DISCERN	UK	Charnock *et al.* [274]; Demir *et al.* [275]; Rees *et al.* [248]
Ensuring Quality Information for Patients Scale (EQIP)	UK	Charvet-Berard *et al.* [276]; Moult *et al.* [143]
Satisfaction with Information about Medicines Scale (SIMS)	UK	Horne *et al.* [277]; Bowskill *et al.* [278]
Package Insert Test (PAINT) Survey	Germany	Fuchs and Hippius [279]
Consumer Evaluation Form (CEF)	USA	Svarstad *et al.* [256]
Consumer Information Rating Form (CIRF)	Australia	Koo *et al.* [280]; Krass *et al.* [267]
Cloze test	USA	Estey *et al.* [281]; Friedman and Hoffman-Goetz [262]; Trifiletti *et al.* [243]
Newest Vital Sign (NVS)	USA	Osborn *et al.* [282]; Weiss *et al.* [125]
Rapid Estimate of Adult Literacy in Medicine (REALM)	USA	Arozullah *et al.* [283]; Chesson *et al.* [269]; Davis *et al.* [230] ; Davis *et al.* [284]; Eames *et al.* [260]; Galloway *et al.* [240]; Hoffmann and McKenna [263]; Murphy *et al.* [117]; Osborn *et al.* [282]; Trifiletti *et al.* [243]
REALM–Revised (REALM-R)	USA	Bass *et al.* [122]
REALM–Short Form (REALM-SF)	USA	Arozullah *et al.* [283]
Rapid Estimate of Adolescent Literacy in Medicine (REALM-	USA	Davis *et al.* [284]

Teen)		
Slosson Oral Reading Test–Revised (SORT-R)	USA	Davis *et al.* [284]; Goodfellow *et al.* [285]
Test of Functional Health Literacy in Adults (TOFHLA)	USA	Chisolm and Buchanan [286]; Parker *et al.* [118]; Weiss *et al.* [125]
Shortened TOFHLA (S-TOFHLA)	USA	Baker *et al* [120]; Osborn *et al.* [282]
Wide Range Achievement Test–Revised (WRAT-R)	USA	Arozullah *et al.* [283]; Bass *et al.* [122]; Davis *et al.* [284]; Estey *et al.* [281]
Patient Education Materials Assessment Tool (PEMAT)	USA	Shoemaker *et al.* [287]; Zellmer *et al.* [288]
Evaluative Linguistic Framework (ELF)	Australia	Hirsh *et al.* [289]; Clerehan *et al.* [290]

SMOG [235] was identified as the most popular readability test, mainly due to the ease of administration [291], good correlation with other reading ability tests [292] and the accuracy of predicting the reading grade level [249]. Design features were most commonly evaluated using the Suitability Assessment of Materials (SAM) [235] which specifically focuses on six key factors, namely the content, literacy demands, graphics, layout, typography, learning stimulation and motivation, and cultural appropriateness [260]. Items included in the PEMAT are based on existing tools identified from literature and this recently developed instrument is used to assess both print and audio-visual educational materials in terms of their understandability and actionability [287]. The ELF is a tool based on systemic functional linguistics and takes into consideration the relationship between language and its functions in social settings [289].

None of the tools highlighted in Table 2.9 were designed or evaluated in a developing country such as South Africa, and they do not appear to be useful in evaluating materials targeting low-literate patients. Their applicability to such materials that commonly contain simply written, basic text and visual elements such as pictograms, appears to be limited.

2.4.3 Impact of WMI on patient knowledge and medicine-taking behaviours

Evidence from numerous reviews suggests that well-designed WMI (such as PILs) can be a useful tool to facilitate the communication of information to patients [293]. Most studies report an improvement in patient knowledge and medicine-taking behaviours when WMI is used although there are a few studies that report otherwise. It is important to acknowledge that WMI that is tested in these studies varies considerably in its content, readability and purpose and this can influence the beneficial outcomes of using WMI.

Several studies that have assessed the impact of using WMI during patient education and counselling process have highlighted the beneficial effects of WMI. A study conducted by Gibbs *et al.* [25] reported that patients who received WMI were better informed and could answer most of the items in the knowledge test, except the name of their medicine. The authors also noted that knowledge of side effects improved significantly and this was not accompanied by an increase in spurious side effect reporting. Furthermore, research indicates that patient satisfaction with medicines has been linked to increased treatment adherence as well as better communication between the patient and the HCP [294]. Generally, patients

who received WMI about their medicine expressed greater satisfaction and the authors concluded that the benefits of WMI justify the need to introduce them in practice [25].

Two studies in which WMI was developed and evaluated for patients with rheumatoid arthritis found that patient knowledge improved significantly and this was accompanied by an improvement in psychological well-being [295,296]. Morris and Halperin [219] conducted a literature review to investigate the effect of WMI on patient knowledge and compliance and reported that WMI can be effective in improving patient compliance, particularly with antibiotic medicines.

Patients who understand their medicines are more likely to practice responsible medicine-taking and have greater perceived self-efficacy [17]. Wolf *et al.* [21] found that amongst 204 HIV-infected patients, limited health literacy and understanding of medicines was associated with lower self-efficacy when taking prescribed medicines. Similar findings were reported in a study by Ishikawa *et al.* [297] amongst diabetes patients. Mansoor and Dowse [138] highlighted in one of their studies that the availability and use of a more complex PIL had no significant effect on either patient understanding or adherence to therapy. In populations with limited health literacy, WMI should be short, simple and contain culturally sensitive pictograms, and should be used in combination with verbal instructions [138]. Studies by Dowse and Ehlers [298], as well as Ngoh and Shepherd [299], have provided evidence to support the use of simple culturally relevant pictograms and their beneficial effects on patient comprehension and adherence to medicines.

2.5 Pharmaceutical pictograms

2.5.1 Introduction

Pharmaceutical pictograms are simple, clear graphic symbols that are able to convey an intended medicine-related message to patients [215]. According to research, pictograms have proven to be an effective tool to employ in order to support spoken medical instructions [33,298,300]. Houts *et al.* [300] reported that populations with limited literacy can remember and recall greater volumes of medical instructions for a longer period of time when pictograms are used, both in the learning as well as the recall process. Studies by Dowse *et al.* [32,215,298,301] have demonstrated the significant impact of inclusion of visuals on patient

comprehension, recall and acceptability of medicine information. Use of pictograms has also shown to be effective in gaining the interest and attention of patients and encouraging them to use educational materials [302]. This is particularly beneficial amongst patients who are illiterate, visually impaired or elderly and are likely to encounter difficulty reading and understanding WMI [215].

Pictograms can be effective in improving patient adherence [138]. Patients display a better understanding of how to take their medicines and express greater satisfaction with medicine instructions received through the use of visual aids [216]. A systematic approach should be adopted in investigating the impact of pharmaceutical pictograms [302]. Delp and Jones [303] have suggested a simple and effective research design that involves all patients receiving the same written text (control group) and only some patients receive written text accompanied by pharmaceutical pictograms (experimental group). This method was used by Dowse and Ehlers [298] to assess the impact of labels for antibiotics prescribed to a population with limited literacy (n=87). The study found that pictograms greatly enhanced comprehension in the experimental group who achieved an average comprehension of 95% whereas the control group achieved a mere 70% ($p<0.01$). Additionally, adherence to therapy was significantly higher ($p<0.01$) in the experimental group (90% versus 72% in control group). In contrast, some studies have reported conflicting findings whereby the use of pictograms has not shown to be beneficial in the acquisition and comprehension of information [304,305]. However, one major reason for this is the poor design and absence of rigorous testing to ensure that the pictograms communicate the intended message [215].

2.5.2 Development of effective pharmaceutical pictograms

Pictures are a non-verbal form of communication and provide an effective way to gain attention, convey information and encourage the brain to remember certain facts [215]. However, this depends on how a person interprets and perceives the picture with research showing that in order to understand the meaning of a picture, a range of skills is required as picture illiteracy is as prevalent as illiteracy itself [306]. Pictures do not constitute a ‘universal language’ as they can be understood and translated in different ways by different people [32,33,215]. There are several factors which may affect how a person may decode a picture, including schooling, language, style of pictures, and cultural norms and values. It is therefore essential that the target population be involved in designing and developing the

visual material to ensure that illustrations and any accompanying text are meaningful in promoting comprehension.

Moll [307] conducted a study amongst 637 participants to determine the effect of comprehension of three versions of an illustrated health information booklet on osteoporosis and his findings indicated that participants preferred the version of the booklet that contained cartoon-like illustrations, followed by stick-figures and lastly the photograph version. A study by Moore [308] reported similar findings in which patients preferred simple line drawings in comparison to shaded images or photographs. In both studies, the study population indicated that they preferred simpler illustrations as too much detail could cause distraction or render the image too complex.

The overall success of pictograms lies in the rigorous design and testing process that ensures that illustrations effectively communicate the intended message to patients. Studies have highlighted several key recommendations to ensure the success of pictograms and these include:

- collaborating with the target population [309-311]
- using familiar objects and symbols [310-313]
- designing simple realistic illustrations [310-314]
- using minimal text placed in close proximity to related illustration [32,33]
- using whole body images [310,312]
- using multi-stage illustrations with caution [310,312]
- using abstract symbols, symbols depicting motion and perspective with caution [309,311,312,315]
- considering cost implications when using colour [310-312]
- using appropriate size and magnification of images [215,312]
- pre-testing of the materials amongst the target population [309,311,312,314]

The design and evaluation of pictograms actually involves a complex multi-stage iterative process and should be done rigorously to ensure that the resultant materials are of a high standard [32].

2.5.3 Evaluation of pharmaceutical pictograms

Ideally, all pharmaceutical pictograms should be developed and tested to provide insight on their success rate, reason for failure and recommended modifications. For the evaluation process, pictograms should firstly be tested amongst healthy individuals from the intended target population and thereafter, they should be tested amongst patients in practice [32]. Subsequent modifications should also be tested and should conform to the standards set to ensure that the pictograms effectively communicate the intended message [215,301]. The American National Standards Institute (ANSI) recommends that comprehension of the intended message of each pictogram should be above 85% to ensure that patients understand the information and take the medicine as directed [316].

In practice, pictograms are accompanied by a verbal and/or written explanation to assist patients in understanding the meaning of each pictogram. Research has shown that counselling using pictograms can potentially act as a stimulus for the recall of information at a later stage [32]. Thus, when evaluating pictograms, it is important to measure a patient's ability to recall information based on the stimulus provided by the pictograms [215]. This follow-up test should not be conducted at the initial interview where the patient is introduced to the pictograms, but rather after a suitable period of time has passed (usually more than a week) [317].

Several studies have investigated the effectiveness of pharmaceutical pictograms in communicating health and medicine information to patients. In 1987, a significant international initiative on pharmaceutical pictograms was launched by staff members of the United States Pharmacopeia (USP) and this resulted in 29 validated pictograms [318] and more than a decade later this increased to 91 pictograms [319]. However, these pictograms were developed and evaluated in the context of American patients and included cultural traits that are common amongst a modern westernised society. Although illustrations are thought to be a 'universal language', research has shown that language and cultural background can play a role in their interpretation [320,321].

Dowse and Ehlers [32] conducted a study to compare and evaluate 23 locally developed, culturally appropriate pharmaceutical pictograms with 23 USP pictograms in 46 black low-literate respondents. The results at follow-up after three weeks showed that 20 of the local

pictograms complied with ANSI criterion of ≥ 85%, compared with 11 USP pictograms. Respondents had higher comprehension at follow-up (after a correct explanation was given at the initial interview) and the majority indicated a greater preference for the local pictograms. Research by Knapp *et al.* [321] compared the comprehension of two sets of pictogram instructions or warnings (from USA and South Africa) by adults in the UK. The authors found that there was great variation in interpretation rates (7.5-90%) with few significant differences between the USA and South Africa versions and only a few pictograms achieved ≥85% comprehension. Overall, this study demonstrated that there may be important cultural and contextual differences that influence patient ability to interpret pictograms, but no consistent pattern was identified in the study. Sorfleet *et al.* [322] conducted a study to evaluate individual pictograms used in humanitarian medical missions. The pictograms were tested in 525 patients at the time of dispensing; 47 of these patients participated in a follow-up interview a day later. Most of the pictograms tested achieved European Commission standard for comprehension (>80%), but were slightly below the ANSI requirement (≥85%).

The success of pictograms as a tool to communicate health and medicine information depends on a comprehensive design and testing process that ensures that pictograms are clear and culturally acceptable [32,215,301,309,313,315,320-322]. Additionally, the provision of verbal and/or written information to reinforce pictogram understanding is important in reducing misinterpretation [32,215,322].

2.5.4 Use of pictograms accompanied by text

Providing pictograms as the sole means of communicating information and instructions to patients is strongly discouraged and constitutes poor communication practice [302]. The visual material must be accompanied by text and/or verbal explanations to clarify and improve patient understanding [215,216,302]. One study investigated the dual text/visual approach to develop a simple medicine information leaflet and the impact of this approach on cognitive behaviour [30]. The results of this study supported Mayer's cognitive theory of multimedia learning [323,324] whereby knowledge acquisition is more effective through pictures and words than through words alone [30]. In addition, the study found that participants tended to understand and recall information more readily when the visual and supporting text were juxtaposed [30]. This supports the 'Spatial Contiguity Principle' in Mayer's Theory [323,324] which emphasises that when pictures and corresponding text are

in close proximity, the learner uses fewer cognitive resources and still retains both (words and picture) in working memory [30]. When pictures are closely linked to written text, they can markedly increase attention and recall of health and medicine information [302].

When using pharmaceutical pictograms in practice, HCPs should be aware of the possible risk of misinterpretation of visuals and must be familiar with some of the misconceptions by patients when decoding visual material, especially for the most commonly used visuals. Health communication can be significantly improved by including rigorously developed and tested pharmaceutical pictograms. Research conducted strongly supports the use of illustrations in patients with limited literacy as it has shown to improve patient understanding and use of WMI [32,216,302].

CHAPTER 3
MEDICINE INFORMATION SEEKING BEHAVIOUR AND INFORMATION NEEDS OF PATIENTS WITH LIMITED LITERACY

Part of this chapter has been prepared as a journal article and is currently in press: Patel S, Dowse R. Understanding the medicine information-seeking behaviour and information needs of South African long-term patients with limited literacy skills. Health Expectations, 2013. DOI: 10.1111/hex.12131

3.1 Introduction

Lack of patient input in the development of WMI has been identified as one of the major reasons for the poor use of currently available materials as they do not cater to patients' information needs, expectations and priorities [15]. A systematic review revealed that only 27 studies over a 30 year period took into consideration patient input when developing WMI [14]. Research has shown that it is best practice to provide evidence-based information, to understand the information needs of the target population and to involve all the main role players in the development and testing process [150].

One common misconception amongst some HCPs is that patients do not want information or cannot cope with information about their health and medicines [150]. However many patients who use medicines want to know what they are for, how to use them, how to tell if they are working and what side effects and possible interactions could occur [145,146]. A study conducted amongst 20 coronary heart failure patients found that being uninformed contributed to a sense of anxiety [325]. The majority felt that they did not have enough information to be able to ask questions and suggested that HCPs should be transparent and honest when providing information. Patients often have a greater appetite for information than HCPs believe [146,150] and this desire for information varies according to patient demographics and their interactions with the healthcare system. Thus it is important that HCPs and those involved with the provision of information are aware of the information needs of their patients as well as barriers that prevent them from accessing the necessary information. For example, in a review conducted amongst indigenous people of several developing countries, Dutta [326] found that education had the largest impact on information needs and information-seeking behaviour of citizens.

Understanding where and how patients look for health and medicine information provides valuable insight into how to effectively disseminate or communicate information [152]. Although much HISB research has been reported in patients with good literacy skills, little is known about HISB in patients with limited literacy skills served by under-resourced healthcare systems. Widespread limited literacy in many developing countries constitutes a serious public health issue [327] and is associated with a compromised ability to seek for and comprehend information [153,328].

Medicines, whilst central to the treatment and management of long-term diseases, demand adequate adherence for successful outcomes. Adherence to long-term treatment in developed countries averages only 50%, with even lower rates predicted for developing countries [80]. Poor health literacy, specifically poor understanding of medicines, has been linked to inappropriate medicine-taking practices and lower adherence rates [329,330]. This study is set within the context of HISB with a specific focus on medicine-related information. The aim of this study was to investigate medicine information needs and MISB in long-term patients with limited literacy skills.

3.2 Method

3.2.1 Study setting and context

South Africa, with a population of approximately 52 million people [109], faces a quadruple public health burden (communicable diseases, infant mortality, non-communicable diseases and violence/injury). The average life expectancy at birth (males 57.7 years and females 61.4 years) is relatively low in comparison to developed countries. Infant mortality is high with 41.7 deaths per 1000 live births, with the HIV/AIDS pandemic being the second highest cause of death in children under five [331]. It is estimated that 10% of the South African population is HIV positive and the prevalence of TB is 857 per 100 000 [331].

The WHO has suggested that countries should spend at least 5% of their gross domestic profit on healthcare every year. South Africa is well above the majority of middle-income countries, spending 8.3% of the gross domestic profit on healthcare. However it still has an extremely high burden of disease along with poor health outcomes [332]. In South Africa, healthcare services are offered within either the private or public sectors. The under-

resourced public sector provides services to approximately 80% of the population but approximately 70% of all doctors and most specialists work only in the private sector [38]. Of the total health expenditure, 60% is spent on the private sector and this gross inequity puts pressure on the under-resourced public sector. Diseases such as HIV/AIDS and TB have also placed an additional burden on the public sector. Government efforts to reduce wealth disparities has led to initiatives such as improved pensions, increase in the number of social grants and improvements in housing, water and sanitation [333].

A General Household Survey conducted amongst 25 653 South African households to investigate utilisation of health facilities, access to health facilities and satisfaction with service provided reported that when a member of their household required medical assistance, the first choice for the majority was to attend a public sector clinic (61.2%) [333]. This was followed by households who went to private doctors (24.3%) and those who went to the public hospital (9.5%). The private hospital, private clinic and other facilities (pharmacies, employer facilities, spiritual healers, homeopaths and traditional healers) were utilized by a total of about 5% of the households as a first option. The survey also established that some households did not use the facilities closest to their residence and the main reasons for this were preference for private health institutions, as well long waiting times and unavailability of drugs needed at public sector clinics.

The Department of Health (DoH) has proposed a national health insurance plan, with the aim of reducing health disparities amongst the South African population and ensuring the population has access to appropriate efficient and quality health services irrespective of socio-economic status [334]. The project is currently being piloted in 11 health districts, across the 9 provinces of South Africa and the DoH hopes to phase-in the national health insurance plan over a 14 year period. There is still on-going debate on the success of this merge as some researchers feel that the public sector has restricted capacity to develop, implement, and monitor health contracts with the private sector and thus caution should be exercised when introducing the new insurance scheme [332].

The research for this study was conducted in a small town in the Eastern Cape Province which is predominantly rural and underdeveloped, has a high rate of unemployment and is the second poorest province in the country [109]. TB is a major public health problem in the area and this is reflected in statistics for 2011 which indicate that the Eastern Cape province,

in addition to being the poorest province, has the third highest number of TB-related mortalities [109].

The WHO recommends that each country has a National Tuberculosis Control Program or its equivalent to highlight the policies and guidelines to ensure adequate TB management [46]. This programme should have specific targets based on the DOTS and Stop TB strategies proposed by the WHO. In 1994, the National Tuberculosis Programme was established in South Africa and this faced several challenges including weak primary healthcare systems, as well as the emergence of the HIV epidemic and drug-resistant TB [2]. This resulted in a four-fold increase in TB cases between 1994 and 2012. To respond to the dual epidemic of HIV and TB, the DoH of South Africa developed an integrated National Strategic Plan for HIV, STIs and TB (2012-2016). The specific TB-related targets were to halve the incidence of TB incidence and mortality by 2016 and have no new TB cases, deaths or stigma by 2032. South Africa has made some progress in improving TB control and management, however, TB still poses a major public health problem [332,334].

In the Eastern Cape, TB treatment and control strategies are in accordance with the National Strategic Plan for HIV, STIs and TB. The government of the Eastern Cape provides an annual budget al.location to the TB directorate who coordinates the programme at the provincial level. District offices are primarily responsible for case monitoring and reporting at public hospitals and clinics. In the Grahamstown area, there are a total of six primary healthcare clinics (Raglan Road Clinic, Settlers Day Hospital, Joza Clinic, V Shumane Clinic, Middle Terrace Clinic and Town Clinic) and three hospitals (Temba TB hospital, Fort England Hospital and Settlers Hospital) serving patients reliant on the public health sector.

Communication between HCPs and patients is often problematic when neither speaks the same language. South Africa is a country with 11 official languages and most healthcare providers can only speak one or two or these, consequently limiting their ability to effectively communicate with patients [335]. Karliner *et al.* [20] found that the use of professional interpreters can have a positive impact on clinical care including communication, utilization, clinical outcomes and patient satisfaction. A study in Cape Town that investigated the effect of language barriers on health worker-patient interactions at a public hospital found that the effect of the language barrier was considerable, with the introduction of ethical dilemmas such as difficulty obtaining informed consent and maintaining confidentiality [21]. Patients

reported several cross-cultural misunderstandings and expressed dissatisfaction with the quality of care provided due to language-related misunderstandings. The study highlights the need for well-trained interpreters in practice, particularly in a country such as South Africa with 11 official languages. According to 2011 census data, isiZulu is the home langue spoken by 22.7% of the South African population, followed by isiXhosa (16%), Afrikaans (13.5%), English (9.6%), Setswana (8%), Sesotho (7.6%) and the remaining official languages contribute less than 5% each [109]. Although the South African Constitution states that services should be provided to the population in their own language, the under-resourced health sector is financially unable to meet this obligation for all patients. Despite this, HCPs have a legal obligation to adopt strategies to optimise communication with patients. As the researcher's first language is English, and the patients who participated in the research reported in this thesis were either first language isiXhosa or Afrikaans, interpreters were recruited and trained.

3.2.2 Study design, participants and interpreters

The study design involved a qualitative approach involving FGDs with patients between October 2011 and July 2012. After discussions with the district health office, two sites were identified for this phase of the research study, Raglan Road Clinic and Temba TB Hospital. Focus groups are widely employed in health research as they enable the researcher to understand, within context, patient attitude and behaviour toward a certain experience such as information seeking or medication taking [336]. They afford the opportunity to explore in-depth what individuals believe or feel and why they behave in a certain manner.

The interpreters chosen were black Xhosa-speaking individuals from the same culture and community as the target population who were able to communicate effectively in both languages. During their training they were instructed to closely translate the exact words used by the researcher and the participants and to avoid providing answers or prompting patients in framing their responses as this would compromise the integrity of the study. As part of the training, the interpreters were introduced to the question guide (Section 3.2.3) and were asked to comment on any questions that they felt were confusing, vague or consisted of complex terminology that could not be translated effectively.

The inclusion criteria for patients were age 18 years and above, taking first-line TB treatment, first language isiXhosa speakers and not more than 10 years of formal schooling, as our aim was to target participants with lower levels of literacy which more closely represents public sector patients. Grade 10 also represents the first exit level within the 12-year curriculum.

Ethical approval was obtained from the Eastern Cape Provincial Department of Health (see Appendix A1) and the Rhodes University Faculty of Pharmacy Ethics Committee (see Appendix A2) and permission to conduct the discussions was obtained from the local District Health Office. Due to the infectious nature of TB, stringent precautions were practiced to ensure infection control. This included conducting FGDs in a well aerated setting, with masks being offered to the researcher, interpreter and study participants to prevent any cross-infection.

3.2.3 Question guide development

EBSCOhost® was used to search multiple databases including MEDLINE and PsycINFO using the term "health information seeking". The search was refined to include peer-reviewed journals and journal articles in English published from 1983 to 2011. A total of 123 articles were identified. The articles were screened on the basis of the title, followed by abstract and then full text. Forty eight abstracts were assessed for eligibility and a total of 17 full-text articles were identified as eligible. From these, seven frequently used models related to HISB were found. These models contribute to conceptualising the process of seeking health-related information and provide a theoretical underpinning with which to understand, analyse and interpret data on how patients look for information. Two HISB models, Longo's Expanded Model [160] and the framework proposed by Anker, Reinhart and Feely [144], were selected to inform the development of the question guide. In contrast to the other five models identified from literature, these two models adopted a patient-centred approach and differentiated HISB into three key areas: patient characteristics, process of information seeking and expected outcomes.

Figure 3.1 shows a summarised version of Longo's expanded model of health information seeking behaviours [160]. The model is based on experiences and reports from patients themselves and takes into account variables that influence information seeking such as demographics, socio-economic factors, education, culture and health status. One unique

feature of this model is that it differentiates the two different phases of information-seeking into active (which is purposely looking for information) or passive (coming across information during daily activities). The Longo model guides questions about active seeking of information, awareness and use of information sources, ability to understand information and act on it.

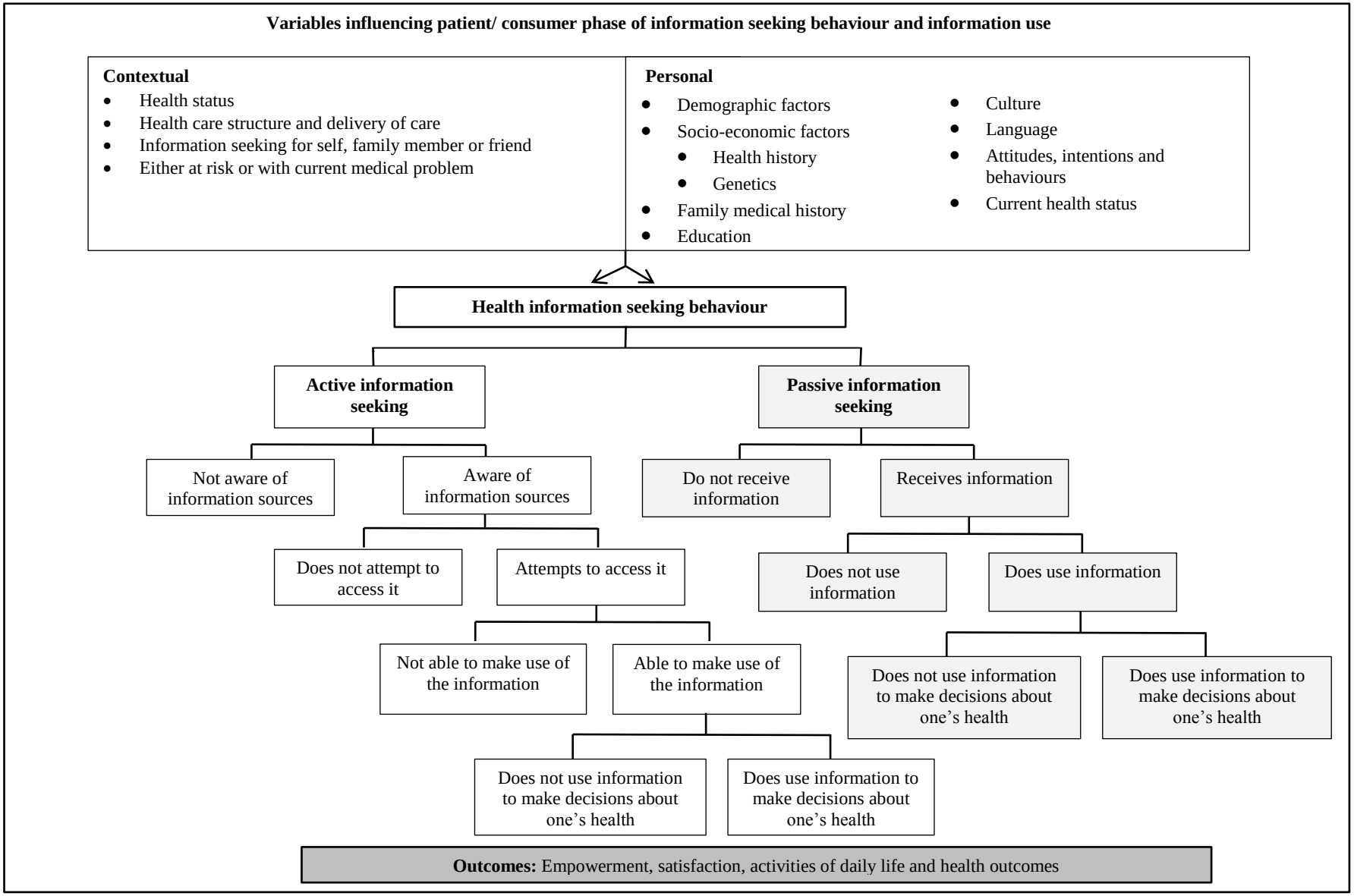


Figure 3.1: Longo's (2005): Expanded model of health information seeking behaviours [160]

The second model used was the basic organizational model developed by Anker, Reinhart and Feeley [144] in 2010 (Figure 3.2). This model was developed as a way to conceptualize a review of measures and methods of health information seeking practices and gives a general overview of information seeking in the health context. It provided the stimulus for understanding barriers to information seeking, what information patients seek, sources of information that are consulted, credibility of information sources and satisfaction with information.

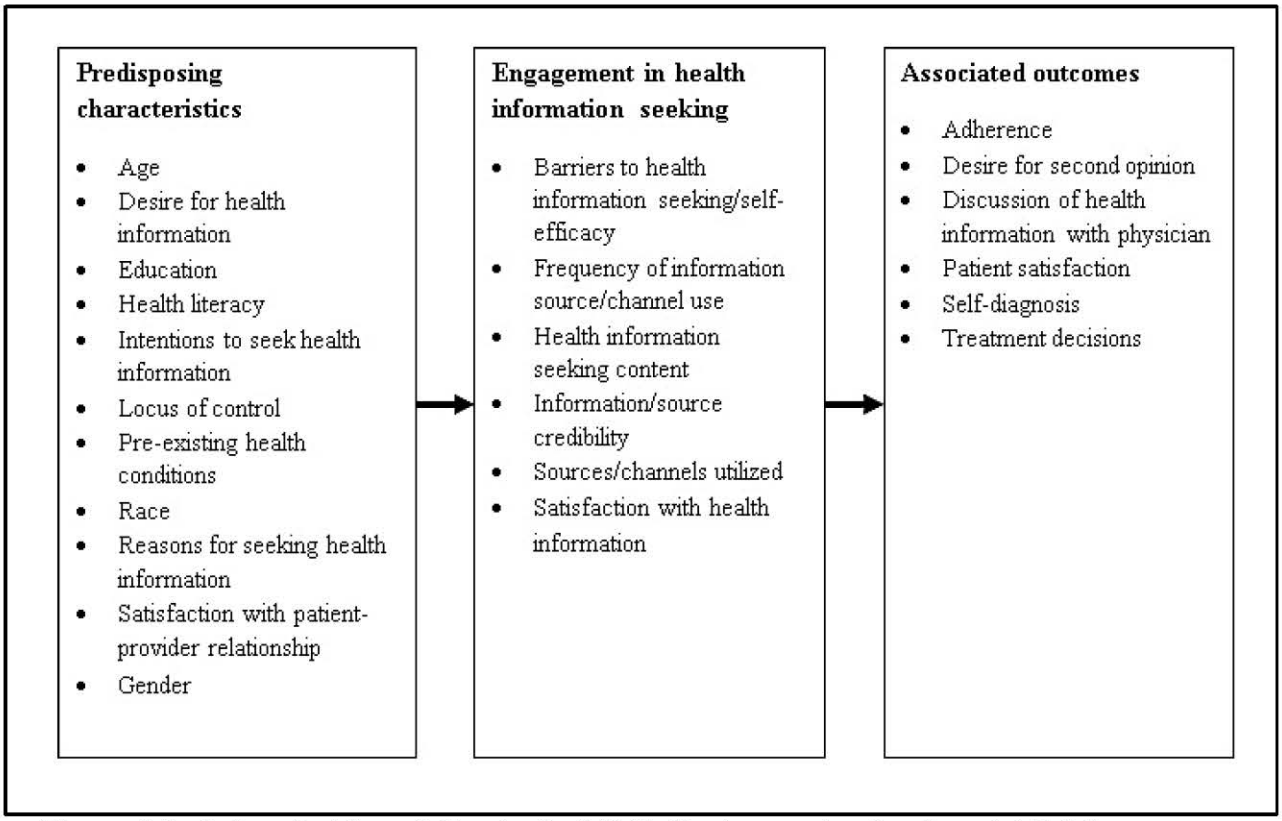


Figure 3.2: Anker, Reinhart & Freeley's (2010): Basic organizational model [144]

The subsequent question guide based on these two models (Appendix B1) was pilot tested prior to use in the main study.

3.2.4 Interview process

3.2.4.1 Pilot study

A pilot FGD was conducted with six patients with the aim of identifying any problems with either the question guide or the interview process. Participants were recruited from Temba

TB Hospital in Grahamstown by the interpreter who communicated the study aim and provided a brief study description as follows:

"Good morning/afternoon, I would like to find out if you are interested in taking part in a research study that is been done here at the hospital/clinic by a student from Rhodes University. She is doing some research about medicine information and she wants to find out what information patients want about their medicines and how they would like to receive this information."

If the patient was eligible and agreed to participate, the interpreter would work through the consent form (Appendix B2) with the patient to ensure a good understanding of the research process and the part s/he would play in it. The patient's signature was then obtained. Patients who had difficultly writing and/or providing a signature were assisted by the interpreter who wrote out their name according to their health passport and the signature was substituted with the patient's thumb print. Patient demographic details (gender, race, age and education) were recorded.

A fun ice-breaker exercise was conducted at the start of each FGD to encourage patients to relax and feel more comfortable with contributing to any discussions. The prepared question guide (Appendix B1) was used to firstly ask general questions and then to focus and narrow the discussion in order to understand the health information needs and information seeking behaviour of TB patients. The discussions were facilitated by a trained researcher assisted by an observer who took notes. Questions were asked in English and translated into isiXhosa by the interpreter. Some patients were able to understand some English whereas others could not speak the language at all. FGDs were audio-taped to ensure that all comments were captured. Patient comment and questions were encouraged and welcomed at all times. Each patient received R40 food stamps (~ US$4) as an honorarium for their contribution to the study.

The feedback obtained from this pilot study informed the following changes:

- The pilot FGD took more than 60 minutes and at the end of the discussions several patients commented on the lengthiness and cognitive demand of the discussions. This resulted in reducing the number of questions that were asked to fewer key questions.

- During the pilot study, patients were asked to give their opinion of different types of information sources but many of them were unfamiliar with these. Thus, for future interviews hard copies of each information source were displayed to allow patients to physically see which information source was being discussed. These included posters, PILs, labels, package inserts and a print out of a health-related text message.

3.2.4.2 FGDs with TB patients and HCPs

Using the modified question guide (Appendix B3), two FGDs were conducted with TB patients: one with six patients who had been taking TB medications for less than 6 weeks, the other with six patients who had been taking TB medications for 4-6 months. The recruitment and interview process was exactly as described in the pilot study. All patients who were approached agreed to participate in the study and signed the consent form (Appendix B4). To determine the preferred format of information delivery, patients were shown different examples of medicine information sources (posters, leaflets, package insert, labels, health-related text message) and were asked to comment on their availability and use. The discussions took between 45 minutes and an hour.

A similar FGD was also conducted with health providers caring for TB patients using the question guide (Appendix B3) and included a doctor, a pharmacist, two nurses and a community health worker. In practice, each health provider has a different role in the continuum of patient care and this could limit their knowledge about TB medicines information and beliefs about patient information needs. However, in this setting, only one pharmacist was present and as a result other health providers were actively involved with TB medicine adherence counselling. The discussion enabled provider opinion and recommendations to be recorded and these were taken into account when designing the information materials.

3.2.4.3 FGDs with patients with long-term conditions

The FGDs with TB patients generated interesting and unexpected findings and raised a number of questions related to medicine-taking knowledge and practices. Despite an intensive literature search, no published articles related to these issues could be sourced. This resulted in a modification and expansion of this phase to include an investigation of HISB

and information needs of patients with a range of long-term conditions including TB. Ethical approval for the expansion of the study was obtained from the Rhodes University Faculty of Pharmacy Ethics Committee (Appendix A3) and from the District Health Office (telephonic communication).

Following the same procedures as for the FGDs with TB patients, interviews were conducted at Raglan Road Clinic. Patients attending the clinic for their monthly consultation and medication refill were recruited by the receptionist at the clinic. Recruitment criteria were exactly the same except patients had to be taking medication for one or more of the following long-term conditions identified as the most common conditions treated in the clinics [337]: diabetes, hypertension, asthma, epilepsy, TB and HIV/AIDS. Although TB is not classified as a long-term disease, treatment duration is between 6-8 months and therefore demands sustained persistence with therapy. Only one patient declined participation in the study due to time constraints. After consultation with the doctor or nurse and collection of medication from the pharmacist or pharmacy assistant, patients were directed to the research team in a different room. The consent form (Appendix B5) was explained in detail and the patients were asked to sign the form if they were willing to take part in the study.

The question guide was modified to investigate the HISB and medicine information needs of patients with long-term conditions (Appendix B6) and a total of four FGDs were conducted at Raglan Road Clinic. Each group of 5-6 patients included more than one long-term condition and the interview process used was exactly the same as that described for the discussions conducted at Temba TB Hospital.

3.2.5 Analysis

After each FDG, a debriefing session was conducted between the two researchers (SP and RD) to discuss the data and emerging themes. After six FGDs (two with TB patients and four with long-term patients), theoretical saturation of data was reached.

Tape recordings were transcribed verbatim and the transcripts were cross-checked by a skilled translator proficient in both English and isiXhosa to ensure that no errors were made in the translation and transcription processes. Data were analysed using thematic analysis [338]. The transcripts were read repeatedly to establish familiarity with the data. A software

program (NVivo 10®) was used to code the entire data set in a systematic fashion, collating data extracts into the relevant codes. Numerous codes were developed, with some data extracts falling within multiple codes. Codes were then analysed and potential themes and subthemes in the entire data set were identified. Each transcript was then analysed individually by two researchers (SP, RD) to reduce bias and ensure validity of results.

3.3 Results

3.3.1 Demographics

Demographic characteristics of the 34 patients are shown in Table 3.1. Approximately 60% were female and the average age was 50 years. The average time spent in formal schooling was five years. Nine patients (26%) had four or less years of education and six patients (18%) had never attended school.

Table 3.1: Patient demographic characteristics (n=34)

Demographics	Frequency n (%)
Gender	
Male	13 (38.2)
Female	21 (61.8)
Race	
Black	34 (100.0)
Age	
21-40	8 (23.5)
41-65	19 (55.9)
>65	7 (20.6)
Education	
None	6 (17.6)
Grade 1-4	9 (26.5)
Grade 5-7	6 (17.6)
Grade 8-10	13 (38.3)

3.3.2 Thematic analysis of patient FGDs

After analysis of the FGD transcripts, five major themes associated with medicine information-seeking practices and information needs were identified.

Disempowered passive patient. Freire [339] describes empowerment as both a process and an outcome. He suggests that empowerment as a process includes encouraging critical thinking

and greater autonomy through an educational intervention whereas empowerment as an outcome is when a person achieves a state of enhanced self-efficacy and this is usually as a result of the process. There are various definitions and conceptualisations of empowerment available in published literature [133]. Gibson [340], in the context of health, defines empowerment as "a process of helping people to assert control over the factors which affect their lives. This encompasses both the individual responsibility in healthcare and the broader institutional, organizational or societal responsibilities in enabling people to assume responsibility for their own health".

From the discussions with our patients it was obvious that many experienced a significant lack of control in maintaining their health and felt powerless in encounters with HCPs. Patients did not ask questions about their medicines and many were unaware that they even had the right to ask questions as they were not encouraged to do so. Through the discussions, it became apparent that the HCP-patient relationship was a one-way process whereby the HCP provided instructions and the patient would follow. Many patients reported simply taking their medicines without asking about or understanding basic information pertaining to their use.

> ***Patient 4c:*** *No I just take the pills. I didn't ask for more information about the medicine but we need more information. We did not know we should ask for information. [others nod in agreement]* ***(FGD-4)***

The majority of patients felt unable to discuss their condition and medicines with the HCP. One patient felt really sick and could not manage to take the medicines, but instead of approaching the HCP for assistance or looking for information about the medicine, he simply discarded them.

> ***Patient 6c:*** *I got the medication and it was really difficult for me to use them because I was sick. I threw them away.* ***(FGD-6)***

Generally, it was evident that the majority felt disempowered and adopted a rather passive role in the information-seeking process, including during their interactions with HCPs. Patients felt unable to take responsibility for their health, instead relied entirely on the minimal verbal instructions from doctors and nurses. There was an apparent lack of health literacy observed in the study population. Nevertheless these patients did indicate enthusiasm about receiving more health and medicine-related information.

Medicine-related knowledge. Discussions established that despite patients taking their medicines on a daily basis, many had a limited understanding of basic medicine-related information to support appropriate medicine-taking. This information included the name, indication and dosing instructions of the medicine, interactions with food or other medicines, commonly encountered side effects and what to do if a side effect is experienced.

When asked to respond to the question 'what information do you feel is important to have about your medicines', it was evident that patients lacked fundamental knowledge to comment on or state the basic information they needed to inform safe medicine-taking practices. Patients were unable to respond to the question by engaging in discussions about their medicines as the "language" or discourse of health seemed to be inaccessible to them. This resulted in their inability to articulate their information needs or desires. Patients could not identify any basic medicine information areas until prompted and reported simply taking their medicines guided only by minimal dosing instructions.

Despite the inability to articulate their medicine information needs, the majority acknowledged the importance of information. For example, when prompted about the need for information about side effects, patients felt that having a basic knowledge of the potential side effects they might encounter would be highly useful.

> ***Patient 6b:*** *Yes, when you have heard something [about side effects] you understand and it is important to know.* ***(FGD-6)***

As discussions progressed and patients were prompted about various medicine-related aspects, it became increasing apparent the patients felt that having some information about their medicines would contribute to better self-care.

Awareness and availability of information sources. Very little was known about the variety of potential sources of medicine information and there was an almost complete lack of awareness of how to access most of these sources (information leaflets, package inserts, brochures and posters, SMS technology, radio, television, internet). Most patients did not look for any additional information other than that routinely provided to them at the clinic during a consultation and as such can be classified as non-seekers rather than active seekers of information. A few patients mentioned coming across information about healthy diet and lifestyle habits on television which they had found useful.

Although some patients indicated that they were given verbal information from the nurse, they felt that the information provided was inadequate.

Facilitator: *So you mainly got information from the nurse? And did you feel this information was enough?*

Patient 3a: *Yes we mainly got information from the nurse. We want more so we can be helped.* ***(FGD-3)***

Almost all patients indicated that our discussions were the first time they had been introduced to various sources of medicine information. They were unfamiliar with the idea of actively seeking information from alternate sources, but expressed much enthusiasm for the possibility of accessing medicine information via these different sources.

Despite this enthusiasm, patients identified several factors that could possibly hinder the use of certain information sources. In South Africa, the package insert is intended mainly for HCPs and consequently is written at an extremely high readability level. A minority of local manufacturer-produced package inserts include a tear-off section which contains information intended for patients. Some patients were aware of the package insert, but most did not refer to it. The only information that was regarded as being useful related to dosing instructions, although this type of information only constitutes a small percentage of the contained information. The package insert was not generally regarded as useful due to difficulty reading the small font size, the complex writing style and medical jargon. After being shown the PIL and the package insert, almost all patients indicated that they preferred the PIL and would welcome a similar format for their medicine information.

Facilitator: *Perhaps some of you have seen this? [showing package insert]*

Patients: *Yes [nodding in agreement]*

Facilitator: *And what do you think of this? Is it good?*

Patient 3c: *It shows directions on how to take your medicine.*

Facilitator: *Can you all use this?*

Patients: *No, it's there in the box but we don't really use it.*

Facilitator: *Comparing the PIL and the package insert, which would be better to use?*

Patients: *This one [pointing to PIL]*

Facilitator: *So you would want something like this about your medicines?*

Patients: *Yes [general agreement]* ***(FGD-3)***

Patients indicated that the only medicine information they received was in the form of verbal dosing instructions. They had never been told about alternate forms of information and had never been given any WMI. However they were keen to be able to access such information.

Facilitator: *Where would you get information about this, whether you can take your pills with food or without food?*

Patient 6b: *There is no information given or that we know about this.* ***(FGD-6)***

Despite high mobile phone usage in South Africa [341] and an increase in interventions targeting their use for health promotion, patients had reservations about using mobile phones for healthcare purposes. No general consensus was reached on the desirability of using medicine-related short text messages. Although some felt it was useful, many did not have mobile phones whereas others mentioned that they are usually stolen, lost or people forget to carry them around.

Patient 5c: *You might get information but you will forget, or phone gets stolen so cannot get your information.* ***(FGD-5)***

Patient 5d: *…you find that you are supposed to take your medicines during the day but maybe you forgot the phone at home, so there is nothing to remind you.* ***(FGD-5)***

In many countries, patients seeking medicine information invariably consult the internet as their primary information source [342-348]. However, the majority of the South African population do not have computers and 64.8% are unable to access internet services [109]. None of our patients had access to the internet and only one patient mentioned it as a source of information.

Information needs. The majority of patients acknowledged that it was important to have some information about their medicines as they felt it would contribute to better health and improve self-care.

Patient 6d: *It's very important because you have to know what is going on about your health.*

Patient 6a: *If you don't take care of yourself you will die.* ***(FGD-6)***

As each discussion progressed, with patients being prompted about the key aspects of medicine-taking practices, a number expressed a desire for written information (posters and PILs) after realising their own lack of knowledge.

> ***Patient 5c:*** *It is very important to have it [medicine information posters] both at the clinics and to take home, because you sometimes don't have an idea of what is happening with your medicines and by looking at the posters you get an idea of how the medicines work.* ***(FGD-5)***
>
> ***Patient 5b:*** *….but the information is good to have because we do have children, you might notice the signs [side effects] which you read from here [PIL] and you can see what is going on.* ***(FGD-5)***

Cultural and social aspects. During discussions with patients, two major aspects identified related to HISB were the sharing of information amongst family or the community and the stigma attached to diseases like TB and HIV. The majority reported that in the close-knit isiXhosa community, it is common practice for patients to ask their neighbours or friends for help or advice about their medications. However, some patients commented that information sought from lay sources could be incorrect.

> ***Patient 5a:*** *…or maybe they [people] are getting advice from their neighbours or friends, but that's not quite right because they are not sure if this person is telling them the right information.* ***(FGD-5)***

As the FGDs progressed and patients were prompted on basic medicine-related issues, many felt their knowledge was inadequate and expressed a desire to receive information so that they were better informed and, importantly, could share their knowledge with their family, friends and their community.

> ***Patient 3a:*** *…and we will pass the information to the others.* ***(FGD-3)***
>
> ***Patient 4b:*** *Yes, so that I can show everyone else at home.* ***(FGD-4)***

Stigma associated with various health conditions has been well documented [349-355] and is still prevalent in many South African communities [355,356]. Patients were aware of the stigma attached to diseases and reported that it was difficult to seek for information when they suffered from a condition that was highly stigmatized as stigma acted as a barrier, particularly in HIV/AIDS and TB.

Patient 2a: *It could be embarrassing to be taking TB treatment because other people who don't have TB don't know about TB.* ***(FGD-2)***

Many reported the need to raise awareness about such conditions, with the ultimate goal being to reduce stigma amongst patients and the community.

Patient 2b: *The more information, the more people will be aware... So [TB] information is very important like any other diseases. People don't have information; it's not that they are backward or anything. So information is very important!* ***(FGD-2)***

Patient 4a: *I think people must be taught that they should not be ashamed of TB, because, if you know you have TB and people will treat you like this. For example we are now sitting here [healthcare facility], other people will see us and go and talk about it. I mean we [patients] are people still.* ***(FGD-4)***

Patient 4b: *Yes it would be helpful and to tell others as well, make them more aware.* ***(FGD-4)***

3.3.3 Design and content suggestions for TB information materials

'Tuberculosis' or 'TB' was reported to be a universally understood term for the disease, however, in isiXhosa it is referred to as 'phosepepa'. Despite both patients and HCPs indicating that TB patients perceive TB as a serious condition, many are nonadherent to their medicines and this is mainly attributed to patient's attitude and knowledge about their medicines.

Patient 1a: *People don't care why they stop taking their TB treatment.*

Patient 1b: *I have done this before that is why I am taking treatment for 8 months. The TB has come back.* ***(FGD-1)***

Provision of targeted information about the importance of adherence to treatment as well as the implications of nonadherence was highlighted as key information to include in the leaflet. One patient reported improved self-efficacy when she knew the medicines were helping her to get better. Understanding how the medicine works in the body could potentially motivate patients to adhere to their TB treatment.

Both HCPs and TB patients acknowledged the importance of information about TB and its treatment. Despite patients being unaware of both the sources and types of information they

require to inform their medicine-taking practices, the HCPs reported that there was a lot of information available about TB as a disease-state and in an effort to promote adherence they indicated that they try to provide patients with all the information necessary. Most HCPs felt that WMI was a good method to communicate information to patients as the patient could take the information home and refer to it when they are in a less anxious or pressured state.

TB-related aspects that should be addressed in the leaflet:

- ***Cause of TB:*** There was confusion about the cause of TB as some patients indicated that it was due to smoke that had entered the lungs, and others indicated that it was hereditary.
- ***Misunderstanding of TB symptoms:*** One patient indicated that anger was a symptom of TB and this prompted them to come to the clinic.
- ***Characteristics of MDR- and XDR-TB:*** Although some patients understood that nonadherence could result in MDR- or XDR-TB, none mentioned or acknowledged the fact that drug-resistant TB was a more virulent form of TB that required more complex medications, including injectables. Patients felt it was important to educate and make others aware of the development of resistant strains of TB and this was also mentioned in the discussions with HCPs.

  Nurse: *The patients must take the treatment for the full duration and not until they feel better. They must take it as long as they are prescribed to take it because of the development of resistance and that is a very big problem. In some cases, due to non-compliance, they end up with XDR-TB.* ***(FGD-HCPs)***
- ***Dosing time:*** There was some disagreement between patients and HCPs about the time of dosing in relation to the meal time. Patients indicated that they take their TB medicines after a meal whereas the HCPs advise patients to take them before meals. HCPs also indicated that some patients do not take their medicines when there is no food available at home. This misunderstanding prompted the need to include information about dosing in relation to meal times or availability of food in the proposed information leaflet. Theoretically, the medicine should be taken before meals (on an empty stomach) as food reduces the bioavailability of some active ingredients in the FDC tablet; however the medicine can be taken with or without food. Some HCPs noted that having a meal before taking the large FDC tablet can reduce nausea.
- ***Difficulty swallowing:*** Some patients have great difficulty swallowing the large tablets and should be counselled on the appropriate method to crush and mix the tablet with

food, juice or water. Placing the tablet between two stainless steel spoons and applying pressure was identified by patients as an ideal method to crush the tablet, and both HCPs and patients indicated that water, yoghurt or porridge were commonly used as a medium to mix with the crushed powder.

- ***Side effects*:** Patients reported side effects, mostly nausea, vomiting and dizziness, as a significant medicine-related problem. HCPs noted the high incidence of side effects, particularly amongst patients taking both HIV and TB treatment. They highlighted the fact that it is often difficult to deduce which drug is causing the side effect and recommended adequate patient counselling about potential side effects.

  Nurse: *…the more they know [about side effects], the more it will help them with their treatment*. ***(FGD-HCPs)***

  Pharmacist: *Also, proper counselling helps them become aware of the side effects and understand what's going on in the body when they take the medication. Also, it's easier for a patient to come back and say I'm experiencing this and that.* ***(FGD-HCPs)***

- ***Social issues:*** Alcohol abuse and smoking were identified by both HCPs and patients as being significant factors influencing medicine-taking practices.

  Community healthcare worker: *…another thing that affects adherence is social traditions. For example, a patient says there was a function at home so I had to have alcohol, it is difficult not to drink, I have to, so we can't question their traditions. So you tell them that they shouldn't and advise them to avoid alcohol but they say only this time. But almost every month there is a 'do'.* ***(FGD-HCPs)***

  Patient 2d: *Another thing is that people take treatment and they are drinking, drink on Saturday and Sunday and then must come collect TB treatment on Monday. You are then 'babalas' [hungover] and you can't come and then say I'll come on Tuesday. You are then worried about what the nurse might say so you don't come and quit your treatment'.* ***(FGD 2)***

- ***HIV and TB:*** In FGDs with TB patients, HIV and TB co-infection was mentioned as a topic that should be included in the leaflet. There is still a great deal of stigma attached to both diseases and this is exacerbated by the likelihood of co-infection with both.

  Community healthcare worker: *Also, some people do not want to be associated with TB and TB treatment because HIV positive patients are more likely to get TB and so people may think they are HIV positive. Some also are reluctant or don't*

want to come to Temba as they will be associated with TB and also HIV. ***(FGD-HCPs)***

3.4 Discussion

Empowering patients involves a behaviour change with a specific focus on helping them become more knowledgeable and enabling them to take control over their bodies, disease and treatment [133]. It is a highly interactive process that requires targeted communication and education in which knowledge, values and power are shared between patients and HCPs. The findings of this study revealed that local patients taking long-term medicines assume a more passive role and do not take responsibility for their self-care. Both patient-related and systemic factors contributed to this passive behaviour and this is typically associated with a disempowered patient [133]. Limited formal education, low self-efficacy, poor awareness of information sources and lack of health-related knowledge contribute to a lack of information seeking practice and self-care, as well as potentially adversely influencing patient-HCP interactions and allowing no place for the patient voice within a healthcare system focused primarily on coping with a high patient load to the detriment of a patient-centred approach [29]. Patient empowerment and patient-centeredness are two different but related concepts that have the potential to improve the quality of healthcare and patient interactions with HCPs [133]. In actual fact through adopting a patient-centred approach one can identify those patients who do not wish to be empowered.

In a review, Edwards *et al.* [41] aimed at conceptualising how information is utilized both within and outside of consultations and presented a model of motivators, barriers and external influences on information use and patient empowerment (Figure 2.5). This model shall hereafter be referred to as the 'Edwards model' and can be used to differentiate patients into the following tiers: 'empowered', 'non-empowered' and 'disempowered'. According to the model, an empowered patient is described as one who is able to access and use information about their health to make informed choices in their interactions with HCPs. The authors acknowledge that the use of information does not necessarily guarantee empowerment. In contrast, the 'non-empowered' patient is described as one who has made a deliberate and active choice not to seek for information, instead relying on the HCP as the ultimate information source and entrusting all decision-making responsibility to the HCP. The 'disempowered' patient is an active information seeker but is disempowered by the HCP who

limits both patient involvement in information exchange and the ability to make choices. We argue that this model is inadequate within which to situate our findings as despite reflecting a lack of empowerment, both the 'non-empowered' and 'disempowered' classifications in this model include an active patient choice, whereas our patients' voices are not encouraged or are not readily heard [29].

Patient ability to access and use health and medicine information effectively is critical to empowerment [357]. Previous studies have found that the level of engagement with HISB is mediated by the individual's level of literacy and health literacy [358], with a subsequent negative effect on overall health outcomes [153,359]. Most of our patients made no attempt to look for additional information outside the consultation as they were unaware of alternate health and medicine information sources and in fact commented that our discussions were the first time they had come across the various sources and forms of information [29]. This lack of awareness and poor use of health information sources could be attributed to the limited availability of user-friendly educational materials at public sector facilities in South Africa. In contrast, other studies conducted in developed countries commonly report awareness and knowledge of health information sources as well as the ability to conduct a search for information from a variety of sources. Longo *et al.* [152] in a USA study of both Latina and non-Latina women reported only two of 158 participants as being unaware of any information sources. However, the majority of the women had pursued studies beyond high school level. Studies from the UK [145], Canada [360] and Australia [361] describe people initiating their own research to find information, using various sources.

Access to health and medicine information is considered a prerequisite to meeting the 2015 MDGs as limited access, especially in remote areas, can compromise the delivery of quality healthcare and result in an increase in preventable mortalities [362]. Along with knowing where to find health and medicine information, it is important for patients to understand what specific information can assist them when taking their medicines. The majority of our patients, with their limited exposure to formal education and literacy skills, lacked basic medicine-related knowledge such as the name of the medicine, its indication, taking it with or without food, interactions with other medicines, side effects, what to do if a side effect is experienced and safe disposal of medicines [29]. Patients with limited literacy skills often face major challenges when trying to understand basic medicines instruction, as shown in a study from the USA where 48% of patients with limited literacy skills could not understand

instructions to take a medicine every six hours, and 54% could not understand what is meant when instructed to take medicine on an empty stomach [363]. This has also been reported amongst elderly patients, for example Zuccollo and Liddell [364] found that 60% of elderly outpatients interviewed did not have a clear understanding of dosing instructions on their medicines.

Research indicates that educating and counselling patients about their medicines empowers them to make informed decisions in their medicine-taking practices [61,145]. Our study identified nurses and doctors as the primary sources of information but patients regarded the information provided as inadequate [29]. This opinion emerged during the course of our discussions only once patients realised how little they actually knew about their medicines. It is possible that HCPs, in acknowledgement of their patients' low health literacy, offered only limited information, but this hypothesis requires further research. The illustrated leaflets and posters shown to our patients during the discussions generated much enthusiasm and resulted in a unanimous desire for medicine information in this format. These information materials had been designed in previous local projects taking into account limited reading skills and local culture [30]. Unfortunately there is a distinct lack of local availability of simple patient-friendly medicine information, representing a further barrier to accessing and understanding medicine information and contributing to patient disempowerment.

From our discussions it was evident that limited education and literacy, along with poor knowledge of disease states and related medicines, impacted significantly on patient ability to identify, access and utilize information sources [29]. In contrast to the active choices described in the Edwards model [41], our patients were not adequately empowered to make any type of active choice, instead passively accepting the HCP as their sole information source [29]. This level of disempowerment and passivity linked to an inability to make any choice has not been previously elucidated in HISB models. We propose that this finding may be applicable to other country settings with similar population characteristics.

Patients described their encounters with HCPs (usually a nurse) as a one-way process in which they were simply given dosing instructions, but almost never asked any questions and were not encouraged to do so by the nurse [29]. The key features of an empowering relationship include continuity, patient-centeredness, understanding and mutual acknowledgement [133]. On the other hand, Patterson [365] reported that the main features of

a disempowering relationship are overlooking experiential patient knowledge and providing inadequate services, particularly in relation to time and continuity. In any under-resourced health system, high patient load translates into limited consultation time and patient awareness of this limitation could further deter patients from asking questions. An Australian study reported doctors as being perceived to have little interest in giving medicine information, providing inadequate information and being difficult to understand, as well as being too busy [148,366]. Edwards [41] noted that health literacy is critical to the process of patient-HCP information exchange, preceding the shared decision-making stage. Our patients, with their poor literacy skills and inadequate health-related knowledge as well as the limited one-way HCP-patient interaction noted above, are ill-equipped to exchange information with the HCP and are consequently precluded from participating in shared decision-making, a characteristic of disempowerment described in a study by Aujoulat *et al.* [133].

The Patients' Rights Charter was generated in 1999 to promote and protect the rights of South African patients and to indicate patient responsibilities [367] and is meant to be displayed on the walls of public healthcare facilities. The Charter states that patients have the right to ask for information and access it in a language or format they understand. Our findings show that the PHCs represented both a facilitator and a barrier to information access as, although they represented the main source of medicine information, they did not actively encourage patient questions or indicate their willingness to receive questions [29]. Many patients are thus totally unaware of their rights to ask for additional information, revealing a distinct lack of compliance with the terms of the Charter.

Disease-related stigma still exists with conditions such as HIV/AIDS and TB. This adversely influences the quality of life by undermining self-esteem and agency [368], negatively influencing attitudes and behaviour towards treatment [352-355,369-371] and acting as a social barrier to help-seeking behaviour [355]. Our patients generally acknowledged TB-associated stigma and linked it to reluctance to engaging in active seeking behaviour for either information or treatment [29]. Research indicates that knowledge could be a mediator in diminishing stigma [349,351,354,355] and this view was shared by our patients who felt that raising awareness and knowledge of certain diseases could diminish the prevalence of stigma [29].

A local survey of 1020 households conducted in a low-income suburb of Grahamstown (the setting of our study), demonstrated that social capital is significantly related to health [372]. Health information is frequently obtained through social interactions and connections [373]. Our study endorses these associations by the frequent reliance by patients on family and friends as a source of health information, despite misgivings about the accuracy of such information as well as the desire to share any learnt health information with the community [29]. The socioeconomic environment of our study includes high density housing, and the African culture is one which holds community involvement paramount in dealing with life's diverse issues. To our knowledge, this focus on social capital and social interaction in describing HISB in limited literacy patients has not been elucidated elsewhere. Research from Pakistan in low-income participants where over 50% had a high school education, reported television and health workers as the main sources for TB-related information, with less than 10% citing family, friends and neighbours [350].

3.5 Limitations of the study

Limitations include the inability to generalize the results obtained from this qualitative study conducted amongst patients taking long-term treatment to the general South African population. Health literacy was not formally evaluated as currently available health literacy tests, as well as having been criticised as inadequate in capturing all aspects of the concept, [88,106] have generally been developed for use in high-income developed countries. This potentially limits their application in developing countries with their different healthcare systems, populations characterised by widespread limited literacy, as well as diverse culturally-based beliefs and understandings of disease and disease causation [130]. As all study patients had limited education, with some acknowledging their inability to read, an assumption was made that functional health literacy skills were limited. During the FDGs, patients were unable to offer information on basic medicine-related information due to their lack of knowledge and therefore in order for the discussion to progress, the facilitator had to prompt the patients with both open and closed-ended questions.

3.6 Conclusions

Minimal research has been conducted to determine the HISB and information needs of South African patients. Our study adds to current knowledge by identifying previously unreported

aspects of HISB that are unique to patients with limited literacy skills. Current HISB models indicate that engaging in health information-seeking practices is associated with outcomes such as empowerment, satisfaction, locus of control, self-efficacy, discussions with HCPs and shared-decision making. However, it was evident that our patient population did not achieve these outcomes due to the various limitations highlighted in the findings of this study.

The significant level of patient disempowerment and passivity noted in our patients underpinned their inability to make any information-seeking choices. This resulted in a basic lack of awareness of the right to ask for information. Limited health literacy skills and inadequate medicine-related knowledge also resulted in uncertainty about the type of questions to ask. A significant gap in knowledge was noted about both the type of medicine information that patients should know, as well as the range of sources offering such information.

Despite being the main source of information, the HCPs provided insufficient information and did not encourage patient questions. Public health action is needed to increase patient empowerment within the healthcare system and HCPs in public clinics should be encouraged to improve the patient education process and to actively encourage patients to ask questions. Future research should investigate the perceptions of HCPs on their role in patient HISB and in promoting patient-centred care involving some shared responsibility in decision-making with patients.

Patients want information about their medicines in a format that is simple and user-friendly. There is a fair amount of information available on TB as a disease state but there is a need for simple targeted TB medicine information to assist patients when taking their medicines. As verbal counselling provided by HCPs is often not retained, providing patients with a take-home leaflet may prove beneficial. This patient-centred approach involving investigating patient information needs and HISB prior to the development of information materials has definitely provided insight on what key areas need to be addressed when providing information to local patients.

CHAPTER 4
DEVELOPMENT OF AN ILLUSTRATED INFORMATION LEAFLET AND RESEARCH INSTRUMENTS

4.1 Introduction

Patients who have inadequate access to technology and the internet rely greatly on the information provided by their HCPs [29]. In the case of TB treatment, very few understandable WMI materials are available to inform patients about their complex medicines. The main goal of this research study was to develop and evaluate a patient-centred information leaflet targeted at TB patients with limited literacy. This chapter describes the comprehensive design and development process that preceded formal evaluation of the leaflet in the target population. The leaflet was designed to enhance user-friendliness and ensure optimal readability with an attractive layout.

There are no validated health literacy screening tools that are suitable for use in a patient population where the majority have limited literacy skills as the health literacy tests are far too complex, and are culturally and contextually inappropriate. A medicine literacy test (MLT) was therefore developed and validated. The MLT was designed to measure patient health literacy with a specific focus on medicine literacy. Patient behaviours related to medicine-taking such as self-efficacy and adherence were to be investigated, but existing tools for measuring these constructs required modification, a process described in this chapter.

4.2 Objectives

The objectives of this stage of the study were:

- To design and develop a simple, user-friendly and attractive illustrated patient-centred information leaflet for low-literate patients taking standard first-line TB treatment
- To design well comprehended and culturally appropriate pictograms for inclusion in the PIL
- To conduct preliminary evaluation of the pictograms and PILs and make the necessary modifications based on the findings

- To develop and validate a MLT that is appropriate for South African patients
- To modify existing HIV-ASES and MMAS-8 tools for local patients attending public healthcare facilities

4.3 Design and development of the experimental PIL

4.3.1 Content

Content included in the PIL was obtained from four key information sources. Firstly, a comprehensive internet search was conducted to obtain standard information provided to patients about TB medicines and to source any TB medicine information materials that were available to patients both internationally and nationally. Several leaflets originated from countries like USA, Australia, China and a few from South Africa. The authorship of these materials predominately belonged to the departments of health of the respective countries, WHO, USAID and several well-established Non-governmental organisations (NGOs). Most of the information leaflets sourced contained information about TB as a disease-state, with only a small section dedicated to medicines. Generally terminology was complex and suitable mainly for readers with high reading abilities. In some cases, the materials were available in different languages.

The second source of information was the clinics and hospitals in the Grahamstown area that provide services to TB patients. At the six primary healthcare clinics and two hospitals in the Grahamstown area, the investigator spoke to at least one HCP and obtained any available written information about TB, and took photographs of the TB-related posters available on the walls. A meeting was held with the nursing sister responsible for TB-outreach and statistics at the District Health Office, where additional posters and information leaflets distributed to clinics and hospitals in the Eastern Cape Province were obtained.

Patients and HCPs comprised the third information source. Discussions were conducted at Temba TB Hospital in Grahamstown to determine patient information needs and HISB and this is described in detail in Chapter 3. The results of this study revealed several gaps in knowledge about TB, highlighted key information needs of TB patients and provided insight

on HCP opinions and recommendations for information to be included in the PIL (Section 3.3.3) [29].

The fourth information source was the package insert for TB medicines available in the public sector. At the time of this study, the following FDC products were available: Rifafour®, Ritib® and Rifinah®. The package inserts obtained were used to extract medicine information that is considered essential for the safe and effective use of TB medicines.

There is a vast amount of written information available about TB as a disease state, but very limited information available about TB medicines. Based on the four information sources described, the following key knowledge areas were deemed essential for inclusion into the PIL:

- **Title:** Indicates the leaflet is for first-line TB medicines.
- **Name of TB medicines:** Provides the common trade names of the medicine available to patients in the public sector and the approximate duration of treatment with the respective medicines.
- **Why take TB medicines:** Provides patients with a motivation to take TB treatment and explains that TB bacteria are killed when medicines are taken for the full duration. A shaded text box containing a key message was included in this section to emphasise the need to continue taking TB medicines for six months or as instructed by the HCP.
- **Before starting TB medicines:** Includes information that the patient should tell their HCP before they start taking TB medicines, including other conditions, allergies and HIV status.
- **How to take TB medicines:** Focuses on three key areas on how to take TB medicines namely the correct time, the dosing in relation to meals and what should be done if an individual forgets to take their TB medicines.
- **Difficulty swallowing:** A brief description of the correct procedure to crush the large TB tablets and mix them with an appropriate medium is provided. The following recommendations are proposed to mix with the crushed tablet: water, juice, jam or yoghurt [374].
- **Side effects:** Provides details on side effects of TB medicines. Highlighted in a box are the more serious side effects that require immediate medical attention.

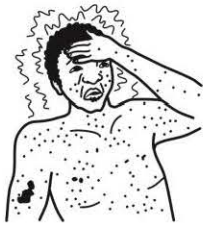
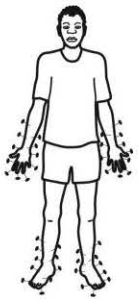
- **Certain things to avoid:** Sharing of medicines, smoking and alcohol use are discouraged when taking TB treatment.
- **Drug-resistant TB:** Provides details on MDR- and XDR-TB and the importance of taking TB treatment to avoid development of resistance. The need for stronger medicines for a longer duration, including injectables, is also emphasised.
- **TB and HIV:** Includes information on the link between TB and HIV with the goal of reducing the stigma attached to both diseases. The possibility of increased occurrence of side effects is mentioned.
- **Footer section (only included in the PIL with no side effect illustrations):** Highlighted the fact that TB can be cured if TB medicines are taken correctly.

The final text included in the leaflet was simple and avoided any medical jargon that could be misunderstood or difficult for the patient to understand. Terminology that was familiar to the target population was used. Additionally, the text consisted of short sentences that were presented in the active voice. All information materials were translated into isiXhosa and Afrikaans using a professional translator, and back-translated by a different language expert. Information materials were available to patients in both these languages or in English (Appendix C1-C6).

4.3.2 Design of illustrations (pictograms)

Illustrations (referred to as pictograms) required for the leaflet were identified and were designed in close collaboration with our expert graphic artist who has previously worked on similar material. The need for a total of 20 individual pictograms and three pictogram sequences was identified for inclusion in the experimental PIL. Eight of these pictograms were developed for previous research studies that focused on patient education on side effects of ARVs (Table 4.1) [30,375].

Table 4.1: Previously developed pictograms included in the PIL

Pictograms		
Vomiting	Stomach pain, nausea and vomiting	Skin rash
		
Severe rash on body and fever	Dizziness	Peripheral neuropathy
		
Do not share medicines	Do not drink alcohol while taking medicines	
		

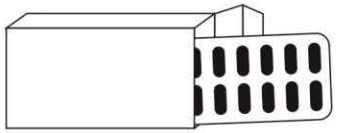
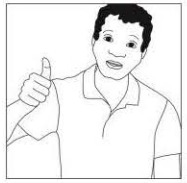
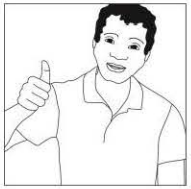
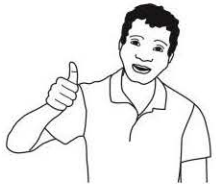
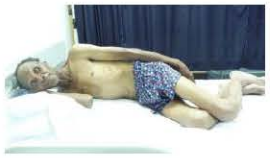
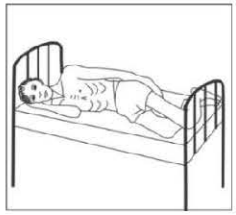
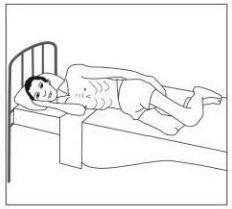
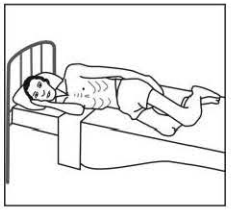
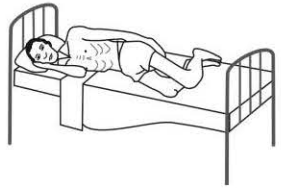
The original design process for these pictograms is described in detail in the study by Dowse *et al.* [375]. This study highlights several important recommendations to consider in the context of a limited literacy population such as in South Africa. These were considered when developing the remaining pictograms and pictogram sequences to be included in the experimental PIL. A short summary of these recommendations is provided in Figure 4.1.

Visual elements to consider	Visual elements to avoid/use with caution
• Use simple pictures with a clear and central focus • Represent objects in a realistic rather than a stylised or a cartoon-like manner • Use analogical images if possible (e.g. humans, a bed) • Include minimal distracting details (e.g. shading, texture lines) • Contextualise the setting by containing familiar images relating to local clothing, hairstyles, eating habits and other lifestyle elements • Be sensitive to cultural and religious norms • Give an accurate realistic representation of the human body • Use expressive power of the human body to construct meaning through body postures, arrangements, and facial expressions	• The use of isolated body parts (e.g. the ear only) • Images showing internal anatomy • Sequences of multiple images • Arrows alone to communicate movement or passage of time • Thought and speech bubbles • Graphic conventions (e.g. a single slash for 'do not') • Metaphorical images (e.g. a heart shape to represent love)

Figure 4.1: Recommendations for the development of simple pictograms [375]

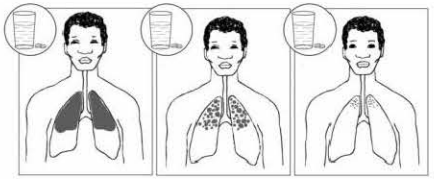
The remaining pictograms required for the PIL were designed using a similar process to that used by Dowse *et al.* [375]. The initial sketches of the proposed pictograms were generated by the graphic artist using photographs, sketched images and/or illustrations from the internet or textbooks. A design team consisted of the investigator, the supervisor of the project (with extensive experience in pictogram development), the expert graphic artist, two interpreters as well as HCPs and patients at Temba TB Hospital. The design team was involved in the multi-stage iterative process whereby each individual pictogram was critically evaluated. Most pictograms underwent a series of successive modifications before arriving at the final version (Table 4.2).

Table 4.2: Iterative pictogram development process

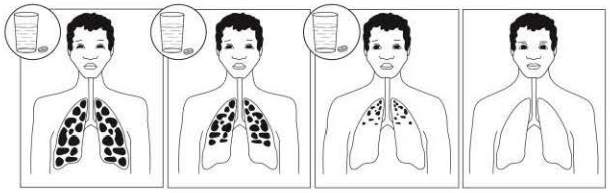
Photograph/Rough sketch	Development and final versions			
1. Tablet box  	Final version 			
2. Glass of water and TB tablets 	Version 2a 	Version 2b 	Final version a 	Final version b 
3. Happy and healthy individual 	Version 3a 	Version 3b 	Version 3c 	Final version 
4. Sick TB patient on hospital bed 	Version 4a 	Version 4b 	Version 4c 	Final version 

5. Lung sequence showing gradual clearing

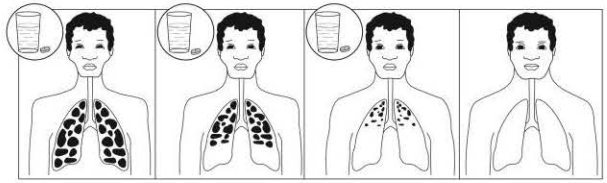
Version 5a



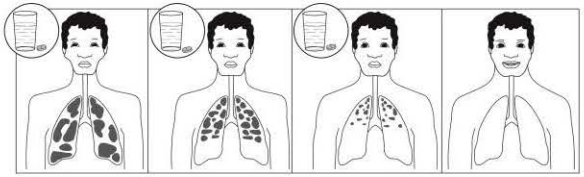
Version 5b



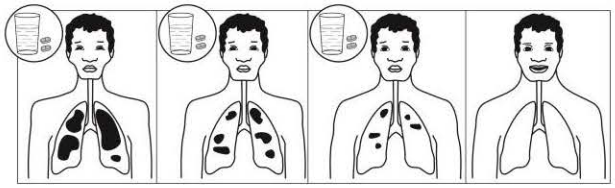
Version 5c



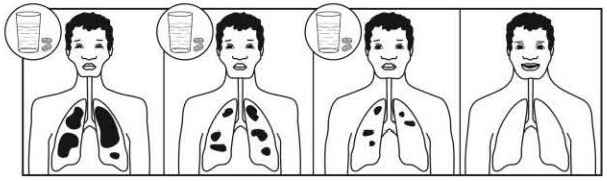
Version 5d



Version 5e



Final version



6. Time to take treatment

Version 6a

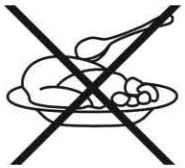
Version 6b

Final version

7. With or without food

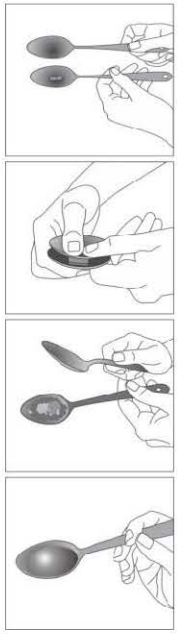
Final version - with food

Final version - without food

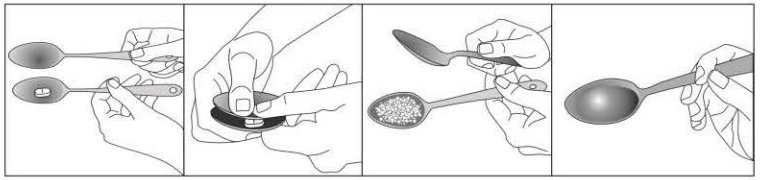


8. Crushing tablet and mixing sequence

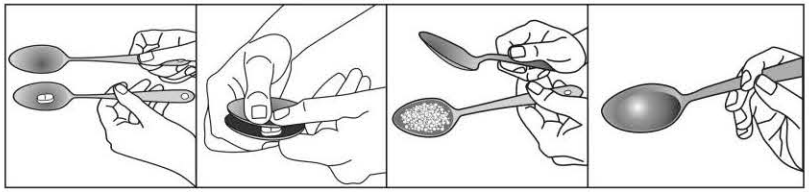
Version 8a



Version 8b

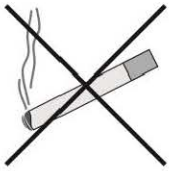


Final version

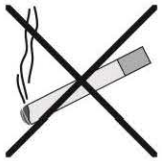


9. Do not smoke

Version 9a

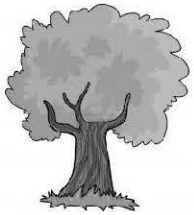


Final version

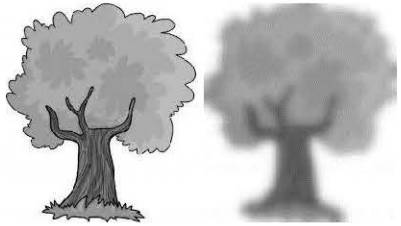


10. Blurred vision

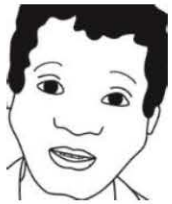
Tree



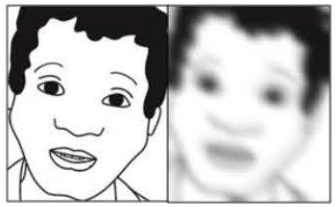
Tree blurred



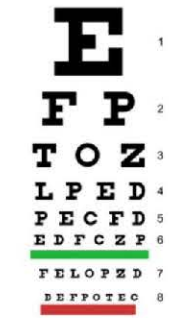
Face



Face blurred



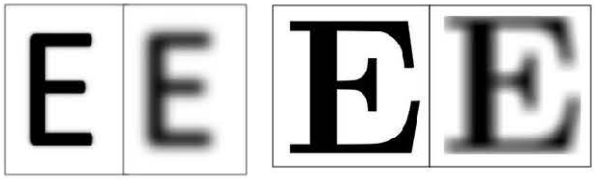
Snellen Chart



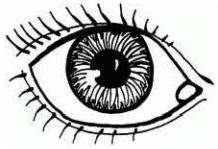
Snellen Chart blurred

Letter ‘E’

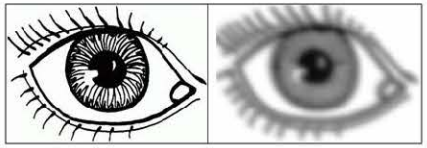
Letter ‘E’ blurred



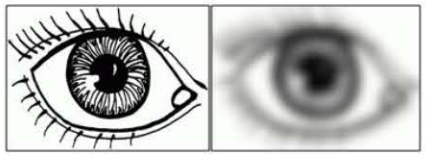
Eye



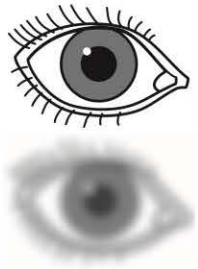
Eye blurred version 10a

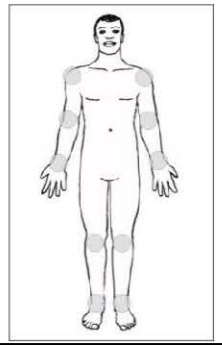
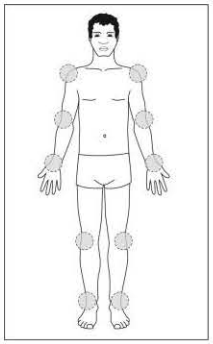
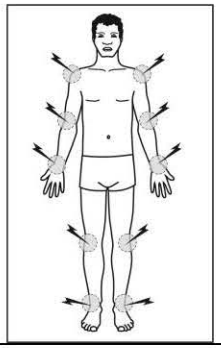
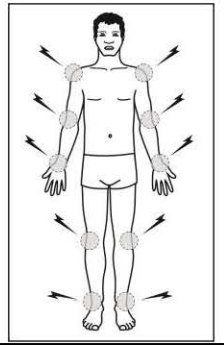
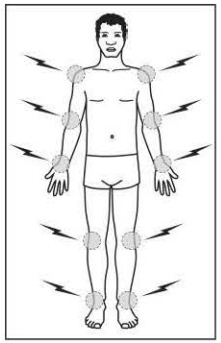


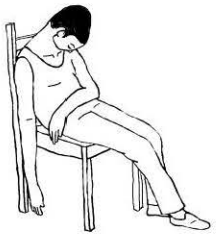
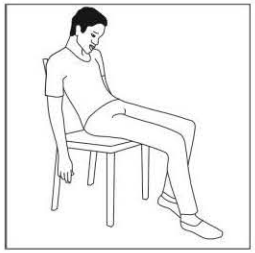
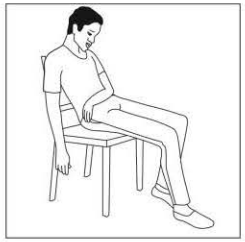
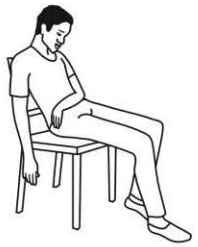
Eye blurred version 10b



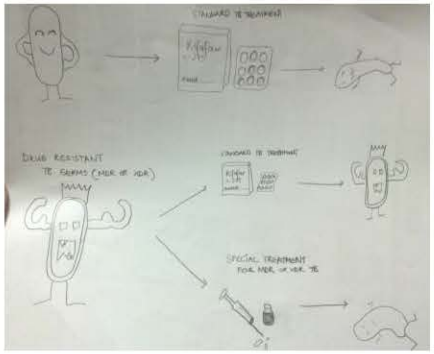
Eye blurred final version



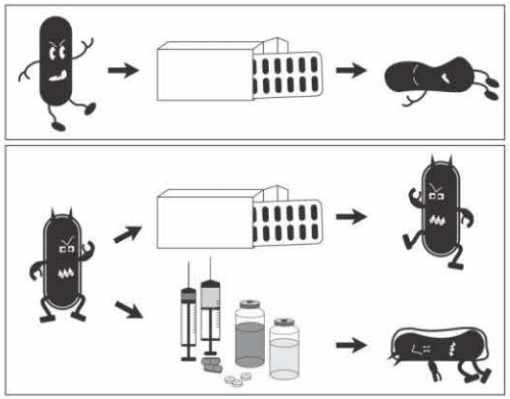
11. Joint pain	Version 11a	Version 11b	Version 11c	Version 11d	Final version
					

12. Muscle weakness		Version 12a	Version 12b	Version 12c	Final version
					

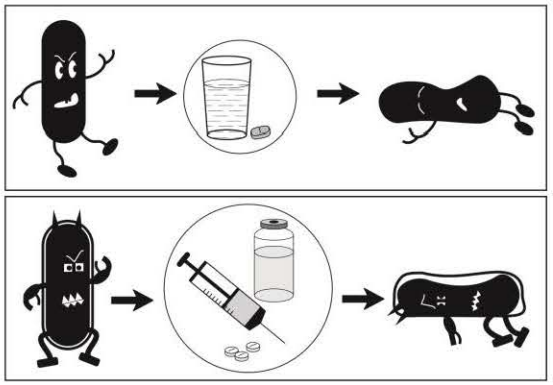
13. Drug-resistant TB sequence



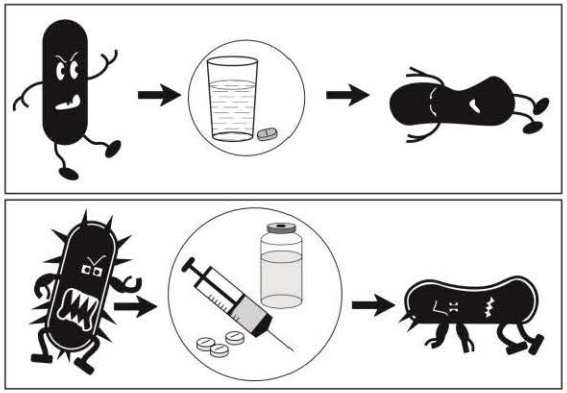
Version 13a



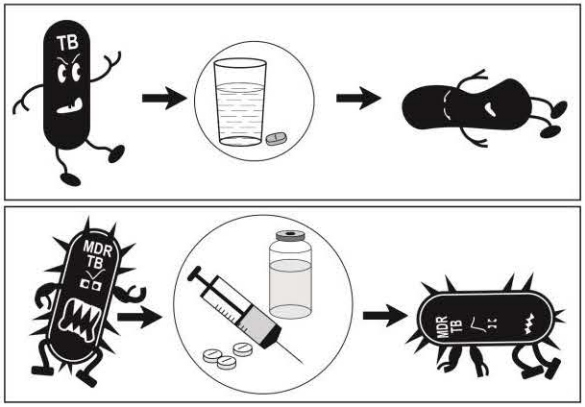
Version 13b



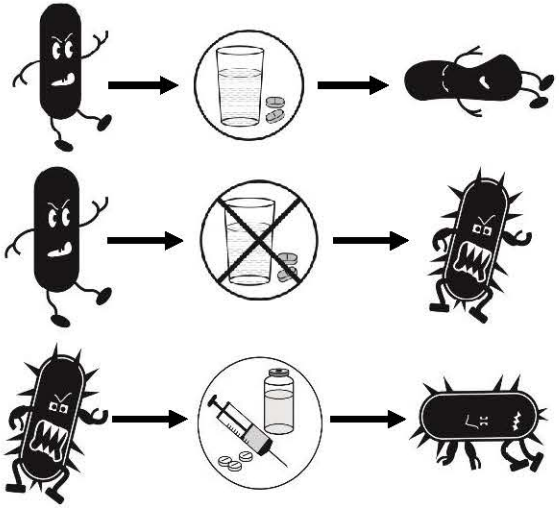
Version 13c



Version 13d



Final version



Discussions with the graphic artist were conducted via email, telephonic and Skype interactions whereas HCPs and patients' opinions were drawn from group discussions and informal one-on-one interviews at Temba TB Hospital. The design, development and modifications made to the new set of pictograms and pictogram sequences are described below and the final version is indicated in brackets alongside the named pictograms.

Pictogram 1: Tablet box. A photograph was taken of the box of tablets that is usually available to TB patients at public healthcare facilities. The box was included in the leaflet to allow patients to easily identify the familiar packaging and to highlight upfront that the leaflet focused on information about their TB medicines. This image was used in the first section communicating the common trade names of TB treatment and the approximate duration of treatment. Both HCPs and patients indicated that the use of trade names like Rifafour®, Ritib® and Rifinah® are better known and are used more commonly than the generic names of individual drugs.

Pictogram 2: Glass of water and TB tablets. A pictogram was designed showing TB tablets next to a glass of water. The number of tablets that a TB patient is required to take varies according to their body weight. Preliminary discussions with HCPs reported that showing two or three tablets would be appropriate but they emphasised that the tablets should not be large and should not be placed in a position that would draw attention to the number of tablets as seen in the initial version of the pictogram (Version 2a). The pictogram was modified by reducing the tablet shading and placing the tablets in a random manner as seen in Version 2b. This version was again criticised by HCPs who felt that the tablets were too prominent and would draw attention. A sketch was developed of the ideal position and arrangement of the two tablets and the result is seen in the final version of the pictogram (Final version a). A black cross was placed over the pictogram to denote 'not taking treatment' (Final version b).

Pictogram 3: Happy-looking and healthy patient. In an effort to motivate and encourage patient adherence, a pictogram showing a happy-looking, healthy patient who has been adherent to his medicines and is now feeling healthier was designed. The first version (Version 3a) was a rough sketch, which underwent multiple modifications before being deemed acceptable. The differences between Version 3b and 3c were minor and entailed changes to the length and darkness of the eyebrows to reduce the dubious appearance of the

patient. The final version was the same as Version 3c but the outlines were darkened and the border was removed.

Pictogram 4: Sick TB patient on hospital bed. A photograph of an individual with severe wasting and a prominent rib cage was used as a template for designing a pictogram communicating the concept that nonadherence leads to disease progression, wasting and hospitalisation. Several minor changes were made in successive iterations e.g. showing a nipple on the right chest area and altering the image of the hospital bed.

Pictogram 5: Lung sequence showing progressive clearing of the lungs when treatment is taken. Both HCPs and patients indicated that one of the major reasons why patients discontinue their TB treatment is because they no longer have symptoms of TB and start to feel much better. To highlight the importance of treatment completion, a pictogram sequence was designed showing the impact of TB medicines on gradual clearing of the lungs over successive time intervals (therapy initiation, 2 months, 4 months and 6 months by which stage the lungs should be clear). Version 5a, which consisted of three time intervals, was modified to include an image showing clear lungs - effectively a cured patient. Several discussions were held with HCPs and radiographers to try and ascertain the most appropriate way to represent the progressive clearing of the lungs as treatment proceeded. An alteration in facial appearance of the patient over time was also considered important to support this concept, with the final sequence showing progression from a sick thin patient at the start of treatment to one that was happier, with a plumper face and was meant to reflect good health. The pictogram illustrating TB treatment (glass of water and tablets) was included in the top left hand corner of each segment and modifications have been described above (Version 2a-c).

Pictogram 6: Time to take treatment. Patients are advised to take their medicines at the same time every day so a pictogram was developed that showed a patient looking at his watch to communicate the idea of checking the time. In the final version, an image of the medicine was shown along with an arrow pointing down at his watch to connect time with taking medicine. Patients felt this was a simple and easily understood pictogram.

Pictogram 7: With food or without food. Due to confusion amongst patients about when to take TB treatment in relation to a meal, pictograms indicating with food or without food were

developed based on photographs of a bowl containing typical local food. This was well received by TB patients at Temba.

***Pictogram 8: Crushing tablet and mixing sequence*.** One major concern associated with the administration of TB medicines is their large size, making them difficult to swallow, especially amongst elderly patients. In practice, HCPs advise patients to crush the tablet and mix it with a small amount of liquid or food. A pictogram sequence illustrating the various steps was designed. The most commonly used method of size-reduction within the target community was determined which was crushing the tablet between two stainless steel spoons and then mixing the crushed powder with a small amount of water, juice, jam or yogurt. This sequence was well understood by most patients and was successful in highlighting key steps. Version 8a consisted of a vertical orientation of the sequence and this was modified to a horizontal orientation to allow for easy inclusion in the PIL. The other modification included changing the appearance of the crushed fine powder in Version 8a, to a more granular powder appearance in the later versions.

Pictogram 9: Do not smoke. Smoking is common in South Africa and it is a huge concern amongst TB patients as both smoking and TB damage the lungs. Research shows that smoking reduces the efficacy of TB medicines and decreases the levels of pro-inflammatory cytokines and circulating immunoglobulins, thus reducing activity of alveolar macrophages [376]. The pictogram showed a conventional lit cigarette overwritten with a negation sign and was well interpreted by patients. The only modification was to increase the darkness of the outline.

***Pictogram 10: Blurred vision*.** Demonstrating blurred vision in a visual form was challenging. The concept adopted included showing firstly a clear image on the left, with a blurred version of the same image right next to it. Various pictures were initially selected: a tree, a face, the Snellen Chart, the letter E and an eye. These were tested for preference in the target population with the majority choosing the eye as being the best representation of blurred vision. Several versions with varying degrees of blurring were proposed. The final version (Eye Blurred Final Version) included an image of an eye with a significantly blurred version of the same image directly below. This was well received by the target population and was deemed acceptable for inclusion in the PIL.

***Pictogram 11: Joint pain*.** The approach taken to illustrate joint pain was to show a full body image and use a visual illustrating pain at specified points on the body i.e. the joints. A rough sketch (Version 11a) was developed and discussed with HCPs and patients at Temba who recommended adding clothing, increasing visibility of the demarcation at the joints and introducing an illustration that portrays a sense of pain. The image was modified to include thunderbolt-like flashes to communicate the sensation of pain at the joints. In a number of iterations, their size and orientation were altered resulting in the Final Version.

Pictogram 12: Muscle weakness. "Weakness in the muscles" is an extremely challenging concept to communicate directly as actual muscles could not be illustrated because of limited knowledge of human biology in this population. We chose to depict this with tiredness and slumping when seated on a chair. In order to determine the best pose that depicts muscle weakness, the investigator underwent heavy physical activity and thereafter took photographs of the various positions that were deemed to be representative of muscle weakness and tiredness. A member of the isiXhosa community was then asked to pose for photos in a similar position. Several modifications were made to Version 12a including changes in the length of the right hand to ensure that it was proportional to the body and chair and changes in the position of the hand over the waist. This was removed in Version 12b, however most members of the design team felt it was important to have the hand over the waist as it displayed a sense of flaccidity that is associated with muscle weakness and thus was reintroduced.

***Pictogram 13: Drug-resistant TB sequence*.** Many patients do not know that bacteria cause TB and to encourage patients to take their treatment, a sequence was developed to show the death of the bacterium (germ) when TB treatment is taken correctly. A cartoon-like version of a TB 'germ' was sketched. As drug-resistant TB is a huge problem in South Africa and is mainly attributed to poor treatment adherence, we included a pictogram sequence to communicate the idea that if the patient did not take their TB medicines, a bigger meaner-looking 'germ' would develop. Several modifications were made to the drug-resistant TB 'germ' to make it look stronger and more threatening and dangerous. Discussion with HCPs revealed that it was important to inform patients about the need to use 'stronger medicines' to kill the 'stronger germs' associated with drug resistance. Parenteral medications (stronger medicines) were therefore included as part of the sequence. Initially, Version 13a consisted of only two steps whereby the TB germ dies when normal treatment (tablets) is taken, and the

drug-resistant TB germ dies with the use of ‘stronger medicines’. However, an additional step was included to show that the ‘TB germ can become stronger’ if the tablets are not taken. The final pictogram sequence was well-received by both patients and HCPs.

4.3.3 Format and layout of the PIL

The PIL developed was a double-sided A4 leaflet with a landscape orientation. Previous research studies in South Africa have found this format to be effective and preferred [377]. The title, ‘First-line TB Medicines’ was easily identifiable, distinct and was much larger than the text included in the various sections of leaflet. The text was easy to read and font size was optimised within the space available. A consistent font (Calibri) was used throughout the leaflet. Font size varied, with headings as 16 point, section headings as 14 point and body text being 12 point.

Each section heading consisted of a clear and concise statement that was clearly demarcated to allow the patient to easily navigate from one section to another. Adequate white space throughout the leaflet was ensured, with consistent line spacing that optimised the available space. Bulleted points were utilized for short lists of key points of simple sentences. A simple appropriate bullet style was chosen to represent each point.

Careful consideration was given to strategically juxtaposing the pictogram and its related text. Pictogram size was optimized according to available space while ensuring adequate white space between text, pictograms and sections to reduce eye fatigue. An important message that HCPs felt should be emphasised was the need to take TB medicines for the full course duration. To highlight this key message, the information was placed in a shaded text box which drew attention and was clearly visible. A version of the PIL with no side effect pictograms was also designed for use in the follow-up interview to determine if patients preferred PIL with or without side effect pictograms. This was available in English, Afrikaans and isiXhosa (Appendix C3-C6).

4.4 Development and validation of the Medicine Literacy Test (MLT)

4.4.1 Introduction

Patients with limited health literacy often have difficulty reading and understanding verbal instructions and WMI including leaflets, labels, posters, appointment slips and medical forms; and as a result are not in a position to make informed decisions in their medicine-taking practices [378]. Identifying such patients is essential so as to provide them with appropriate counselling and support to compensate for their limited ability to navigate the healthcare system. There are currently no tools or instruments that have been developed in South Africa to identify patients with limited health literacy. This project specifically focuses on medicines which are central in promoting and maintaining good health. The objective of this sub-study therefore was to develop and validate a test to evaluate medicine literacy in a population with limited reading skills.

This sub-study of developing and validating the MLT was part of a larger health literacy study conducted by two 4th year Pharmacy students as part of their final year research project (Gray and Marimwe, personal communication). The author of this dissertation (SP) was involved in the conceptualisation of the project with her supervisor (RD) and participated actively in all other aspects as a co-supervisor together with RD. This included initial discussions with the students, ongoing communication with all group members related to background reading, development and reviewing of the research proposal, application for ethics approval, development of the MLT and other health literacy tests, development of the questionnaire, training the students for data collection interviews and analysing the results.

4.4.2 Method

4.4.2.1 Development of MLT

Functional health literacy includes having adequate reading, writing and numeracy skills that allow individuals to function in their day-to-day lives [101]. This level of health literacy forms the foundation for other types of health literacy, including interactive and critical health literacy. In clinical practice, the ability to read and understand a medicine label demands some level of functional health literacy thus questions included in this health

literacy test were based on a standard medicine label. Ciploxx® (ciprofloxacin hydrochloride), an antibiotic usually prescribed for upper and lower respiratory tract infections, skin infections, gastro-intestinal infections, bone infections and gonorrhoea [379] was chosen. The text included in the medicine label (Figure 4.2) was obtained from the package insert and contained basic instructions for administering this medicine. The medicine label was translated into isiXhosa and Afrikaans by language experts and back-translated into English by different experts (Appendix D1-D3).

Eight questions were developed to test comprehension of the information on the label; six comprehension and two numeracy questions. Participants were asked to read the label (Figure 4.2) and answer eight questions based on the information contained in the label. One mark was allocated for each question answered correctly, with eight being the maximum total score. For two of the questions, patients were required to provide two correct answers in order to score a point. Individual scores were categorised according to the following three categories of medicine literacy: 0-3 (inadequate); 4-5 (marginal); and 6-8 (adequate).

CIPLOXX® 250 (28 tablets)

Take two tablets twice a day with a full glass of water. The medicine may be taken with or without food. Take the medicine at the same time every day. Do not drink or eat dairy products or antacids less than two hours before or after taking the medicine. This medicine may lead to drowsiness, especially when taken with alcohol. Complete the course. Store in a cool place, away from children.

Figure 4.2: Ciploxx® (ciprofloxacin hydrochloride) medicine label developed for the MLT

4.4.2.2 Study setting, study participants and interview process

A questionnaire (Appendix D4) was developed to collect demographic data and to evaluate medicine literacy using the following tools: MSFHL, MLT, Newest Vital Sign-South Africa (NVS-SA) and modified screening questions [124]. Only results pertaining to the validation of the MLT will be presented.

The study was conducted amongst members in the Rini township, a lower socioeconomic district in Grahamstown East (details of the area are provided in section 3.2.1) and interviews conducted at a local community development centre. A member of the community was trained as a recruiter for the project. A flyer about the study was designed and distributed to potential participants and placed in local businesses. Participants were also recruited using the snowball technique. Individuals were included if they were first-language isiXhosa speakers, 18 years and above, had a maximum of 12 years of schooling and a basic ability to read (either in isiXhosa or English). Exclusion criteria included the presence of cognitive, hearing or visual impairment.

Interviews were conducted by one student research assistant with the assistance of a trained interpreter. A pilot study with four eligible participants served to test the clarity and comprehension of the questionnaire as well as to determine the approximate length of each interview. Based on feedback from the pilot study, no modifications to the questionnaire were necessary.

To establish the reliability of the MLT, the study design was a test-retest design, with a 2-week interval between the baseline and follow-up interview. A total of 35 participants were recruited for the study, with three lost at the 2-week follow-up. Data from 32 participants were included in the final analysis. Prior to conducting the interview, each participant was given a comprehensive verbal explanation of the study and asked to sign a consent form (Appendix D5). Participants were informed that they were free to withdraw from the study at any point and were remunerated for their contribution to the study with a food voucher worth R40 (US $4) at the first interview and for the follow-up interview they received a food voucher worth R20 (US $2). Participants were asked to read the label information and to answer the questions based on information sourced in the label. They were requested not to

answer based on their own experience with taking medicine, but were constantly directed to the label and asked to identify the reason for their answer in relation to the label.

Ethical approval was sought from the Rhodes University Faculty of Pharmacy Ethics Committee (Appendix A4) and permission to conduct the interviews was sought from the Rhodes University Community Engagement office and the Project Director at the development centre. All data were kept confidential at all stages of the project and for identification purposes a participant number was used. Data obtained shall be retained for the duration of the study and then archived at the Faculty of Pharmacy for a minimum period of 5 years. Thereafter, it will be disposed of in a manner that protects its confidentiality and does not allow for its retrieval by any means.

4.4.2.3 Data analysis

Individual scores for the MLT were calculated and were categorised into inadequate (0-3), marginal (4-5) and adequate (6-8) health literacy. The minimum, maximum and average times taken to administer the MLT were determined. Additionally, an age, gender and education effect on final MLT score was computed using the Chi-squared test. Internal consistency was determined by calculating Cronbach's alpha where internal consistency is indicated by an alpha coefficient of at least 0.70 [380]. To assess the reproducibility of results over a period of time (in this case two weeks), test-retest reliability was estimated using Pearson's correlation coefficient. Significance level was set at $p < 0.05$.

Convergent validity is evaluated by determining the correlation between the MLT and another validated health literacy tool. As there are no health or medicine literacy tests validated in this population, or tests that have been validated in isiXhosa, this was not possible. Face validity of the health literacy test was ascertained through informal discussions with HCPs and patients.

4.4.3 Results

Demographic characteristics of the 32 participants are shown in Table 4.3. Approximately two thirds of the participants were female and the mean age was 41.5 ± 17.1 years. Mean time spent in formal schooling was 9.0 ± 2.1 years. Most participants had attended some

primary school, with 62.5% having between eight and 12 years of schooling. More than three quarters were unemployed and from the few who were employed, the work done was predominantly manual.

The majority (96.9%) indicated that they were able to read in isiXhosa whereas only 50% reported that they were able to read in English. Participants were offered a choice of the MLT label in English or in isiXhosa, with most (75%) choosing the latter. At the follow-up interview, the number of participants choosing the isiXhosa label increased to 81%.

A total of 18 patients (56.3%) reported having a chronic condition and thus went to the clinic every month. The remaining patients (43.8%) indicated that they went to the clinic less than once a month.

Table 4.3: Demographic characteristics of participants (n=32)

Demographics	**Frequency n (%)**
Gender	
Male	11 (34.4)
Female	21 (65.6)
Race	
Black	32 (100.0)
Age	
18-29	10 (31.3)
30-44	9 (28.1)
45-59	10 (31.3)
≥ 60	3 (9.4)
Education	
None	0 (0.0)
Grade 1-4	0 (0.0)
Grade 5-7	12 (37.5)
Grade 8-12	20 (62.5)
Home language	
isiXhosa	32 (100.0)
Afrikaans	0 (0.0)
English	0 (0.0)
Other	0 (0.0)
Employed	
Yes	7 (21.9)
No	25 (78.1)
Type of employment	
None	25 (78.1)
Predominantly manual	6 (18.8)
Predominantly non-manual	1 (3.1)

Table 4.4 shows the results at the two interview times. It was evident that patients had greatest difficulty in answering the two numeracy questions (Questions 4 and 5). At the first

interview, only four participants (12.5%) got question 4 correct and this increased to six participants (18.8%) at the second interview. For question 5, initially five participants (15.6%) got the question correct and surprisingly this decreased to two participants (6.3%) at follow-up.

Table 4.4: Correct responses to individual questions in the MLT at baseline and follow-up interviews, n (%)

Medicine Literacy Test (MLT)	**Baseline (n=32)**	**Follow-up (n=32)**
1. How many tablets must be taken each time?	28 (87.5)	31 (96.9)
2. Do you have to take this medicine after eating a meal?	10 (31.3)	10 (31.3)
3. What should you take this medicine with?	30 (93.8)	32 (100.0)
4. For how many days would you take this medicine?	4 (12.5)	6 (18.8)
5. If you take this medicine at 7 pm (in the night), what time (before and after 7 pm) will it be okay to drink milk?	5 (15.6)	2 (6.3)
6. Would you keep any of this medicine to use if you got sick again?	12 (37.5)	11 (34.4)
7. How might this medicine make you feel, especially if you take it with alcohol?	19 (59.4)	27 (84.4)
8. How should you this medicine be stored?	20 (62.5)	19 (59.4)

Comprehension questions 2 and 6 were particularly poorly answered. Less than a third were able to identify when it was acceptable to take the medicine in relation to eating and just over a third said it was permissible to retain some of the tablets to use at a later time if necessary. Well-answered comprehension questions were questions 1 and 3 which asked about basic medicine-taking instructions such as dose and taking with water.

The mean MLT score of 4.0 at baseline increased slightly to 4.3 at follow-up (Table 4.5). A strong significant correlation was noted between results from the two interview times ($r=0.621$, $p<0.001$). The mean MLT score at both interviews indicated marginal health literacy. There were no significant differences in the number of participants in each health literacy category at baseline and follow-up. Less than a quarter of the study population (n=7, 21.9%) was classified as having adequate health literacy, with just over a third classified as having inadequate health literacy. The average time taken to administer the MLT was four and a half minutes, which decreased to just over two and a half minutes on re-administration. No age, gender or education effect on medicine literacy was observed for both individual questions and for categorisation into the three literacy categories.

Table 4.5: Miscellaneous MLT results

	Baseline (n=32)	Follow-up (n=32)
MLT scores		
Mean MLT score ± SD	4.0 ± 1.8	4.3 ± 1.5
Minimum score	1	2
Maximum score	8	7
Health literacy categories		
Inadequate health literacy (0-3)	12 (37.5)	12 (37.5)
Marginal health literacy (4-5)	13 (40.6)	13 (40.6)
Adequate health literacy (6-8)	7 (21.9)	7 (21.9)
Time taken to administer the MLT (mins)		
Mean ± SD	4m 33s ± 1m 49s	2m 47s ± 1m 16s
Minimum time	1m 48s	1m 51s
Maximum time	9m 24s	7m 54s

To establish face validity of the newly designed tool, informal consultations with individual HCPs, African language experts and members of the target population were consulted and they indicated that the text included in the label and the questions asked was appropriate and not overly complex. An individual (not a language expert) fluent in both isiXhosa and English was asked to back-translate the isiXhosa label and confirmed that the isiXhosa version contained simple Xhosa text and was identical to the English version. Three local first-language isiXhosa speakers were asked to read the label and to identify if there were any sentences that did not make sense or individual words that were difficult to understand. The label was deemed to be of an acceptable reading level.

Internal consistency was determined using Cronbach's alpha. The coefficients obtained were 0.64 (baseline) and 0.56 (follow-up), slightly lower than the acceptable 0.70. These did not change when selected individual items were removed from the test. Test-retest reliability was calculated by determining Pearson's correlation coefficient between baseline and follow-up scores. There was a strong and statistically significant correlation between the MLT scores obtained at both interviews ($r=0.621$; $p<0.001$). Minimal difference in the mean scores at baseline (4.0 ± 1.8) and follow-up (4.3 ± 1.5) was reported. The distribution into the medicine literacy categories remained consistent between the two interviews.

4.4.4 Discussion

To our knowledge, this is the first study that attempted to develop and validate any form of health/medicine literacy tool for a typical South African population. The MLT was successful in differentiating patients into medicine literacy categories, with only a fifth (22%) of this study population having adequate medicine literacy skills. This is reflective of the current situation in South Africa, whereby most patients encounter difficulties with WMI. The two questions that were poorly answered focused specifically on numerical abilities, supporting previous research from other countries that has identified inadequate numeracy skills when assessing health literacy [381-384]. The two comprehension questions that were poorly answered included when to take the medicine in relation to a meal (question 2) and completing the course of antibiotics (question 6). This could potentially be as a result of the need to apply greater cognitive abilities whereby participants had to read, understand and apply the information provided in the label in order to get to the correct response. In contrast, the questions about the number of tablets to take (question 1) and what to take them with (question 3) were well answered and this may be attributed to the fact that the responses to these two questions were in the first sentence of the medicine label.

Establishing the reliability of a research tool means that it should consistently reflect the construct it is designed to measure [385]. Despite demonstrating a slightly lower internal consistency than the value of 0.70 that is considered acceptable, the MLT showed excellent reliability on re-testing, showing a strong and significant correlation between the two MLT scores. Further investigation using a larger sample size could result in more accurate results and greater insight on items that should be excluded from the MLT, as Cronbach's alpha coefficient can be influenced by the number of items in the tool [386]. The corrected item-total correlation gives an indication of the correlation between each item and the total score, with a reliable tool having a value less than 0.3. All items apart from question 4 of the MLT showed a good correlation with total score. This was a numeracy question that required the participant to divide the total number of tablets received by the number taken in one day in order to calculate the duration of therapy. The correlation with total score for this question was only 0.20. However, removing this item from the MLT did not increase Cronbach's alpha.

Age, gender and education did not appear to influence the MLT score. Although it was anticipated that education would influence the ability to answer the questions correctly, this was not established. However, the limited size of the study and the lack of participants in the lower education categories may have negatively influenced the ability to investigate this relationship. As age is generally associated with education, it is unsurprising that no age effect was found.

When offered a choice between reading the medicine label in English or isiXhosa, three quarters selected the latter, illustrating the preference for health and medicine information in their first language. In South Africa, there are 11 official languages and this serves as a major challenge to individuals and/or organisations that develop health-related information. According to the South African Patient's Rights Charter of 1999 [367], patients have the right to simple user-friendly information in a language or format that they understand. HCPs and those tasked with the provision of information should ensure that they are able to effectively communicate information to patients and the community, especially those with limited literacy and health literacy.

4.5 Modification of tools to evaluate different medicine-taking patient behaviours

There is currently a paucity of reported research investigating the impact of patient counselling about TB medicines on adherence and self-efficacy. Two instruments were identified as potentially useful for the study population: MMAS-8 that measures self-reported adherence and the HIV-ASES that evaluates self-efficacy.

4.5.1 Adherence assessment: modifications to the MMAS-8

The original version of the MMAS-8 was developed to evaluate self-reported adherence amongst hypertensive patients [199]. It is easy to administer, useful to use in practice and the authors highlight the need to develop similar tools for other disease-states. Table 4.6 shows the modifications made to the MMAS-8 to ensure its applicability for TB patients with limited literacy skills.

Question 1. Terminology was changed from 'high blood pressure pills' to 'TB medicines'. The term 'pills' was replaced with 'TB medicines' as this is the term commonly used by local HCPs and patients.

Question 2. The following statement: 'Sometimes people may not forget to take their medicines but miss taking it for other reasons' was added to encourage patients to answer openly without necessarily having to admit they forgot to take their medicines. The time frame was changed from two weeks to a month to mimic the public sector setting whereby patients usually return to the clinic after a month for their repeat prescription. However, this increased time frame (double the original MMAS-8) could potentially translate into a higher proportion of patients reporting nonadherence to their medicine than seen with the original MMAS-8.

Table 4.6: Modifications made to the original MMAS-8

Original MMAS-8	Modified MMAS-8
1. Do you sometimes forget to take your high blood pressure pills?	Do you sometimes forget to take your TB medicines?
2. Over the past two weeks, were there any days when you did not take your high blood pressure medicine?	Sometimes people may not forget to take their medicines but miss taking it for other reasons. Over the past month (since your last clinic visit) were there any days when you did not take your TB medicines?
3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?	Have you ever reduced or stopped taking your TB medication without telling your doctor, because you felt worse when you took it?
4. When you travel or leave home, do you sometimes forget to bring along your medications?	When you travel or leave home, do you sometimes forget to bring along your TB medicines?
5. Did you take your high blood pressure medicine yesterday?	Did you take your TB medicines yesterday?
6. When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?	When you feel healthy, do you sometimes stop taking your TB medicines before the end of the 6 months?
7. Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your blood pressure treatment plan?	During the last weekend, did you miss taking any of your TB medicines?
8. How often do you have difficulty remembering to take all your blood pressure medication?	Some people find having to take TB medicines everyday tiresome. Do you ever feel irritated or get cross about taking your TB medicines every day?

Question 3. The term ‘cut back’ is not commonly used in South Africa and was replaced with ‘reduced or stopped’.

Questions 4 and 5. The only change was to replace ‘hypertension medicines’ with ‘TB medicines’.

Question 6. The phrase ‘When you feel like your blood pressure is under control’ was replaced with ‘When you feel healthy’ as one of the major reasons why patients discontinue their TB medicines is because they no longer feel sick and the persistent cough has disappeared. Additionally, as TB treatment is not chronic but long-term (usually for 6 months), the added words reflect the duration of treatment.

Question 7. This question was replaced with the following: ‘During the last weekend, did you miss taking any of your TB medicines?’ The time frame of ‘weekend’ was chosen as this is considered a period when people typically engage in social activities and forego the weekday routine which may include taking medicines. Many HCPs expressed concern that patients default therapy on the weekends, mainly due to alcohol intake.

Question 8. This question was altered to enable a yes or no answer. The original question demanded a response on a Likert Scale and it is known that, unless properly explained, the use of this scale is often problematic in the study population. This question was also modified to determine patient attitude towards medicine-taking and to establish patient ability to adhere to therapy as one of the common problems noted amongst TB patients is the reluctance or inability to take the large TB tablets every single day.

4.5.2 Self-efficacy assessment: modifications to the HIV-ASES

Although the HIV-ASES is primarily centred on adherence to HIV medicines, it also covers other important aspects that influence adherence and promote healthy outcomes such as regular visits to the healthcare facility, monitoring the progression of the disease, integrating treatment into daily activities and engaging in healthy habits (exercise and diet). The authors highlighted its value in clinical practice and research especially in anticipating and addressing

problems with treatment adherence and self-efficacy, they suggested adapting the tool for other chronic diseases.

There is currently no validated tool to evaluate medicines self-efficacy for the study population who is at high risk for limited ability and confidence in medicine-taking practices. The original HIV-ASES was modified for use in our study population to produce the TB Treatment Adherence Self-Efficacy Scale (TB-ASES). When formulating questions to include in the TB-ASES, we identified factors that contribute to poor patient self-efficacy when taking TB medicines. A total of nine items were included. Figure 4.3 shows the changes made to the original HIV-ASES. Significant modifications were made to the original HIV-ASES to make it applicable for use amongst South African TB patients.

Original Version of the HIV-ASES

I am going to ask you about situations that could occur during your treatment for HIV. Treatment can involve different things for different people. Sometimes, this might refer to taking medications, and other times it could refer to other things that you do to deal with HIV such as diet and exercise or taking vitamins. So, in these questions, when I ask you about your "treatment" or your "treatment plan," I am talking not only about any medications that you might be taking for HIV, but also other things that make up your self-care. For the following questions I will ask you to tell me in **the past month, including today**, how confident you have been that you can do the following things. Use this response scale ranging from 0 ("cannot do at all") to 10 ("completely certain can do"). [Note: The term "clinic" may be replaced by "doctor's office" if participant does not receive care in clinic settings.]

In the past month, how confident have you been that you can:

1. Stick to your treatment plan even when side effects begin to interfere with daily activities?
2. Integrate your treatment into your daily routine?
3. Integrate your treatment into your daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV-infected?
4. Stick to your treatment schedule even when your daily routine is disrupted?
5. Stick to your treatment schedule when you aren't feeling well?
6. Stick to your treatment schedule when it means changing your eating habits?
7. Continue with your treatment even if doing so interferes with your daily activities?
8. Continue with the treatment plan your physician prescribed even if your T-cells drop significantly in the next three months?
9. Continue with your treatment even when you are feeling discouraged about your health?
10. Continue with your treatment even when getting to your clinic appointments is a major hassle?
11. Continue with your treatment even when people close to you tell you that they don't think that it is doing any good?
12. Get something positive out of your participation in treatment, even if the medication you are taking does not improve your health?

Newly developed TB-ASES

I will now ask you a few questions about how confident you feel about certain things that are related to taking TB medicines. This scale will help you answer the questions (holding up scale). This scale is from 1 to 5- choose a number between 1 to 5 with 1 being the lowest level of confidence and 5 being the highest level of confidence. I will show you how to use the scale by asking the interpreter a question and he/she will give an answer using the scale.

Interviewer: You have been told to take your medicine three times a day by the doctor. How confident do you feel that you can take your medicine three times a day? Are you completely certain you can do it, are you slightly certain you can do it or do you feel you are not able to do it?

Interpreter: I usually take my medicines but sometimes at lunchtime I forget to take it because I am busy with some work. So I think I am slightly certain I can take my medicines three times a day.

Interviewer: Did that demonstration help you understand how to reply using this scale? If yes, continue. If no, explain again.

1. How confident do you feel that you can take your TB medicines every single day?
2. How confident do you feel that you will be able to come to the clinic to collect your TB medicines every month?
3. How confident do you feel that you can avoid alcohol when taking TB treatment?
4. How confident do you feel that you can talk to your doctor/nurse/pharmacist about your TB medicines?
5. How confident do you feel that you can take your TB medicines even if they make you feel a bit sick?
6. How confident do you feel that you can take your TB medicines in front of other people who do not know you have TB?
7. How confident do you feel that you can avoid smoking whilst taking TB treatment?
8. How confident do you feel that you can take your TB medicines even if you feel better and no longer have a cough?
9. How confident do you feel that taking the TB medicines will make you get better?*

*Question relates to patient perception of medicines efficacy

Figure 4.3: Original HIV-ASES and modified version (TB-ASES)

The modifications made to the original HIV-ASES are described below.

Introductory paragraph.

- The first sentence briefly explained the purpose of the test.
- Substantial changes were made to the introductory paragraph with one major difference being inclusion of an explanation on how to answer the nine questions using the proposed graphic scale. Most individuals in our target population are not familiar with the Likert Scale, appear to overlook subtle differences as represented by a 1-10 scale and many are unable to comprehend the numerical nature of the scale [37]. This necessitated the inclusion of a brief explanation and scenario. The language used is simple and avoided unfamiliar terminology.
- Each question started with the following phrase: 'How confident do you feel…' This was to encourage patient to openly express their perceived confidence-level with reference to each aspect questioned in the TB-ASES.
- The phrase 'stick to your treatment' was replaced with 'Take your TB medicines'. This modification was necessary as the phrase is not commonly utilised amongst South African patients and it did not specifically refer to TB medicines. Additionally, the phrase used in the HIV-ASES, 'stick to treatment', could be understood as medicines to treat other conditions the patient may have.

Question 1. The first question in the revised version focused on the patient's ability to take TB medicines on a daily basis, unlike the original first question which related to perceived ability to take medicines despite encountering side effects. The concept of side effects is quite foreign to many of our patients [29] so this question was asked in a different manner at a later stage in series of questions.

Question 2. This was based on the original question 10. South African patients often have to travel long distances in order to access healthcare facilities and the majority do not have enough money to use public transport to get to the clinic. Thus, question 10 was rephrased accordingly and the term 'hassle' which is not commonly used was removed.

Question 3. One major issue identified by both patients and HCPs as being associated with the appropriate use of medicines, is the use of alcohol. When phrasing the question, we used

the terms ‘avoid alcohol’ as opposed to ‘do not drink alcohol’ to decrease the authoritative tone in the question.

Question 4. From initial discussions with TB patients, it was noted that the majority were passive and disempowered in their encounters with HCPs [29] so it was considered critical to include a question that focused on this key aspect. Lack of confidence to ask questions could potentially impact on an individual’s ability and knowledge to perform a certain task. No question with this focus appeared in the original HIV-ASES.

Question 5. This was based on original question 1. As the term ‘side effects’ is not familiar to many South African patients [29] it was alluded to with the words ‘even if they make you feel a bit sick’.

Question 6. This question was based on original question 3 and highlights the stigma associated with taking medicines for certain conditions in front of other people. In South Africa, there is still a significant amount of stigma linked to diseases like HIV and TB, and patients reported hiding the fact that they have TB for fear of being associated with having HIV. This question was phrased in a similar way to the original HIV-ASES.

Question 7. Smoking was identified by HCPs as another habit that affected medicine-taking practices and it can also influence health outcomes. This was another focus that was not included in the original HIV-ASES.

Question 8. Premature discontinuation of treatment was not addressed in the original HIV-ASES but was considered essential to include in the TB-ASES as many patients discontinue their TB medicines because they no longer have a cough and start feeling better after a few weeks of treatment.

Question 9. The last question pertained to belief in the effectiveness of TB medicines. Patients who feel that their medicines are helping them may be more likely to adhere to their treatment.

Another component of the HIV-ASES that demanded consideration was the 11-point Likert Scale used to express the patient's level of confidence in response to each question. In a previous study conducted at Rhodes University, the original Likert scale (0-10) was adapted to present a visual representation of the numerical elements [37]. For my study, the range of the scale was reduced from 0-10 to 1-5. Each number was depicted with a bar graph approximately proportional to the magnitude of the numerical value. For the extreme options (1 and 5), images were added to reflect the confidence to perform a stated behaviour. The original HIV-ASES Likert scale and newly developed TB-ASES Likert scale are presented in Figure 4.4.

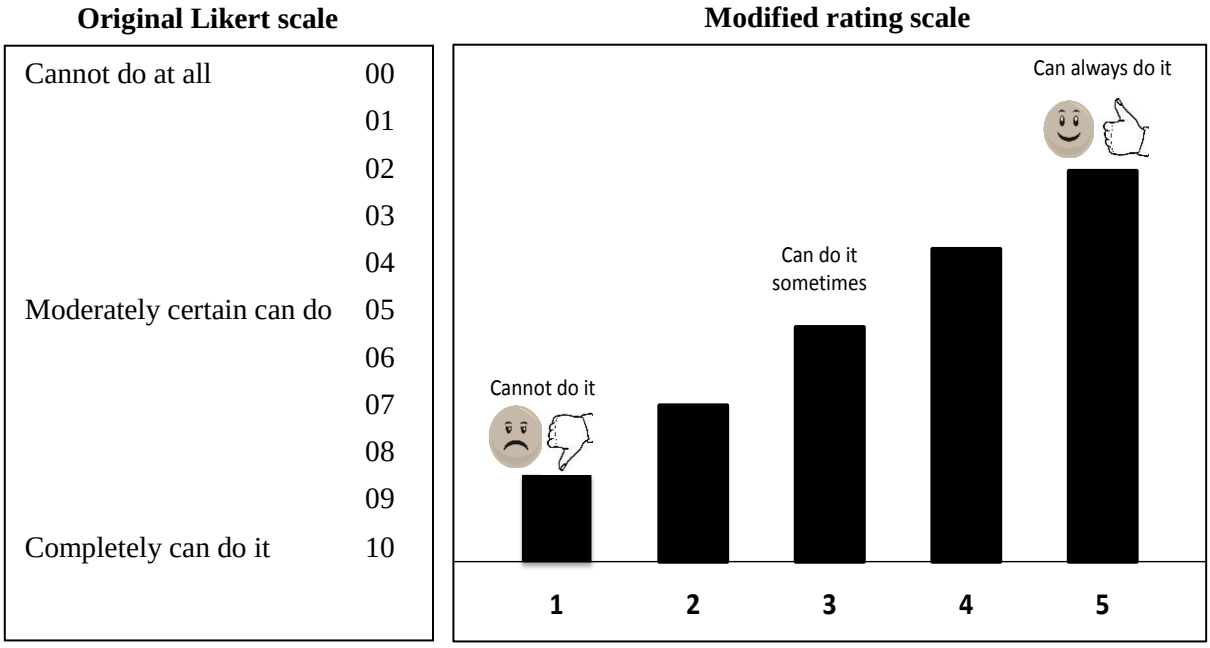


Figure 4.4: Original and modified illustrated version of the Likert scale

The two modified instruments to evaluate patient self-reported adherence and self-efficacy were included in the question guide for the RCT discussed in the next chapter.

CHAPTER 5
METHOD: RANDOMISED CONTROLLED TRIAL TO EVALUATE THE INFORMATION LEAFLET IN TB PATIENTS

5.1 Introduction

This chapter describes the design of the intervention in which an information leaflet was evaluated for its influence on knowledge and health behaviours. The patient-centred approach that had been adopted through all the phases of this project was continued in this chapter by involving patients in the evaluation of the PIL. The chapter describes the method used to evaluate the impact of the PIL on patient knowledge, self-efficacy and adherence over a one month period.

5.2 Aim and Objectives

The overall aim of this project was to improve patient knowledge about their TB medicines through the use of a simple illustrated patient information leaflet (PIL).

5.2.1 Objectives:

- To evaluate the impact of the experimental PIL on patient knowledge, self-efficacy and adherence by conducting a RCT
- To assess patient opinion on the acceptability and usefulness of the PIL
- To investigate the association of selected variables (gender, age, education) with knowledge, self-efficacy, adherence and medicine literacy
- To compare inter- and intra-group knowledge, self-efficacy, adherence and medicine literacy at baseline and at the one month follow-up
- To validate the newly developed MLT

5.3 Method

5.3.1 Study site and study population

This part of the project was done in collaboration with a well-established global company, University Research Co., LLC (URC), who are involved with improving the quality of healthcare in up to 45 different countries, including South Africa. One of the projects managed by URC is the five-year Tuberculosis Program in South Africa, which is funded by the USAID. The purpose of this USAID project is to assist the South African National DoH in their efforts to address the high TB burden in South Africa by providing assistance and strengthening TB-care initiatives in the nine provinces.

A large number of research projects involving local Grahamstown and Rini TB patients have been conducted over the past few years by various groups within Rhodes University, and in order to avoid research fatigue, a decision was made to investigate other options. Collaboration with high profile organisations such as URC and USAID TB South Africa, with links in all nine provinces, would ensure greater exposure for our materials and an opportunity for our research to have an impact at a national level. Following meetings, a memorandum of agreement was drawn up between URC/USAID TB South Africa and Rhodes University. URC/USAID TB South Africa was responsible for identifying a suitable study site, obtaining ethical approval from the national DoH and funding the project.

A high TB burden clinic was identified in Uitenhage, a small industrial town in the Eastern Cape Province. This clinic provides services to patients from the rural townships surrounding the Rosedale area. Most of these patients do not have an income and rely solely on government subsidy. Housing and sanitation is extremely poor with several members of one family residing in a single informally built shack.

In addition to TB services, the clinic also provides general doctor or nurse consultation, dental, radiography, family planning and pharmacy services. The TB unit consists of three consultations rooms staffed with a total of two nurses and 4 community healthcare workers (CHWs). The two nurses are responsible for screening, diagnosing and initiating TB treatment. The CHWs assist the nursing staff in educating and counselling the patients to

ensure that they understand the condition and their treatment. However, being a high burden clinic, staff often face the challenge of time constraints and this compromises the counselling process. Clinic records show that over the 12 month period from July 2012 till June 2013, a total of 584 new cases were registered, reflecting the high TB burden at the clinic.

A preliminary meeting was conducted with clinic staff to introduce the project and its requirements. Feedback and suggestions were welcomed and one important point raised was the need to provide the materials in Afrikaans, a language commonly spoken by the patients attending the clinic. Staff were also briefed on the importance of limiting the use of the leaflet to the experimental group patients only. Additionally, the most ideal method for recruitment of patients was discussed and finalised.

Ethical approval was sought from the Rhodes University Ethical Standards Committee (Appendix A5), the Eastern Cape Department of Health (Appendix A6), and the national Department of Health. Due to the infectious nature of TB, stringent precautions were practiced to ensure infection control. This included conducting interviews in a well aerated room, with masks being offered to the researchers, interpreter and study participants to prevent any cross-infection.

Patients were included in the study if they were over the age of 18 years, taking first-line TB medicines (rifampicin, isoniazid, pyrazinamide and ethambutol), had a maximum of 10 years of formal schooling, their first language was either isiXhosa, Afrikaans or English and if they had at least a basic ability to read in either one of the three commonly spoken languages mentioned above. Patients who had attended TB workshops in the last 6 months, or who had received any formal TB education other than that provided with standard TB care, as well as those who had any visual disabilities and were taking TB medicines not included in the standard first-line treatment, were excluded.

5.3.2 Data collection tool and materials

A questionnaire (Appendix E1) consisting of 13 sections was developed to collect data at baseline and follow-up. Each of these sections is described below:

Section 1. Demographic details including gender, age, race, home language, employment status were included. Several questions about socio-economic conditions were incorporated and these investigated the number of people living in the house, type of housing and availability of electricity and water.

Section 2. The SILS is a single-item instrument that is used to identify patients who require help when reading health-related information materials [128]. It consists of one question "How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?" and patients are required to respond using a Likert scale ranging from one to five (1=never, 2=not often, 3=sometimes, 4=often and 5=always). Any patients responding with "2" or above are classified as patients who require assistance. To contextualise the single item screener for use in our population, the question was slightly modified and read as follows: "Can you tell me how often you need help reading instructions, pamphlets or other written medicine information given to you at the clinic?" Additionally, several examples of information materials were shown to the patient as many patients are unfamiliar with these [29]. Lastly, for this section, medicine literacy was investigated using the newly developed MLT described in Chapter 4, Section 4.4.

Section 3. Clinical data from the patient's file and health passport were obtained including body mass, treatment regimen, adverse reactions, regimen changes, sputum conversion, co-morbidities, HIV status and pharmacy refill dates. Patients were also asked to identify the TB tablets they were taking from a collection of five different tablets with varying colour and sizes and were questioned about the dosing of their TB medicine. The answers given were marked correct or incorrect based on the treatment prescribed by the nurse or doctor, as indicated in patient records.

Section 4. Patient opinion about the severity, prevalence and stigma associated with TB was determined in this section.

Section 5. Baseline knowledge was assessed via 24-items that focused on five key TB-related knowledge areas: disease, medicine-taking, side effects, MDR/XDR-TB and co-infection with HIV and TB. Each item had one mark allocated for a correct response and thus a total score was calculated out of 24.

Section 6. This section focused on investigating selected information pertaining to HISB.

Section 7. Assessed self-reported adherence at baseline using the modified version of the 8-item Morisky self-reported adherence scale (Chapter 4 - Section 4.5.1).

Section 8. Baseline self-efficacy was investigated using the modified version of the HIV-ASES (Chapter 4 - Section 4.5.2).

Section 9. This section only applied to the experimental group who were counselled using the leaflet. Patient language preference for the PIL was ascertained as well as the time taken to counsel the patient using the leaflet.

Section 10. This section consisted of the same 24-items included in Section 5 and was used to determine knowledge at the follow-up interview.

Section 11. Assessed self-reported adherence at follow-up using the modified version of the 8-item Morisky self-reported adherence scale (Section 4.5.1).

Section 12. Self-efficacy was investigated at follow-up using the modified version of the HIV-ASES (Section 4.5.2).

Section 13. Patients in the experimental group were asked for their opinion of the leaflet in terms of its acceptability and usefulness. Both the experimental and control group were asked to explain the meaning of each of the pictograms included in the leaflet. The experimental group were previously exposed to these in the PIL whereas the control group were seeing these for the first time. Patient preference for different versions of information leaflets (with or without side effect pictograms) was elicited.

Data collected at baseline and the follow-up interview is summarised in Table 5.1. The effect of the educational intervention on TB treatment outcomes (smear conversion rates and mortalities) was also considered however in order to derive meaningful results, data should be collected over a period of several years [387]. Additionally, studies have revealed a

number of subjective factors that influence smear conversion rate after two months including gender, high initial sputum acid-fast bacilli grades, cavitary diseases, presence of HIV and drug-resistance [388,389]. Due to these various reasons identified, the effect of my intervention on TB treatment outcomes was not pursued.

Table 5.1: Data collected at the four different interviews

Data collected	Baseline	Follow-up
Demographics	√	
Literacy assessment	√	
Patient records	√	
Stigma and prevalence	√	
Knowledge	√	√
HISB and information sources	√	
Adherence	√	√
Self-efficacy	√	√
Acceptability and usefulness of PIL		√

The label for the MLT and the experimental PIL were translated by a language expert into Afrikaans and then back-translated by a different person who is fluent in both English and Afrikaans (Appendix D1-D3). A pilot study was conducted with five TB patients to pre-test both the questionnaire as a data collection tool and the experimental leaflet. Based on the findings, there were no changes necessary to either the question guide (Appendix E1) or the various versions of the PIL (Appendix C1-C6).

5.3.3 Recruitment and interview process

When patients report to the clinic, the first interaction is with the CHW who enters their attendance into a tick register, after which they are either directed to the nurse or are given a repeat of their TB medicines. The CHW at the registration desk was given a copy of the inclusion and exclusion criteria for the study and was tasked with recruiting patients as they presented at the clinic by giving them a brief explanation of the study and assessing their eligibility to take part in the study. The information they were asked to communicate included the purpose of the study, how long the interview would take and the follow-up

interview after a month. If the patient agreed and was eligible, he or she was directed to the next consultation room assigned for the study.

As the interviewer (SP) was not fluent in isiXhosa and Afrikaans, an interpreter was used for all interviews. The importance placed on the use of an interpreter is discussed in Section 3.2.2. A CHW fluent in isiXhosa, Afrikaans and English was identified and trained as the interpreter for the study. Prior to taking part in the study, each patient was required to complete a consent form (Appendix E2) which outlined the importance of the study, patient contribution to the study, right to leave the study and the fact that all data would be kept completely confidential. This information was verbally explained to patients by the interviewer via the trained interpreter to allow them to make an informed choice to participate in the study. If they agreed to participate, a signature or thumb print was obtained.

Patients were randomly allocated and stratified based on level of education (primary and secondary) to one of two groups using a computerised random number generator: a control group where TB patients received standard care, and an experimental group where, in addition to standard care, TB patients were also briefly counselled using the experimental PIL. They were encouraged to refer to the PIL when at home.

Patients were interviewed at baseline and four weeks later at the follow-up interview (for details of data collected see Section 5.3.2). A period of four weeks was selected since patients in the public sector setting are usually given a supply of TB medicine for 28 days. Patients in the control group who did not receive the leaflet were given a copy at the follow-up interview. As an honorarium for their contribution to the study, each patient received a cap with a TB awareness message as well as food stamps worth R40 (~ US$4) at each interview.

5.3.4 Importance of establishing in-house support for the research project

Throughout the data collection process the staff at Rosedale were extremely helpful and supportive. They ensured that the data collection proceeded smoothly and would follow-up on any patients who missed their subsequent interview dates by sending a message to the patient via the TB DOTs supporter (usually CHWs or volunteers) stationed in the patient's

residential area. Below are a few photographs captured during the data collection period (patient consent to take pictures was obtained).

Patient [R] describing the pictogram to the interviewer [L]

L to R: Mrs Elizabeth Lakey (interpreter), Miss Sonal Patel (interviewer), Ms Elmarie Cowie (community healthcare worker)

Patient describing the pictogram illustrating the clearing of the lungs during therapy

5.3.5 Data analysis

To calculate sample size, it was predicted that 'knowledge' would increase by 25% from a baseline of 60%, to a post-baseline predicted knowledge of 85%. This was based on a previous study conducted in a similar target population with HIV which also evaluated the influence of illustrated information materials on knowledge. Knowledge in the group who received the materials increased by 26.5%.[24] Thus, for a level of significance of 5% and statistical precision of 10%, at least 53 patients were required in each group (control and experimental) thus the target was set at 60 patients per group.

Data were captured in an Excel spreadsheet. Analysis included the generation of frequency tables for all data and the calculation of a percentage knowledge score, self-efficacy score and self-reported adherence score at baseline and follow-up. The paired t-test (non-categorical data) and Pearson Chi-squared tests (categorical data) were used to investigate the significance of any changes from baseline to follow-up. The association of selected variables (gender, age, education) with knowledge, self-efficacy, adherence and medicine literacy was analysed using regression analysis, chi-square tests and Analysis of Variance (ANOVA). Correlations between knowledge, self-efficacy, adherence and medicine literacy were determined using Pearson and Spearman rho correlation tests. The various statistical tests were conducted at a 0.05 level of significance. Analysis of MLT data was conducted as described in Section 4.4.2.3.

CHAPTER 6

RESULTS: IMPACT OF THE INFORMATION LEAFLET ON KNOWLEDGE AND BEHAVIOURAL OUTCOMES IN TB PATIENTS

6.1 Introduction

This chapter reports the findings of the RCT that was conducted to evaluate if a brief counselling process using the simple illustrated take-home TB PIL would improve patient knowledge and medicine-taking behaviour. A study conducted by Koo *et al.* [390] reported the influence of patient characteristics (age, gender, education, health literacy) on evaluation and use of WMI. The authors suggest that identifying these associations can assist in tailoring materials that are suitable for the intended audience. The influence of patient characteristics on knowledge, self-efficacy and adherence are presented, along with patient opinion and acceptability of the designed PIL. Reliability of the MLT and other medicine literacy data are presented as well as patient HISB and satisfaction with current health information sources.

6.2 Patient characteristics

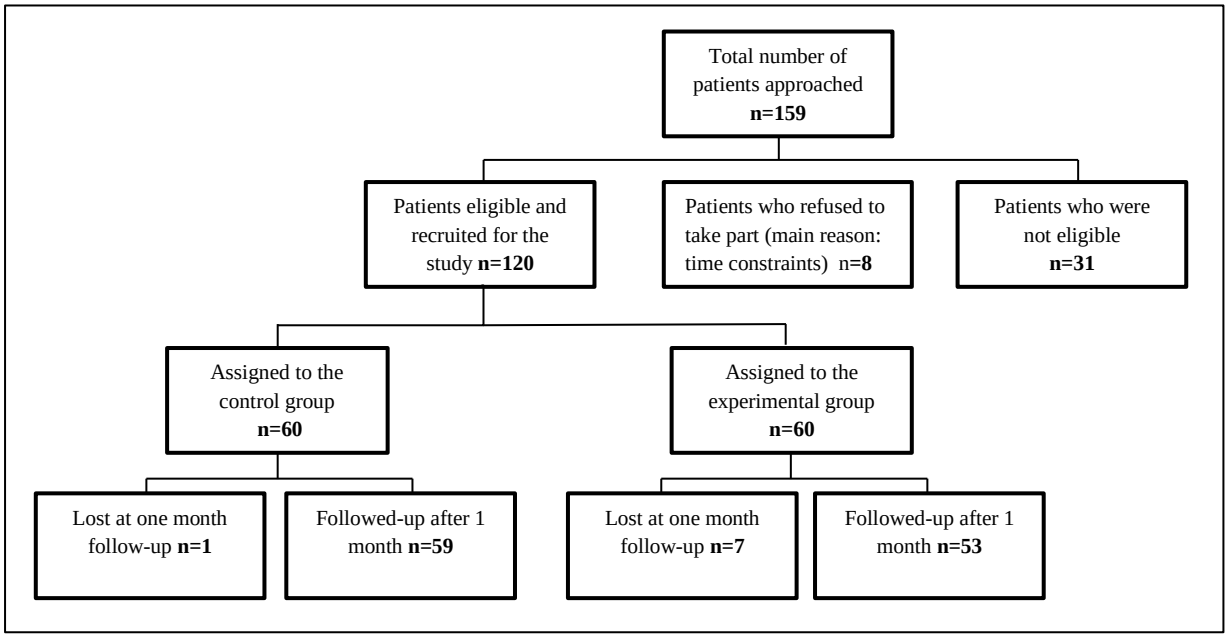


Figure 6.1: Recruitment and group allocation of TB patients

Figure 6.1 illustrates the recruitment and group allocation of patients for the study. A total of 159 patients were approached to participate. Due to time constraints eight patients refused to take part in the study and 31 patients were not eligible mainly because they had more than 10

years of formal education. Thus a total of 120 patients were recruited for the study and they were stratified according to level of education (primary or secondary) into either the control (n=60) or the experimental group (n=60). At the one month interview, a total of one (control) and seven patients (experimental) were lost to follow-up.

6.2.1 Demographics

From the 120 patients interviewed, 72 (60%) were male and the majority (77%) were between the age of 18 and 44 years (Table 6.1). Most of the patients attending the clinic are from two racial categories: black African or coloured (referred to as mixed-race in other countries). A total of 65 patients (54.2%) were black African and the remaining 55 patients (45.8%) were coloured. The majority of the patients (80%) spoke Afrikaans at home. The number of unemployed patients was extremely high with 95 patients (79.2%) being unemployed at the time of the interview. There was no significant difference in demographic characteristics noted between the control and experimental groups.

Patients were stratified according to their level of education into either primary (Grade 1-7) or secondary (Grade 8-10). Although secondary education in South Africa is from Grade 8-12, this study focused on limited education participants. Grade 10 represents the first formal exit level from the schooling system. The need to stratify patients into primary and secondary education was considered important as past research studies conducted in this population group have generated significantly different educational qualifications in the experimental and control groups with patients having secondary education being easier to recruit. A statistician was consulted to establish how to stratify and randomly allocate patients and, using an online computer program (Research Randomizer-Version 4.0), a list of random allocations was generated.

Table 6.1: Demographic parameters for the study population n (%) at baseline and follow-up

Demographic parameter	Baseline				Follow-up				p-value[b]
	Control (n=60)	Experimental (n=60)	p-value[a]	Total (n=120)	Control (n=59)	Experimental (n=53)	p-value[a]	Total (n=112)	
Gender									
Male	35 (58.3)	37 (61.7)	0.709	72 (60.0)	34 (57.6)	34 (64.2)	0.406	68 (60.7)	0.912
Female	25 (41.7)	23 (38.3)		48 (40.0)	25 (42.3)	19 (35.8)		44 (39.3)	
Age (years)									
18-29	17 (28.3)	25 (41.7)	0.184	42 (35.0)	17 (28.8)	23 (43.4)	0.476	40 (35.7)	0.904
30-44	31 (51.7)	20 (33.3)		51 (42.5)	30 (50.8)	17 (32.1)		47 (42.0)	
45-59	8 (13.3)	12 (20.0)		20 (16.7)	8 (13.6)	11 (20.7)		19 (17.0)	
≥ 60	4 (6.7)	3 (5.0)		7 (5.8)	4 (6.8)	2 (3.8)		6 (5.3)	
Race									
Black	30 (50.0)	35 (58.3)	0.360	65 (54.2)	29 (49.2)	31 (58.5)	0.372	60 (53.6)	0.991
Coloured	30 (50.0)	25 (41.7)		55 (45.8)	30 (50.8)	22 (41.5)		52 (46.4)	
White	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	
Asian	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	
Home language									
isiXhosa	8 (13.3)	16 (26.7)	0.124	24 (20.0)	8 (13.6)	15 (28.3)	0.052	23 (20.5)	0.956
Afrikaans	52 (86.7)	44 (73.3)		96 (80.0)	51 (86.4)	38 (71.7)		89 (79.5)	
English	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	
Education									
≤ Grade 7	26 (43.3)	26 (43.3)	1.000	52 (43.3)	25 (42.4)	22 (41.5)	0.843	47 (42.0)	0.861
Grade 8-10	34 (56.7)	34 (56.7)		68 (56.7)	34 (57.6)	31 (58.5)		65 (58.0)	
Employment									
Yes	9 (15.0)	14 (23.3)	0.165	23 (19.2)	9 (15.3)	13 (24.5)	0.091	22 (19.6)	0.924
No	51 (85.0)	44 (73.4)		95 (79.2)	50 (84.7)	38 (71.7)		88 (78.6)	
Scholar	0 (0.0)	2 (3.3)		2 (1.6)	0 (0.0)	2 (3.8)		2 (1.8)	

[a] Significance of difference ($p<0.05$) between the control and the experimental group
[b] Significance of difference ($p<0.05$) between baseline versus follow-up

6.2.2 Socio-economic characteristics and access to healthcare

Just over half of the patients (56.7%) reported having less than five residents per household while the remaining 52 patients (43.3%) had more than six (Table 6.2), with the average house in the area having about two to three rooms in total. Limited living space and overcrowding are major issues, especially when patients are still infective and this is often the case when patients have not taken their prescribed TB medicines for more than two weeks or are nonadherent in different ways. A total of 32 patients (26.7%) indicated that there was another individual staying at their home that was currently diagnosed with TB and was also taking TB medicines.

Table 6.2: Socio-economic characteristics and access to healthcare

Parameter	Control (n=60)	Experimental (n=60)	p-value	Total (n=120)
Number of people living in the house				
1-5	33 (55.0)	35 (58.3)	0.924	68 (56.7)
6-10	24 (40.0)	21 (35.0)		45 (37.5)
>10	3 (5.0)	4 (6.7)		7 (5.8)
Others in house with TB				
Yes	22 (36.7)	10 (16.7)	0.013[a]	32 (26.7)
Building material for the house				
Brick or cement	43 (71.7)	45 (75.0)	0.680	88 (73.3)
Built shack	17 (28.3)	15 (25.0)		32 (26.7)
Running water in house				
Yes	52 (86.7)	56 (93.3)	0.224	108 (90.0)
No	8 (13.3)	4 (6.7)		12 (10.0)
Electricity in house				
Yes	51 (85.0)	54 (90.0)	0.408	105 (87.5)
No	9 (15.0)	6 (10.0)		15 (12.5)
Hospital admission[b]				
Yes	31 (51.7)	26 (43.3)	0.361	57 (47.5)
No	29 (48.3)	34 (56.7)		63 (52.5)
Availability of TB medicines				
Available	55 (91.7)	58 (96.7)	0.243	113 (94.2)
Out of stock	5 (8.3)	2 (3.3)		7 (5.8)

[a] Significant difference ($p<0.05$) between experimental and control group

[b] Hospital admissions for any health-related problem; patients were asked to specify

There were no significant differences observed for most parameters. However, the control group had a significantly larger number of individuals diagnosed with TB staying at their house ($p=0.013$). Measures were taken to ensure that only one TB patient per household participated in the study. This was done to eliminate the possibility of exposing the control group to the experimental PIL.

Most of the patients (73.3%) indicated that their homes were constructed of brick and just over a quarter lived in informal housing which comprised of a built shack. The majority of households had running water (90.0%) and electricity (87.5%).

Almost half of the patients had been admitted to hospital, with the most common reasons for admission being injuries caused by assault and TB. Only 7 patients (5.8%) indicated that there were instances when the clinic could not supply them with their TB medicines. Relative to other public health clinics this is low but it is still concerning that TB treatment could be disrupted in just under 1 in 20 cases.

6.2.3 Opinions on TB prevalence and stigma

Patients were asked to comment on how people in their family and those in their community treat people with TB. Only six patients (5%) indicated that their family members ignored or rejected individuals known to have TB, and this number doubled to 12 when commenting on the behaviour of community members.

The majority (95.8%) knew that anyone could get TB with the remaining five patients (4.2%) suggesting that TB only occurs if you are a smoker or during childhood. Most patients (85.0%) acknowledged that TB was a problem in South Africa and affected a lot of people, and 113 patients (94.2%) agreed that TB could result in death. A total of 43 patients (35.8%) were HIV positive. Only one patient (0.8%) mentioned that community members reject TB patients because they associate them with having HIV/AIDS.

6.3 Health and medicine literacy

Patients were given the option to read the MLT label in Afrikaans, isiXhosa or English (Appendix D1-D3). Most chose to read the Afrikaans label (80%), followed by isiXhosa (15%) and English (5%). There were no significant differences in label language preference between the groups ($p=0.196$).

Table 6.3: Frequency of correct responses to MLT questions

MLT questions	Control (n=60)	Experimental (n=60)	Total (n=120)
1. How many tablets must be taken each time?	48 (80.0)	48 (80.0)	96 (80.0)
2. Do you have to take this medicine after eating a meal?	38 (63.3)	32 (53.3)	70 (58.3)
3. What should you take this medicine with?	52 (86.7)	51 (85.0)	103 (85.8)
4. For how many days would you take this medicine?	15 (25.0)	5 (8.3)	20 (16.7)[a]
5. If you take this medicine at 7pm (in the night), what times (before and after 7pm) will it be okay to drink some milk?	18 (30.0)	19 (31.7)	37 (30.8)
6. Would you keep any of this medicine to use if you got sick again?	44 (73.3)	41 (68.3)	85 (70.8)
7. How might this medicine make you feel, especially if you take it with alcohol?	44 (73.3)	43 (71.7)	87 (72.5)
8. How should this medicine be stored?	43 (71.7)	47 (78.3)	90 (75.0)

[a] Significant difference ($p<0.05$) between experimental and control group

Table 6.3 displays the frequency of correct responses to each of the questions included in the MLT. It was evident that patients had the greatest difficulty in answering the two numeracy questions as only 20 (16.7%) got question 4 correct and 37 (30.8%) got question 5 correct. In contrast questions 1 and 3 that asked about basic instructions on how to administer the medicine were well answered, with respective scores of 80% and 85.8%. When the mean score for the two numeracy questions was calculated, no significant inter-group difference ($p=0.168$) was observed. Internal consistency of the MLT was determined using Cronbach's alpha and the coefficient obtained was 0.75.

In the MLT validation study, the percentage of participants with the correct response to several of the questions (specifically question 2, 5, 6 and 8) was much lower than that obtained in the RCT. This difference could be attributed to the fact that the MLT validation study population comprised of community members supported by healthcare workers with minimal training in patient education and counselling. In contrast, the RCT study included TB patients attending a USAID-affiliated high burden clinic that provides health provider training that promotes patient counselling and support.

The mean literacy rating out of 8 for all 120 patients was 4.90 ± 2.07, and the percentage was 61.3% (Table 6.4). No significant difference was observed between the groups ($p=0.483$). Just under half (46.7%) were classified as having adequate medicine literacy, a third (33.3%) had marginal medicine literacy and a fifth (20.0%) had inadequate medicine literacy. There

was no significant difference in rating categories between the control and experimental groups (p=0.254).

Table 6.4: Mean literacy score for the MLT and medicine literacy categories

	Control (n=60)	Experimental (n=60)	Total (n=120)	p-value[a]
Literacy score				
Mean ± SD[b]	5.03 ±2.17	4.77 ± 1.98	4.90 ± 2.07	0.483
Score %	62.9	59.6	61.3	
Medicine literacy categories				
Inadequate medicine literacy (0-3)	12 (20.0)	12 (20.0)	24 (20.0)	
Marginal medicine literacy (4-5)	16 (26.7)	24 (40.0)	40 (33.3)	0.254
Adequate medicine literacy (6-8)	32 (53.3)	24 (40.0)	56 (46.7)	

[a] Significance of difference (p<0.05) between experimental and control group

[b] Maximum score = 8

No gender effect on MLT score was seen in either group. Age only showed a significant effect when control and experimental group data were combined with patients between 30-44 years having a significantly greater MLT score in comparison to those aged 60 and above. A one-way ANOVA testing the effect of education on MLT score indicated that education does have a significant effect on the MLT score (p<0.001). This trend was also noted when data were analysed for the separate groups (control p=0.011; experimental p=0.004). In both groups, patients with less than a Grade 4 education had a significantly lower MLT score than patients in other two education categories.

The SILS is used as a quick method to screen if patients need help when engaging with written information about their health and medicines. The results obtained for this literacy screening test are present in Figure 6.2. The majority (55%) declared that they never need help when reading WMI from the clinic with the remaining (45%) indicating that they needed varying degrees of assistance with the written health information provided at the clinic.

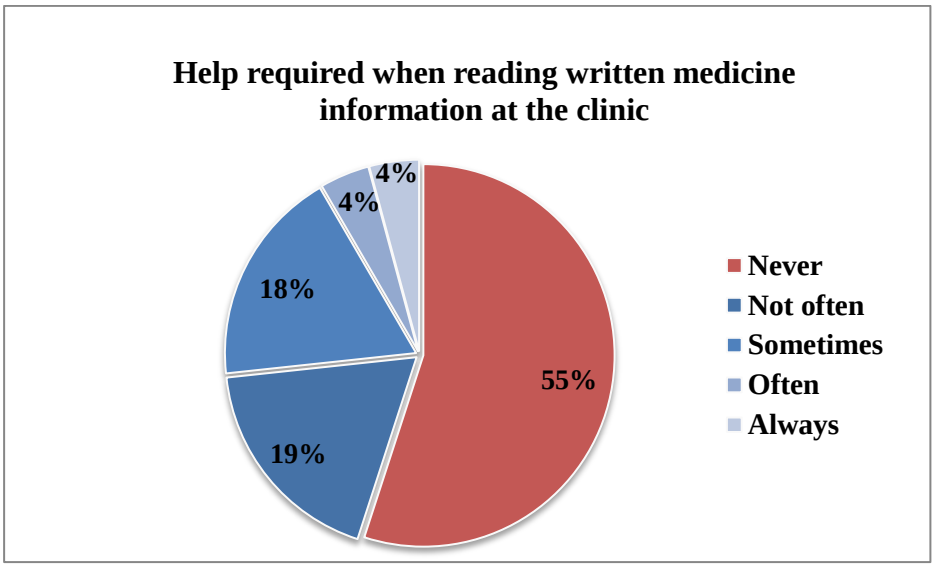


Figure 6.2: Results obtained for the SILS

A significant correlation was observed between MLT score and SILS response ($p<0.001$). Post-hoc tests revealed that patients who indicated "never" or "not often" in response to the SILS question, had a higher MLT score in comparison to those who indicated "sometimes" ($p<0.001$) in addition to "often" or "always" ($p<0.001$).

6.4 Impact of PIL on knowledge

Patients in the experimental group were given the choice of an Afrikaans, isiXhosa or English version of the PIL. The majority (71.7%) chose the Afrikaans PIL, followed by isiXhosa (18.3%) and English (10%). A brief counselling session using the experimental PIL as a tool took under two minutes. Patients were encouraged to take the PIL home and read it but were not allowed to refer to it for the follow-up knowledge test.

6.4.1 Individual knowledge questions

The 24-item knowledge test was divided into five broad knowledge areas: disease, TB medicine-taking, side effects, MDR/XDR-TB and HIV and TB co-infection. At baseline, there were only three questions with a significant difference observed between the control and experimental groups (Table 6.5). In contrast, at follow-up there were statistically significant differences noted between the two groups for 13 of the 24 questions. The control group only

showed a significant intra-group increase from baseline to follow-up for one question while this was observed for 17 questions in the experimental group.

6.4.1.1 Disease

When designing the questionnaire, the first question asked was an easy one to allow patients to gain confidence and relax into answering the questions that would follow. The majority knew that TB could be cured with medication. At baseline, all patients in the control group (100%) answered the two questions about curing TB correctly.

The most common baseline response from both groups to the causative TB agent was that it was due to a virus as opposed to a bacterium. At the follow-up interview, 38 patients (71.7%) in the experimental group got this question correct, significantly more than the control group (29 patients; 49.2%; p=0.015).

6.4.1.2 TB medicine-taking

This category had the most questions, largely because the PIL intervention primarily targeted patient knowledge about their TB medicines. At baseline, there were no significant differences between groups for the individual knowledge questions in this category, except for one question where patients in the control group had significantly greater knowledge about what to do if they were taking other medicines and TB medicines at the same time.

Specific gaps in knowledge that were identified included: name of TB medicines, information to tell the HCP, implications of nonadherence to TB medicines, measures taken to alleviate difficulty in swallowing large tablets and steps to follow when an individual forgets to take TB treatment.

Table 6.5: Frequency of correct responses to individual questions in the 24-item knowledge test

Questions	Baseline			Follow-up		
	Control (n=60)	Experimental (n=60)	p-value	Control (n=59)	Experimental (n=53)	p-value
Disease						
Can TB be cured?	60 (100.0)	58 (96.7)	0.154	60 (100.0)	52 (98.1)	0.289
How can person with TB get better?	60 (100.0)	56 (93.3)	0.042[a]	60 (100.0)	60 (100.0)	1.000
What causes TB?	25 (41.7)	28 (46.7)	0.581	29 (49.2)	38 (71.7)[b]	0.015[a]
TB medicine-taking						
How long do you have to take TB treatment?	52 (86.7)	52 (86.7)	1.000	54 (91.5)	50 (94.3)	0.564
Name/s of TB medicines	5 (8.3)	3 (5.0)	0.464	6 (10.2)	19 (35.8)[b]	0.001[a]
Information to tell the doctor before you start TB treatment	13 (21.7)	10 (16.7)	0.487	7 (11.9)	37 (69.8)[b]	<0.001[a]
What to do if you are taking other medicines and TB medicines	43 (71.7)	38 (63.3)	<0.001[a]	46 (78.0)	60 (100.0)[b]	<0.001[a]
Implication of non-adherence: MDR and XDR-TB	23 (38.3)	25 (41.7)	0.709	19 (32.2)	49 (92.5)[b]	<0.001[a]
TB medicines and food	54 (90.0)	53 (88.3)	0.769	53 (89.8)	47 (88.7)	0.844
Alcohol and smoking when taking TB treatment	53 (88.3)	54 (90.0)	0.769	57 (96.6)	52 (98.1)	0.623
Difficulty swallowing	35 (58.3)	30 (50.0)	0.360	40 (67.8)	50 (94.3)[b]	<0.001[a]
Forget to take TB medicines	38 (63.3)	38 (63.3)	1.000	44 (74.6)	52 (98.1)[b]	<0.001[a]
Sharing medicines	52 (86.7)	53 (88.3)	0.783	50 (84.7)	60 (100.0)[b]	0.003[a]
Stop taking TB medicines	58 (96.7)	55 (93.2)	0.390	57 (96.6)	52 (98.1)	0.623
Side effects						
Awareness about what side effects are	47 (78.3)	44 (73.3)	0.522	45 (76.3)	46 (86.8)	0.154
Side effects of TB medicines	12 (20.0)	9 (15.0)	0.471	15 (25.4)	34 (64.2)[b]	<0.001[a]
What to do if you have a side effect	43 (71.7)	48 (80.0)	0.286	54 (91.5)[b]	51 (96.2)[b]	0.305
MDR/XDR-TB						
What is MDR and XDR-TB?	14 (23.3)	10 (16.7)	0.361	12 (20.3)	27 (50.9)[b]	<0.001[a]
Stronger type of TB if you do not take your medicines	56 (93.3)	48 (80.0)	0.032[a]	55 (93.2)	52 (98.1)[b]	0.211
Is MDR or XDR-TB curable?	34 (56.7)	27 (45.0)	0.201	41 (69.5)	49 (92.5)[b]	0.002[a]
Same treatment for TB and drug-resistant TB	31 (51.7)	21 (35.0)	0.065	33 (55.9)	44 (83.0)[b]	0.002[a]
How long would it take to cure MDR or XDR-TB?	12 (20.0)	7 (11.7)	0.211	15 (25.4)	31 (58.5)[b]	<0.001[a]
TB and HIV						
Does everyone with TB have HIV?	50 (83.3)	41 (68.3)	0.055	52 (88.1)	47 (88.7)[b]	0.929
Can TB be cured if you have HIV?	49 (81.7)	45 (75.0)	0.375	53 (89.8)	49 (92.5)[b]	0.627

[a] Significant difference ($p<0.05$) between the control and the experimental group

[b] Significant difference ($p<0.05$) between baseline versus follow-up

For the question asking the names of their TB medicines, patients could either give the generic names of the four medicines (rifampicin, isoniazid, pyrazinamide and ethambutol) or the commonly used trade name (Rifafour®, Ritib® or Rifinah®). Only one patient was able to state the generic names of their medicines and the remaining seven patients provided the relevant trade name. At follow-up, significantly more patients in the experimental group were able to name their medicines.

During a consultation, patients should ideally engage with their HCP and provide them with important information including their current health status, medical history, allergies, HIV status and past TB infections. At baseline, only 13 (control) and ten (experimental) patients could identify at least two of these key aspects; however at follow-up this increased significantly in the experimental group ($p<0.001$).

Patients were asked "What serious problem (other than feeling very sick and possible death) could occur if someone does not take their TB medicines as they are supposed to"? Only 38.3% (control) and 41.7% (experimental) were initially able to specify that nonadherence to TB medicines could potentially lead to drug-resistant TB. After counselling using the PIL, a significant increase to 92.5% was observed in the experimental group ($p<0.001$).

Approximately half of this cohort of 120 patients knew what to do if they encountered difficulties swallowing the large FDC tablets. However, this lack of knowledge may be attributed to the fact that most patients stated that they were able to swallow the tablets and as a result were unaware of the measures that could be taken to size reduce and administer the tablets with food, water or juice. In the experimental group this increased from 50.0% at baseline to 94.3% at follow-up ($p<0.001$).

Particularly concerning was the fact that less than 65% of patients knew what to do if they forgot to take their TB medicines, with many patients indicating that they would skip the dose and take a double dose the next day. At follow-up, knowledge on the correct steps to follow increased significantly in the experimental group with 98.1% reporting that if they forgot to take their TB medicines, they would take it as soon as they remembered.

There were a few questions that were well answered by both groups. Most patients knew the duration of TB treatment and not to stop taking it before being told to do so. Additionally, the majority knew that they should not drink alcohol or smoke cigarettes when on TB treatment. Most patients were aware that TB medicines can be taken on either an empty stomach or with food, and that they should not share their TB medicines. However, it is still of concern that just under 15% in each group indicated at the baseline interview that they would share their medicines with a neighbour whose TB medicines were finished.

6.4.1.3 Side effects

In Chapter 3, it was reported that local patients know very little about their medicines, including side effects, thus a question was included in the RCT questionnaire to determine if study participants knew what a side effect was before we investigated their knowledge about possible side effects of TB medicines and what to do in the event that they experienced a side effect. At baseline, 78.3% in the control group and 73.3% in the experimental group knew that administering a medicine could have some negative effect on the body; after the intervention, a larger percentage (86.8%) of the patients in the experimental group understood the concept of a side effect.

Baseline knowledge revealed that 71.7% (control) and 80.0% (experimental) patients knew that they should report any side effects to the HCP at the clinic. This improved significantly in both groups at follow-up to 91.5 % (control) and 96.2% (experimental).

Despite more than three quarters of the patients in both groups knowing what side effects are and what they should do when they encounter a side effect, only 20% in the control group and 15% in the experimental group could identify four or more side effects of TB medicines, and these were identified based on their personal experiences of side effects. One mark was allocated only if they were able to specify at least four of the total 14 correct side effects of TB medicines.

6.4.1.4 MDR/XDR-TB

Only one significant inter-group difference was noted at baseline for the five questions pertaining to MDR/XDR-TB. Additionally, only 20.0% could explain what MDR/XDR-TB is, and only just over half (50.8%) knew that these could be cured. At the follow-up interview, knowledge doubled in the experimental group from 45.0% to 92.5%, whereas only a minimal increase was seen in the control group who were not counselled using the illustrated PIL.

It was not generally known that the medicines used to treat MDR/XDR-TB were not the same as standard first-line TB medicines (43.3%) and that the duration of treatment of MDR/XDR-TB was much longer than 6 months (15.8%).

At the follow-up interview, knowledge was significantly higher in the experimental group for four of the five questions, with minimal increase seen in the control group. However, knowledge increased significantly within the experimental group for all five questions.

6.4.1.5 TB and HIV

In Chapter 3, TB patients reported that there is a certain stigma attached to having TB, whereby a patient with TB inevitably has HIV/AIDS. Thus, two questions relating to TB and HIV were included in the questionnaire and addressed in the PIL. In the control group, there was a minor increase from a baseline 83.3% to 88.1% at follow-up, whereas in the experimental group the increase in knowledge was much greater and was significant, increasing from 68.3% to 88.7% ($p=0.022$).

In response to the question "Can TB be cured if you have HIV?", 78.3% of patients gave the correct answer. However, at follow-up, the experimental group again displayed a significant increase, from 75.0% to 92.5% ($p=0.022$), whereas the control group only showed an increase of 8%.

6.4.2 Mean TB knowledge scores

Table 6.6 shows that, at baseline, there was no significant difference in the overall mean percentage knowledge score between the control and experimental groups (p=0.074), although the control results did tend to be higher. At follow-up, the percentage knowledge score for the experimental group increased significantly from 59.0% to 84.6% (p<0.001) and showed a significantly higher score than the control group (p<0.001), displaying evidence of the impact of the PIL as a counselling tool on patient knowledge.

Table 6.6: Mean score for knowledge areas

Category	Baseline			Follow-up		
	Control (n=60)	**Experimental (n=60)**	**p-value**	**Control (n=59)**	**Experimental (n=53)**	**p-value**
Disease	81.0	78.9	0.623	83.1	89.9[a]	0.027[b]
Medicine-taking	64.5	62.4	0.407	66.7	88.2[a]	< 0.001[b]
Side effects	56.7	56.1	0.915	64.4	82.4[a]	< 0.001[b]
MDR/XDR-TB	49.0	37.7	0.029[b]	52.9	76.6[a]	< 0.001[b]
HIV and TB	82.5	71.7	0.077	89.0	90.6[a]	0.723
Overall mean % knowledge	63.8	59.0	0.074	67.5	84.6	<0.001[b]
Overall mean ± SD	15.4 ± 15.2	14.3 ± 13.8		16.2 ± 12.1	20.4 ± 10.6	

[a]Significant difference (p<0.05) between baseline versus follow-up
[b] Significant difference (p<0.05) between experimental and control group

At baseline, no significant differences in mean percentage knowledge were found in four of the five knowledge areas, apart from the MDR/XDR-TB category, where the control group had a significantly higher score in comparison to the experimental group (p=0.029).

The three knowledge categories that were poorly answered with results less than 65% were medicine-taking, side effects and MDR/XDR-TB. There were significant improvements in these categories within the experimental group at follow-up, with results ranging between 76.6% and 88.2% (all with p<0.001). At follow-up, the only knowledge category for which the experimental group showed no significant difference to the control group was HIV and TB co-infection. However, the intra-group increase from 71.7% to 90.6% was significant (p<0.001), whereas within the control group a mere 6.5% increase was seen (p=0.117).

6.4.3 Classification of overall knowledge scores

Individual knowledge scores were grouped into four categories as seen in Table 6.7. At baseline, only one patient in the control group and none in the experimental group achieved an excellent knowledge score. Most patients fell within the moderate and poor knowledge categories and overall there was no significant difference between the groups (p=0.308).

Overall, at follow-up there was a significant difference in distribution into the four categories between the groups (p<0.001), with over 70% of the experimental group achieving a good or excellent rating at follow-up, compared with only 5.0% of this group at baseline and 13.6% of the control group. Between the baseline and follow-up interview, both groups had a decrease in number of patients in the poor knowledge category.

Table 6.7: Categories of knowledge scores at baseline and follow-up

Knowledge score	Baseline			Follow-up		
	Control (n=60)	Experimental (n=60)	p-value	Control (n=59)	Experimental (n=53)	p-value
Excellent (≥95%)	1 (1.7)	0 (0.0)	0.308	1 (1.7)	13 (24.5)	<0.001[a]
Good (80-94%)	7 (11.7)	3 (5.0)		7 (11.9)	25 (47.2)	
Moderate (50-79%)	42 (70.0)	42 (70.0)		48 (81.4)	15 (28.3)	
Poor (<50%)	10 (16.7)	15 (25.0)		3 (5.1)	0 (0.0)	

[a]Significant difference (p<0.05) between experimental and control group

The control group did not show a significant intra-group change from baseline to follow-up (p=0.094) whereas this was observed for the experimental group (p<0.001). At baseline only 3 patients in the experimental group achieved a score ≥ 80% and at follow-up this number increased to 38 patients. In contrast, only 8 patients in the control group achieved this score and this remained the same at the follow-up interview.

6.4.4 Gender, age and education effect on knowledge

There was no gender effect on knowledge score at either baseline or follow-up. No age-related effect on both the total knowledge score and individual questions was found in either the control or the experimental group at baseline and follow-up (Table 6.8). Although the lowest mean knowledge score occurred in patients ≥60 years old, this difference was not significant at baseline or follow-up in either group.

Table 6.8: Mean knowledge score ± SD (%) in each age category

Age group (years)	Control		Experimental	
	Baseline (n=60)	Follow-up (n=59)	Baseline (n=60)	Follow-up (n=53)
18-29	59.8 ± 13.4	63.0 ± 8.2	58.3 ± 13.4	87.3 ± 9.3
30-44	66.7 ± 15.1	72.1 ± 11.8	60.6 ± 14.5	84.3 ± 11.2
45-59	64.6 ± 19.2	63.5 ± 16.3	59.0 ± 11.8	83.3 ± 11.2
≥60	56.3 ± 15.4	59.4 ± 8.6	54.2 ± 15.0	70.8 ± 10.6
p-value[a]	0.361	0.221	0.866	0.171

[a]Significance of age effect ($p<0.05$) on knowledge score

Table 6.9 shows the mean percentage knowledge score in each education category. Surprisingly, at baseline, patients with ≤ Grade 4 education had a higher mean percentage knowledge score than those with a Grade 5-7 education. This same trend was observed at follow-up only in the control group.

Table 6.9: Mean knowledge score ± SD (%) in each education category

Education	Control		Experimental	
	Baseline (n=60)	Follow-up (n=59)	Baseline (n=60)	Follow-up (n=53)
≤ Grade 4	61.8 ± 19.6	70.8 ± 14.9	60.4 ± 15.1	78.3 ± 12.6
Grade 5-7	57.1 ± 14.2	64.7 ± 11.0	54.4 ± 12.5	83.1 ± 9.4
Grade 8-10	68.0 ± 15.3	68.4 ± 12.4	61.5 ± 13.3	87.0 ± 10.6
p-value[a]	0.035[a]	0.447	0.158	0.167

[a]Significance of education effect ($p<0.05$) on knowledge score

Post-hoc tests revealed that in the control group at baseline, those with a Grade 8-10 education had a significantly higher knowledge score than patients with a Grade 5-7 education. Experimental patients at follow-up showed an increasing trend in knowledge as education increased, although this was not significant.

6.5 Impact of PIL on self-efficacy

Patient self-efficacy was assessed using the TB-ASES with a 1-5 Likert scale (described in section 4.5.2). At baseline, the only question that showed a significant difference between the control and experimental group was question 3, for which the control group reported greater confidence in their ability to avoid alcohol when taking medicine (Table 6.10). Smoking is another social habit that affects TB treatment and it was apparent that the experimental group had a lower level of confidence in avoiding smoking when on treatment as this was the only

question with a self-efficacy score below 4. No significant difference was observed between the control and experimental group for this question.

Question 1 asked patients to comment on their level of confidence in taking their medicines every single day. At the follow-up interview, all patients reported being extremely confident about this task (a perfect score of 5). Generally, there were no significant differences observed between the control and experimental groups for individual items in the TB-ASES at the follow-up interview.

From baseline to follow-up, the experimental group showed a significant intra-group increase in self-efficacy for four out of the nine questions (question 1, 2, 4, and 8) while for the control group a significant increase was only seen for question 4.

The mean overall self-efficacy scores ranged from 4.53 – 4.78, indicating a high degree of perceived self-efficacy. Despite the control group having a greater self-efficacy score at baseline, there was no significant difference between the groups after the intervention. However, self-efficacy increased significantly within the experimental group from baseline to follow-up ($p=0.002$).

Table 6.10: Mean score (± SD) for individual questions in the TB-ASES

TB-ASES questions	Baseline			Follow-up		
	Control (n=60)	Experimental (n=60)	p-value[a]	Control (n=59)	Experimental (n=53)	p-value[a]
1. How confident do you feel that you can take your TB medicines every single day?	4.90 ± 0.44	4.78 ± 0.61	0.234	5.00 ± 0.00	5.00 ± 0.00[b]	1.000
2. How confident do you feel that you will be able to come to the clinic to collect your TB medicines every month?	4.83 ± 0.59	4.75 ± 0.70	0.483	4.92 ± 0.38	4.96 ± 0.27[b]	0.455
3. How confident do you feel that you can avoid alcohol when taking TB treatment?	4.52 ± 1.07	4.03 ± 1.44	0.039[a]	4.49 ± 1.14	4.28 ± 1.23	0.355
4. How confident do you feel that you can talk to your doctor/nurse/pharmacist about your TB medicines?	4.57 ± 0.89	4.40 ± 0.96	0.326	4.90 ± 0.44[b]	4.83 ± 0.64 [b]	0.520
5. How confident do you feel that you can take your TB medicines even if they make you feel a bit sick?	4.87 ± 0.43	4.70 ± 0.70	0.118	4.93 ± 0.37	4.85 ± 0.50	0.319
6. How confident do you feel that you can take your TB medicines in front of other people who do not know you have TB?	4.65 ± 1.02	4.68 ± 0.87	0.848	4.80 ± 0.61	4.49 ± 1.01	0.059
7. How confident do you feel that you can avoid smoking whilst taking TB treatment?	4.10 ± 1.27	3.75 ± 1.50	0.171	4.08 ± 1.30	4.08 ± 1.17	0.968
8. How confident do you feel that you can take your TB medicines even if you feel better and no longer have a cough?	4.87 ± 0.47	4.73 ± 0.71	0.227	4.92 ± 0.47	4.92 ± 0.27[b]	0.896
9. How confident do you feel that taking the TB medicines will make you get better?	4.97 ± 0.26	4.90 ± 0.40	0.280	4.98 ± 0.13	4.92 ± 0.43	0.347
Mean overall self-efficacy score	4.70 ± 0.33	4.53 ± 0.46	0.022[a]	4.78 ± 0.27	4.70 ± 0.26 [b]	0.133

[a]Significance of difference ($p<0.05$) between experimental and control group

[b]Significance of difference ($p<0.05$) between baseline versus follow-up

The influence of demographic variables on self-efficacy was investigated but no significant associations were found for gender, age or education (Table 6.11).

Table 6.11: Effect of gender, age and education on self-efficacy

Demographic variables	p-values[a]			
	Control		Experimental	
	Baseline (n=60)	Follow-up (n=59)	Baseline (n=60)	Follow-up (n=53)
Gender	0.414	0.086	0.247	0.444
Age	0.811	0.555	0.425	0.788
Education	0.860	0.419	0.621	0.678

[a]Significance of influence ($p<0.05$) of various demographic variables on self-efficacy

6.6 Impact of PIL on adherence

Self-reported adherence was assessed using a modified version of the MMAS-8 and the results obtained are presented in Table 6.12. At baseline, no significant differences were noted between the control and experimental groups except for question 8 ($p=0.035$) which asked if patients felt bored or irritated because they had to take TB medicines every single day. Approximately 30% in both the control and the experimental groups indicated at the baseline interview that over the last month there were days when they had not taken their TB medicines. Most patients reported having taken their medicines the previous day. Many also stated that they had continued to take their treatment despite feeling healthy. Although many could not name the side effects of TB medicines, the majority indicated that they had continued to take their TB medicines as instructed by the doctor even when encountering side effects.

Table 6.12: Frequency of adherent patients to 8-items n (%) and overall mean adherence score (out of 8)

Adherence assessment (8-items)	Baseline			Follow-up		
	Control (n=60)	Experimental (n=60)	p-value	Control (n=59)	Experimental (n=53)	p-value
1. Do you sometimes forget to take your TB medicines?	48 (80.0)	50 (83.3)	0.637	44 (74.6)	43 (81.1)	0.405
2. Sometimes people may not forget to take their medicines but miss taking it for other reasons. Over the past month (since your last clinic visit) were there any days when you did not take your TB medicines?	43 (71.7)	43 (71.7)	1.000	41 (69.5)	37 (69.8)	0.971
3. Have you ever reduced or stopped taking your TB medication without telling your doctor, because you felt worse when you took it?	59 (98.3)	56 (93.3)	0.171	58 (98.3)	52 (98.1)	0.939
4. When you travel or leave home, do you sometimes forget to bring along your TB medicines?	51 (85.0)	56 (93.3)	0.142	56 (94.9)	50 (94.3)	0.893
5. Did you take your TB medicines yesterday?	58 (96.7)	59 (98.3)	0.559	56 (94.9)	50 (94.3)	0.893
6. When you feel healthy, do you sometimes stop taking your TB medicines before the end of the 6 months?	56 (93.3)	58 (96.7)	0.402	58 (98.3)	53 (100.0)	0.341
7. During the last weekend, did you miss taking any of your TB medicines?	56 (93.3)	54 (90.0)	0.509	57 (96.6)	52 (98.1)	0.623
8. Some people find having to take TB medicines everyday tiresome. Do you ever feel irritated or get cross about taking your TB medicines every day?	40 (66.7)	50 (83.3)	0.035[a]	45 (76.3)	46 (86.6)	0.154
Mean overall adherence score ± SD[b]	6.9 ± 1.29	7.1 ± 1.15	0.263	7.0 ± 1.31	7.2 ± 1.07	0.400

[a]Significant difference ($p<0.05$) between control and experimental group

[b]Mean adherence score interpretation: 8 (high adherence), 6-<8 (moderate adherence), <6 (low adherence)

At follow-up, no significant differences were noted in self-reported adherence between the groups. However, there were several (non-significant) decreases in the percentage of positive (desirable) responses, possibly attributable to the fact that patients were now more comfortable in acknowledging any negative medicine-taking behaviour. No intra-group differences were observed from baseline to follow-up for the individual items included in the adherence test.

For both groups at baseline, a moderate significant association between self-efficacy and adherence was observed (control: r=0.470, p=<0.001; experimental: r=0.471, p=<0.001) however this correlation between the two medicine-taking behaviours was not significant at the follow-up interview.

The association of demographic variables on adherence scores was determined; as for self-efficacy, no significant gender, age or education effect was found at either baseline or follow-up in either group (Table 6.13).

Table 6.13: Effect of gender, age and education on adherence

Demographic variables	p-values[a]			
	Control		Experimental	
	Baseline (n=60)	Follow-up (n=59)	Baseline (n=60)	Follow-up (n=53)
Gender	0.141	0.178	0.763	0.431
Age	0.069	0.598	0.521	0.538
Education	0.450	0.063	0.505	0.438

[a]Significance of influence (p<0.05) of various demographic variables on adherence

Mean overall adherence scores indicated a generally moderate adherence (6 - <8), with no significant difference noted between the groups at either interview.

6.7 Correlation between knowledge and various parameters

Pearson's correlation coefficient was used to determine if there were any statistically significant correlations between the TB knowledge score and medicine literacy, self-efficacy and adherence (Table 6.14). The results obtained were interpreted using the guidelines proposed by Taylor [391] in a basic review on the interpretation of the correlation coefficient.

There was a moderate, positive and significant correlation noted between the MLT score and baseline knowledge in both control and experimental groups, indicating that an increase in medicine literacy is moderately correlated with positive linear increase in TB knowledge. At follow-up, significance was established only for the experimental group.

Table 6.14: Correlation between knowledge score and other scores

Scores	Control		Experimental	
	Baseline (n=60)	**Follow-up (n=59)**	**Baseline (n=60)**	**Follow-up (n=53)**
MLT score	r=0.418	r=0.251	r=0.433	r=0.417
	p=0.001[a]	p=0.055	p=0.001[a]	p<0.001[a]
Self-efficacy score	r=0.416	r=0.191	r=0.142	r=-0.054
	p=0.001[a]	p=0.147	p=0.279	p=0.700
Adherence score	r=0.286	r=0.079	r=0.04	r=0.010
	p=0.026[a]	p=0.550	p=0.916	p=0.941

[a]Significant influence($p<0.05$) of knowledge score on specific parameter

The correlation of the knowledge score with the two medicine-taking behaviours of self-efficacy and adherence varied between groups and interview times. A significant and moderate correlation of knowledge with self-efficacy was established only for the control group at baseline, when there was also a significant but weak correlation with adherence. All other correlations were not significant.

A significant correlation was also observed between SILS response and baseline TB knowledge ($p=0.023$). Patients who indicated “never” or “not often” tended to have a higher knowledge score at baseline than those who “often” or “always” needed help reading health information supplied at clinics ($p=0.031$).

6.8 Acceptability and usefulness of PIL

Patients in the experimental group were asked to comment on the acceptability and usefulness of the take-home PIL. Almost all patients indicated that they had used the PIL over the last month and that it definitely helped to enhance their TB medicine-related knowledge (Table 6.15). Just over three quarters of the patients indicated that family members and friends read the PIL and wanted their own personal copy.

Table 6.15: Acceptability and usefulness of the PIL (experimental group only)

Question	Experimental (n=53)
Usefulness	
Used the PIL in the last month	49 (92.5)
PIL helped enhance TB medicine-related knowledge	52 (98.1)
Family members or friends read the PIL	41 (77.4)
Family member or friend wanted their own copy of the PIL	41 (77.4)
Information in the PIL was helpful and no unnecessary information included	43 (81.1)
Most useful information in the PIL	
Lung sequence	23 (43.4)
Why to take TB treatment	12 (22.6)
MDR/XDR-TB	10 (18.9)
Side effects	3 (5.7)
Taking TB medicine with or without food	3 (5.7)
Least useful information in the PIL	
Crushing tablet sequence	5 (9.4)
Side effects	3 (5.7)
Text	
Certain words in PIL not understood by patient	5 (9.4)
Pictograms	
Like having pictures on the PIL	53 (100.0)
Pictures enhance understanding and recall of medicine information	53 (100.0)

The most useful information in the PIL, identified by 23 patients, was the lung sequence that illustrated the need to take TB medicines for the full duration and the effect it had on the clearing of the lungs. Several patients commented that they would have liked this information at an earlier stage as they had been infected with TB several times, primarily due to prematurely discontinuing their TB medicines based on the false assumption that their cough had resolved and therefore they were cured. Twelve patients particularly liked the section illustrating the importance of taking TB treatment and many linked this to avoiding the development of drug-resistant TB. The MDR/XDR section was identified by 10 patients as the most useful information in the PIL. Three patients found the information on side effects most helpful as they had encountered these and another three patients felt the information on when to take their TB medicines in relation to a meal most helpful. One patient commented that he did not know he could take TB medicines on an empty stomach. Avoiding smoking and alcohol was identified as the most useful information in the PIL by two patients and one patient identified the tablet crushing sequence as the most important aspect in the PIL.

Overall, the majority felt that all the information in the PIL was helpful and felt that there was no information that was unnecessary or of no help to them (81.1%). However, five patients indicated that they did not have any difficulties in swallowing and thus found the information on how to crush their tablets least helpful. Three patients indicated that they did not feel the need to have information about side effects and one male patient commented that the information about informing the doctor or nurse about pregnancy and breast-feeding before being initiated on TB medicines was not personally useful.

Patient input in improving the content of the PIL and making it more acceptable and useful resulted in a question that sought patient opinion about information they would like to see in the PIL. Out of the 53 patients, 22 offered feedback on what could be added or what information they would like to know:

- TB-disease related information including infection, re-infection and prevention (n=8)
- MDR/XDR TB - patients felt they knew very little about this aspect and wanted as much information as possible (n=5)
- Advice on when an individual is no longer infective (n=5)
- Additional information about side effects including their occurrence and management (n=2)

Only five patients indicated that there were words included in the PIL that they did not understand. Two of these patients disclosed that they had only a basic ability to read thus they encountered difficulties reading certain words and got a family member to read it to them. Side effects, medicine names and MDR/XDR were the terms that were poorly understood by the remaining three patients.

Patients in the experimental group were also asked to comment on their preference for inclusion of pictograms in the PIL. All patient (n=53) were enthusiastic about the pictograms and felt that their presence in the PIL helped them to understand and recall information about their medicines (Table 6.15). Two patients had difficulty with understanding the pictogram sequence on MDR/XDR-TB, and one patient indicated problems with understanding the side effect pictograms, in particular the pictogram about peripheral neuropathy.

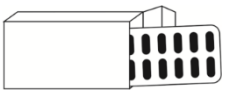
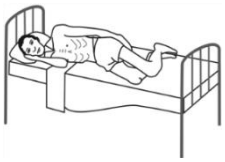
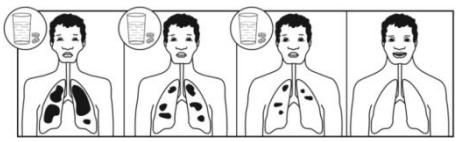
6.9 Pictogram interpretation

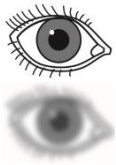
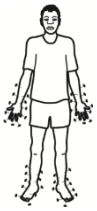
A total of 25 pictograms were included in the PIL and each of these was tested in the control and the experimental group. Generally, most of the pictograms were well interpreted, with only four of the 25 pictograms not complying with the ANSI criterion of 85% correct interpretation. All patients (100%) in the experimental group obtained a correct interpretation for 12 of the 25 pictograms whereas in the control group, this occurred for half that number i.e. six pictograms correctly interpreted by all patients (Table 6.16).

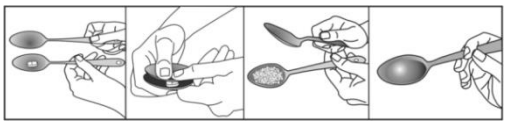
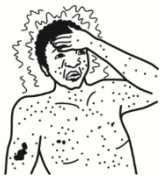
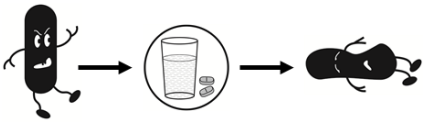
Only three pictograms showed a statistically significant difference in comprehension between the control and experimental group: pictograms 13 (peripheral neuropathy; $p<0.001$), 14 (joint paint; $p=0.019$), and 19 (severe rash and fever; $p=0.041$). None of these three pictograms complied with the ANSI criterion and were the most poorly interpreted in both groups. Their use would require supplementary verbal and written information to enhance understanding. Pictogram 24 (do not share medicines) was also not well interpreted.

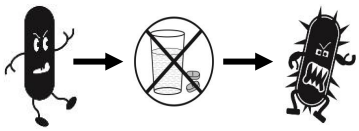
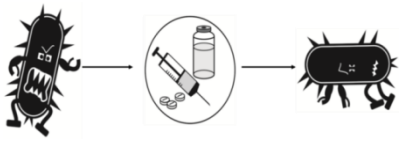
In contrast, interpretation of the three pictogram sequences on MDR/XDR-TB (pictogram 23, 24 and 25) were remarkably well understood in the control group despite the fact that they had never seen them before. Although pictogram 15 illustrating muscle weakness as a side effect of TB medicines was an extremely challenging concept to illustrate pictorially, the final product was well understood by the majority of patients in both the experimental (98.1%) and control group (91.5%).

Table 6.16: Correct interpretation of individual pictograms, n (%)

Pictogram	Control (n=59)	Experimental (n=53)	p-value	Total (n=112)
1. TB medicines 	58 (98.3)	53 (100.0)	0.341	111 (99.1)
2. Take TB medicine/tablets with water 	57 (96.6)	53 (100.0)	0.176	110 (98.2)
3. Do not take TB medicine/tablets 	58 (98.3)	53 (100.0)	0.341	111 (99.1)
4. Sick TB patient/ person who did not take TB treatment 	59 (100.0)	53 (100.0)	1.000	112 (100.0)
5. Healthy TB patient/ person who took TB treatment 	59 (100.0)	53 (100.0)	1.000	112 (100.0)
6. Checking if it is time to take TB medicine 	59 (100.0)	52 (98.1)	0.289	111 (99.1)
7. Effect of TB medicines on clearing TB in the lungs 	58 (98.3)	53 (100.0)	0.341	111 (99.1)

8. With food 	58 (98.3)	53 (100.0)	0.341	111 (99.1)
9. Without food 	57 (96.6)	52 (98.1)	0.623	109 (97.3)
10. Vomiting 	56 (94.9)	53 (100.0)	0.096	109 (97.3)
11. Skin rash 	58 (98.3)	52 (98.1)	0.939	110 (98.2)
12.Blurred vision 	51 (86.4)	51 (96.2)	0.070	102 (91.1)
13. Peripheral neuropathy/ pins and needles 	17 (28.8)	35 (66.0)	<0.001[a]	52 (46.4)
14. Join pain 	32 (54.2)	40 (75.5)	0.019[a]	72 (64.3)
15. Dizziness 	57 (96.6)	52 (98.1)	0.619	109 (97.3)

16. Muscle weakness 	54 (91.5)	52 (98.1)	0.122	106 (94.6)
17. Vomitting and stomach pain 	57 (96.6)	53 (100.0)	0.176	110 (98.2)
18. How to crush large TB tablets 	58 (98.3)	53 (100.0)	0.341	111 (99.1)
19. Severe rash and fever 	39 (66.1)	44 (83.0)	0.041[a]	83 (74.1)
20. Do not share medicines 	46 (78.0)	41 (77.4)	0.939	87 (77.7)
21. Do not smoke 	59 (100.0)	53 (100.0)	1.000	112 (100.0)
22. Do not drink alcohol whilst taking medicines 	59 (100)	53 (100.0)	1.000	112 (100.0)
23. If you take your TB medicines, the TB germs are killed 	59 (100)	50 (94.3)	0.064	109 (97.3)

24. If you do not take your TB medicines, a stronger form of TB can develop 	55 (93..2)	47 (88.7)	0.400	102 (91.1)
25. Stronger medicines (injections and tablets) are needed to treat the stronger type of TB 	50 (84.7)	47 (88.7)	0.542	97 (86.6)

[a]Significant difference ($p<0.05$) between control and experimental group

The mean interpretation scores (± SD) for the 25 pictograms in the control and experimental group were 22.54 ± 2.03 and 23.62 ± 2.04, respectively. Pictogram interpretation was significantly higher in the experimental group (p=0.006). This was anticipated since these patients had been exposed to the pictograms at the first interview when they were briefly counselled using the PIL which they then took home. In contrast, the control group had never seen the PIL or the pictograms prior to the second interview where interpretation was evaluated.

The effect of gender, age and education on pictogram interpretation was investigated and results are shown in Table 6.17. There was no gender effect on pictogram interpretation for either group.

Table 6.17: Effect of gender, age and education on pictogram interpretation

Demographic variables	**p-values**	
	Control (n=59)	**Experimental (n=53)**
Gender	0.125	0.341
Age	0.423	0.002[a]
Education	0.310	<0.001[a]

[a] Significant influence ($p<0.05$) of demographic variable on pictogram interpretation

Both an age and an education effect were seen in the experimental group. Patients in the experimental group who were more than 60 years old had a significantly lower correct pictogram interpretation than those who were 18-29 years (p=0.003), 30-44 years (p=0.002) and 45-59 years (p=0.035). Patients with an education less than or equal to Grade 4 had a significantly lower interpretation score than both patients with a Grade 5-7 education (p=0.004) and those with a Grade 8-10 education ($p<0.001$).

6.10 Information needs and HISB of TB patients

A total of 98 patients (81.7%) indicated that they only knew a little bit of information about TB as a disease state. Two thirds (n=80) felt that they did not know enough about their TB medicines, with the majority (99.2%) reporting that they would like to learn more about their TB medicines, including information about side effects. Despite the common misconception amongst some HCPs that patients do not want to know about side effects and certainly do not want these presented in pictorial form, at the follow-up interview, when the patients were shown two versions of the PIL (one with side effect pictograms and one without), three quarters (n=89) preferred the PIL with side effect pictograms and two thirds (n=75) felt that side effect pictograms would not adversely influence patient adherence.

To determine baseline information sources consulted, patients were given a list of options and were asked to comment whether they used these sources for information about their health and medicines (Table 6.18).

Table 6.18: Frequency of information sources consulted, n (%)

Sources of information	Total (n=120)
People	
Nurse	103 (85.8)
Family or friends	87 (72.5)
People at school	84 (70.0)
Doctor	75 (62.5)
Religious leader	51 (42.5)
Pharmacist	35 (29.2)
Sangoma	9 (7.5)
Media	
PILS, brochures and posters	110 (91.7)
Television and radio	107 (89.2)
Newspapers and magazines	96 (80.0)
Labels on medicine containers	82 (63.3)
Package insert	74 (61.7)
Personal experience	99 (82.5)

Written medicine information (PILs, brochures and posters) were the most commonly used sources of information (91.7%), followed by nurses (85.8%) and television and radio (89.2%). The three least consulted sources of information were sangomas (7.5%),

pharmacists (29.2%) and religious leaders (42.5%). If we rank the 13 sources of information from most utilised to least, it is particularly concerning that pharmacists are 12th on the list.

At the follow-up interview, all patients (n=112) were asked to comment on whether they preferred the package insert they were shown or the experimental PIL as a source of information about their TB medicines. Patients were given an example of each so that they could make an informed decision. Almost all patients (92.0%) indicated that they would like the PIL as opposed to the package insert because the PIL was simple, contained pictures and was easier to understand. Most patients (91.7%) indicated that giving the PIL to a new patient would be useful. Additionally, patients were enthusiastic about learning more about their medicines at the clinic via posters (99.1%), take-home PILs (100%) and group education activities (95.5%).

CHAPTER 7
GENERAL DISCUSSION

As the complexity of healthcare increases and the interventions and systems designed to deliver healthcare become increasingly sophisticated, the demands on the patient have expanded. The system requires patients to be informed, engage with their HCPs and participate in decision-making. This evolution of the patient role has become increasingly apparent in literature from developed countries, but patients in developing countries are often unable to access health information sources other than those offered by primary care providers. These patients still adopt the previously dominant passive, uninformed patient role. However even a developed country such as the USA has reported that nearly half of the American population may have difficulties acting on health information, a phenomenon referred to as a "health literacy epidemic" [9]. Studies have highlighted the association of limited health literacy with improper use of medicines, inadequate treatment outcomes, increased hospitalisations, increased medical costs as well as inadvertent consent for surgical procedures [359,392]. The role of PILs in patient education is increasingly being recognised [16] and the provision of information has shown to result in an increase in patient knowledge, patient behaviour and satisfaction [25,294].

7.1 Health and medicine information for TB patients

The experimental leaflet developed and tested in the RCT is the first patient-centred TB medicine information leaflet that has been designed to assist patients with their complex first-line TB medicines. It was successful in improving patient knowledge about the disease, TB medicines-taking, side effects, MDR/XDR-TB and HIV and TB co-infection. At baseline, there was no significant difference in mean knowledge score between the control group and the experimental groups but this changed significantly at follow-up with the experimental group showing a significant increase in knowledge. Overall, the PIL generated a highly positive response in the experimental group who indicated that they had used the leaflet over the last month and that it had helped enhance their TB medicine-related knowledge. This was reflected in the knowledge score, as almost three quarters of the patients in the experimental group obtained a knowledge score greater than 80%. The TB knowledge scale was developed to quantitatively evaluate patient knowledge in the RCT study, however, it can also be used

as an instrument to evaluate basic TB-related knowledge amongst other populations and settings.

At baseline, RCT patients reported poor knowledge about certain aspects of medicine-taking including the name of their TB medicines, information to tell the HCP, implications of nonadherence to TB medicines, measures taken to alleviate difficulty in swallowing large tablets and steps to follow when an individual forgets to take TB treatment. To enable patients to play a more active, informed role in their medicine-taking practices, the need to educate them about basic medicine-related knowledge has become an increasingly important aspect of healthcare. Patients with a better understanding of their treatment regimen have shown improved medicine-taking behaviour, including enhanced self-efficacy and adherence [17,297]. At the follow-up interview, it was encouraging to observe that some patients in the experimental group actually specified information that they would like to know and what they felt should appear in health information materials including aspects related to TB infection, prevention and management, drug-resistant TB and occurrence and management of side effects.

HCPs are often reluctant to provide information about side effects to patients as they feel that the information may frighten patients and deter them from taking the required medicine [393]. However, it was evident that local TB patients wanted side effect information and by law are entitled to receive all the necessary information about their medicines. This desire is consistent with other studies where patients feel that HCPs should be transparent and forthcoming with side effect information as it improves their understanding of their medicines with the result that they are less likely to needlessly discontinue the treatment when they encounter a known minor side effect [145,148,393]. In addition to alerting patients about possible side effects, they should also be educated about management of side effects if they do occur [393]. The experimental PIL presented minor and severe side effect information separately and provided appropriate guidance for management within each category. When providing information about side effects to patients with limited literacy, the study established that it is useful to firstly explain what a side effect is, and to mention that not all patients will encounter the listed side effects. Baseline side effect knowledge in TB patients was particularly poor, but improved markedly after exposure to the experimental PIL.

The current version of the PIL developed for the study does not address side effect frequency but does separate them according to severity. There is on-going debate about how the frequency of side effects should be presented in PILs. Qualitative representation of side effect data appears to result in an overestimation of occurrence [394]. Knapp *et al.* [395] investigated interpretation and preference of side effect incidence information when presented as either percentage, frequency or a combination of the two, and reported no differences in interpretation. However participants did express preference for the combined frequency plus percentage format. No research was found in the literature that addressed the presentation of side effect frequency to patients with poor health literacy skills and, although this is extremely challenging, is an area that needs to be investigated.

Another area where knowledge was found to be poor is drug-resistant TB which is particularly concerning as it is a huge public health problem in South Africa [396]. It was surprising that, despite the terms "MDR-TB" and "XDR-TB" being commonly mentioned in the South African health arena, most patients could not describe what these terms meant. Additionally, the duration of treatment for drug-resistant TB as well as the use of more potent antibiotics and injectables was not known to the majority. Patients were enthusiastic to learn more about drug-resistant TB, which could possibly motivate patients on standard first-line TB treatment to adhere to their therapy and avoid the development of resistance.

Treatment for drug-resistant TB is expensive and is more poorly tolerated due to the high side effect profile. Disconcertingly, a recent study that investigated the emergence of drug-resistant TB found that patients who were adherent to therapy were still developing resistant strains and this was mainly due to incorrect diagnosis and poor infection control measures [397]. Given the high cost of treatment, poor tolerability and poor health outcomes of drug-resistant TB, this information should be a focus in public health interventions. The introduction of the new Gene Xpert® diagnostic technology has resulted in accurate and faster diagnosis of drug-resistant TB cases and with the rising number of cases of drug-resistant TB there is also a need for simple targeted information materials that focus on this type of TB and its treatment.

7.2 Availability, use and format of medicine information

A lack of availability of patient information to facilitate understanding of complex TB medicines was identified in this study. The package insert in the original packaging is often removed or discarded when the medicine is repacked for public sector patients into a plastic packet or medicine box. It is well established that the readability of industry-generated package inserts intended mainly to inform HCPs is inappropriate for patient use [30]. The few patients who had encountered the package insert reported difficulty reading it due to the small font and complex terminology. Bandesha *et al.* [398] from the United Kingdom investigated early versions of the manufacturer-produced patient package inserts that consisted of a similar format to package inserts currently available in South Africa and reported that many patients have difficulty relating to and comprehending the content of these leaflets and could not read the small font size. A recent South African study reported that package inserts are ineffective in communicating information due to their poor design features and incomprehensibility attributed to the use of technical language, medical jargon and information overload [35]. For my study, all patients at the follow-up interview were shown a copy of the package insert and the experimental PIL and asked to specify their preference and provide a reason. The majority chose the latter as they felt it was simple, contained illustrations and was easy to understand.

Providing a PIL about health and medicines could supplement the limited information provided by HCPs who are often faced with a high patient load and thus have limited time to counsel patients adequately. Studies have shown that patients forget 40-80% of the information provided during a consultation and almost half of the information that is remembered is incorrect [399] thus PILs can serve as a reference if information is forgotten. In contrast to other studies that have indicated that patients do not value WMI [400,401], my study population appreciated the medicine leaflet and were enthusiastic about taking the leaflet home attach on their walls as a reminder. Most patients reported that the PIL was an appropriate and user-friendly reference and shared the information with their friends, family and the community. This phenomenon of sharing of information is common in a close-knit community who largely lack access to technology and rely heavily for information from the people around them, including their HCPs [29]. In the healthcare setting, it is important to acknowledge the importance of ‘community’ and the impact it can have on social and

behavioural change [402]. Patients should be acknowledged as key protagonists and by involving them in the design, implementation and evaluation of interventions, more informed empowered individuals could evolve within the community [402].

Unsurprisingly, most patients preferred information in their home language rather than English, however most health information materials, including package inserts, are available only in English and Afrikaans. According to the Patient's Rights Charter (1999), patients have the right to access information in a language or format that they understand and HCPs have a legal obligation to provide patients with the necessary information in this way [367]. Nevertheless, the high number of South African official languages contributes to the difficulty in providing patients with WMI in their home language.

The Medicines and Related Substances Act 101 of 1965 (as amended), stipulates that each medicine package should have a PIL that contains basic medicine information in at least English and one other official language. However, there are very few products in South Africa that contain PILs and most patients are unaware that the packaging should contain these key information materials. The few PILs available are often attached to the end of the package insert and have not undergone any form of user-testing to ensure that the design and content meet the needs of the target population. In contrast, countries like the UK, USA and Australia have legislation which ensures that each registered medicine is accompanied by a well-designed regulated PIL [403-405]. In the European Union, obligatory user-testing to ensure legibility of WMI accompanying medicines has been introduced and it is encouraging to see that EU legislators have placed importance on ensuring the legibility of WMI [406,407]. This concept should be adopted in South Africa to improve the quality and effectiveness of PILs.

There is an absence of simple targeted WMI to support patients with limited literacy taking complex medicines across the various disease states. Patients have expressed enthusiasm about receiving information about their medicines in the form of WMI, particularly PILs such as the one developed for this study. Unlike the regulatory approach to design, a rigorous patient-centred approach was adopted and resulted in an effective and acceptable PIL that catered to the needs of TB patients with limited literacy.

7.3 Inclusion of pictograms in WMI

Studies from both developed [220,321,408-411] and developing countries [299,412], including South Africa [31-33,138,215,298,301] have demonstrated the positive influence of pictorial aids when included in medicine information. Research in the field of both psychology and marketing has also shown that individuals have a cognitive preference for picture-based information as opposed to text-based as the illustrations allow them to create a mental image that assists in problem-solving [413]. All patients in the experimental group liked having pictograms and strongly felt that they helped them to recall and understand the textual content included in the PIL. A few studies have reported contrasting results where the use of pictograms has not been beneficial in the communication of health information to patients [304,305] and one major reason for this is the lack of attention paid to the design and testing process of the pictograms.

When developing the pictograms for my study, a rigorous design process was followed involving, in most cases, several iterations before the pictogram was deemed acceptable. Both patients and HCPs were involved in this pictogram development process. Interpretation of the 25 pictograms used in the PIL was generally high given that on average patients interpreted 23 out of the 25 pictograms correctly. Despite patients in the control group having no prior exposure to the pictograms, interpretation was good and this demonstrates the relatively low cognitive demand required to interpret these simple pictograms. Pictogram interpretation was found to be significantly higher in the experimental group and this was anticipated given the fact that they had been exposed to the pictograms in the take-home experimental PIL.

A study by Sorfleet *et al.* [322] reported that the use of pictograms was valuable in medication counselling however the introduction of the pictograms resulted in an increased workload for HCPs. The influence of pictograms on HCP workload in the South African public healthcare setting has not been researched and further studies should focus on this aspect. In relation to the RCT, the brief counselling session using the illustrated experimental PIL took under two minutes; introducing this intervention into clinical practice could potentially decrease the time taken to explain key TB medicine information to patients.

When evaluating pictograms, the ANSI recommends that comprehension of the intended message of each pictogram should be above 85% to ensure adequate understanding [316]. Despite good overall interpretation of the pictograms, there were four pictograms that were less well understood and these depicted the concept of not sharing medicines, peripheral neuropathy, joint pain, and severe rash and fever. The latter three are side effects with which most TB patients were unfamiliar. The pictogram advising not to share medicines was often misinterpreted as emptying their medicine packet. For these pictograms, verbal and written information to supplement the lack of understanding would be essential. The Spatial Contiguity Principle that forms part of Mayer's Cognitive Theory highlights the need to place text in close proximity to corresponding illustrations [323,324]. Testing these four pictograms with their corresponding text labels may provide insight on possible enhanced effectiveness when combining pictograms and text.

Demographic characteristics such as age, education, language and culture have been reported to impact on pictogram interpretation [414]. A significant effect of both age and education on pictogram interpretation was seen in the experimental group where patients below 60 years and those with lower education attainment showed reduced visual literacy in their ability to interpret pictograms. In the previous apartheid regime, in addition to significant inequities in the quality of education, many from the Black community did not have the opportunity to attend school at all or only did so for a few years. This resulted in widespread limited reading literacy which has been found to be associated with inadequate visual literacy amongst this population cohort [415].

7.4 Information needs and HISB of patients in developing countries

HCPs often underestimate the amount of information patients want about their health and medicines, assuming that providing this would overload the patient [148]. However, literature shows that there is a significant patient demand for information, a demand that was demonstrated in my study by patients who wanted to know more about their disease and medicines, including side effect information. The majority of the TB patients in the RCT acknowledged their limited knowledge of the disease and its treatment and freely expressed their desire to learn more. Raynor *et al.* [145] in investigating the medicine information needs of asthma patients reported similar findings, with patients identifying the specific basic

medicine information they would like. This included name and purpose of treatment, duration, administration instructions, side effects and their management, medicine-medicine interactions and how to determine the efficacy of treatment. In contrast, none of my study patients attempted to seek for information about their medicines despite specifying that they wanted health and medicine-related information. They could not articulate the specific information they desired and in fact had to be prompted about various medicine-taking aspects in order to elucidate their medicine information needs.

Both the information needs as well as the preferred sources of information vary within a specific setting and population, and should be investigated prior to conducting an intervention [148]. It was obvious that patients did not know what information would inform safe medicine-taking practices and were unaware that they could ask their HCP for this type of information. This varies significantly from patients in developed countries who, in addition to having well-resourced healthcare systems, have access to technology which enables them to search for the necessary information.

The two HISB models described in Section 3.2.3 were used as a theoretical underpinning to understand, analyse and interpret data on how the study population looked for information in the healthcare setting. When situating my study findings within Longo's expanded model of health information seeking behaviours [160] it was evident that patients adopted a passive approach to information seeking, receiving only minimal medicine information from the HCP which they did not use to make informed health decisions. This resulted in outcomes such as disempowerment and dissatisfaction. In relation to the basic organizational model developed by Anker, Reinhart and Feeley [144], our findings indicated a lack of engagement in health information seeking and as a result patients did not achieve the outcomes listed in this model. These include engaging in discussions with HCPs, need or desire for a second opinion and the inability to participate in any form of self-diagnosis. This could be due to certain predisposing characteristics of which poor health literacy was identified as a major contributor.

TB patients reported no access to information about their medicines other than that provided by the nurse or occasionally the doctor, with the only WMI available at the clinic being in the form of posters, with most of these focusing on TB as a disease state and none providing

information about TB medicines. The need for simple, understandable TB medicines identified in the early stages of this study was met by the illustrated experimental PIL, which fulfilled its mandate to enhance knowledge as it resulted in a significant increase in medicine-related knowledge, and enhanced the patient behaviour of self-efficacy.

7.5 Applicability of existing research tools for evaluating self-efficacy and adherence

No appropriate tools to measure self-efficacy and adherence of local patients taking TB treatment were available as those identified from literature focused on other disease states and were established for use in a developed country. Self-efficacy was deemed important to include as, according to Bandura [165], the stronger an individual's perceived self-efficacy, the greater their ability and motivation to succeed when challenged. The HIV-ASES and MMAS-8, which have previously been modified for use in the South African setting to determine self-efficacy and adherence of patients taking ARV treatment [37], were identified as potential tools and were further modified to make them applicable for local TB patients. Patients taking complex TB medicines are often faced with several challenges and the study attempted to understand both perceived self-efficacy in relation to specific aspects that impact on patient's ability to take their TB medicines as well as to investigate self-reported adherence, and establish whether these behaviours improved when they were briefly counselled using an illustrated take-home PIL.

Substantial modifications to the original HIV-ASES tool resulted in the TB-ASES (reported in Section 4.5.2). The original 11-point Likert rating scale was modified and converted to a 5-point visual rating scale which included cartoon-like icons, as previous research had established the failure of the more extended 11-point scale, and recommended a more contracted one [37]. Patients appeared to easily understand both the content of the questions and the visual rating scale, and they readily quantified their level of confidence by usually pointing to the relevant number or bar on the visual scale.

Baseline self-efficacy in both groups was extremely high at baseline (above 4.5 out of 5) and this is reportedly typical of self-reported measures [416]. At follow-up, only the experimental group demonstrated a significant intra-group increase in self-efficacy, supporting several

studies that reported a greater understanding of medicines resulting in higher self-efficacy [21,297]. Self-efficacy did not appear to be influenced by gender, age or education effects.

Despite efforts by the National DoH to integrate the treatment of HIV, TB and sexually transmitted infections in the form of a National Strategic Plan, the national cure rate for TB is a low 79% and mortality is high (49/100 000) [417]. Successful outcomes require 90% adherence [3] so any treatment defaulting can have detrimental effects on both individual health and the broader community. Given the reported difficulty of obtaining a reliable adherence rating, the use of both a subjective and objective method may prove useful. Unfortunately, a pill count process could not be incorporated into the study design and this became apparent during the initial discussion with clinic staff. This RCT was deliberately designed to fit as seamlessly as possible into the standard working routine of the clinic in an attempt to make any findings applicable to standard everyday practice. Pill counts are unfortunately not routinely conducted, are time-consuming and patients do not return to the clinic with their remaining tablets after a month.

Using the modified MMAS-8, patients in both groups were classified as having moderate adherence to their TB medicines at both baseline and follow-up. A slight increase (non-significant) was seen in adherence at follow-up but was not limited to the experimental group. Literature is divided on the influence of knowledge on adherence with some studies finding a strong correlation between the two [418,419] and others finding no such association [420,421]. My study only reported a baseline significant but weak association of TB medicine knowledge on adherence in the control group, and no such association in the experimental group.

Individual item analysis revealed that patient adherence decreased in relation to two items on the scale; forgetting to take their treatment and admitting to missing treatment on certain days over the last month. At the follow-up interview a greater number of patients reported occasional nonadherence and this is possibly due to patients feeling more comfortable in expressing their nonadherent behaviour in the second interview. A combination of a pill count and self-reported measure of adherence may assist in more accurately evaluating patient adherence.

Bandura [165] proposed that patients with greater self-efficacy are more likely to be adherent to their prescribed therapy and this is consistent with other studies [21,422,423]. A qualitative study that explored the determinants of adherence amongst local Grahamstown patients found that patients' health beliefs, particularly their self-efficacy and motivation, are important in adherence to TB treatment [424]. Findings from my study revealed a moderate but significant correlation between self-efficacy and adherence at baseline only in both groups. No age, gender or education effect on patient self-reported adherence was found.

7.6 Proposed framework for the development and implementation of patient-centred health and medicine information in a developing country context

Based on the literature and the various phases in my study, a proposed framework to use as a guideline when developing medicine information materials for limited literacy patients is presented. It outlines five primary developmental stages (Figure 7.1).

- **Stage 1 -** Investigation of information needs and HISB as well as the preferred format of information delivery. In this stage, gaps in knowledge and preferred channels for information exchange can be identified.
- **Stage 2 -** Evaluation of currently available information materials to determine if information needs can be met and if materials are appropriate in their design, format, content and user-friendliness.
- **Stage 3 -** Informed by Stage 1 and Stage 2, information materials are designed and developed. Patient and HCP input should be considered and careful consideration given to design, content and layout. In the case of patients with limited literacy, the use of pictograms should be considered to supplement the text in communicating certain key messages.
- **Stage 4 -** The developed information undergoes user testing before being used in practice to ensure acceptability, appropriateness, readability and comprehensibility.
- **Stage 5 -** Informed by Stage 4 findings, the information materials are modified if necessary and can then be introduced into practice. Information materials are often developed but may not be disseminated or made available to HCPs and patients. HCPs should be encouraged to distribute them to their patients. Materials should be updated when deemed necessary.

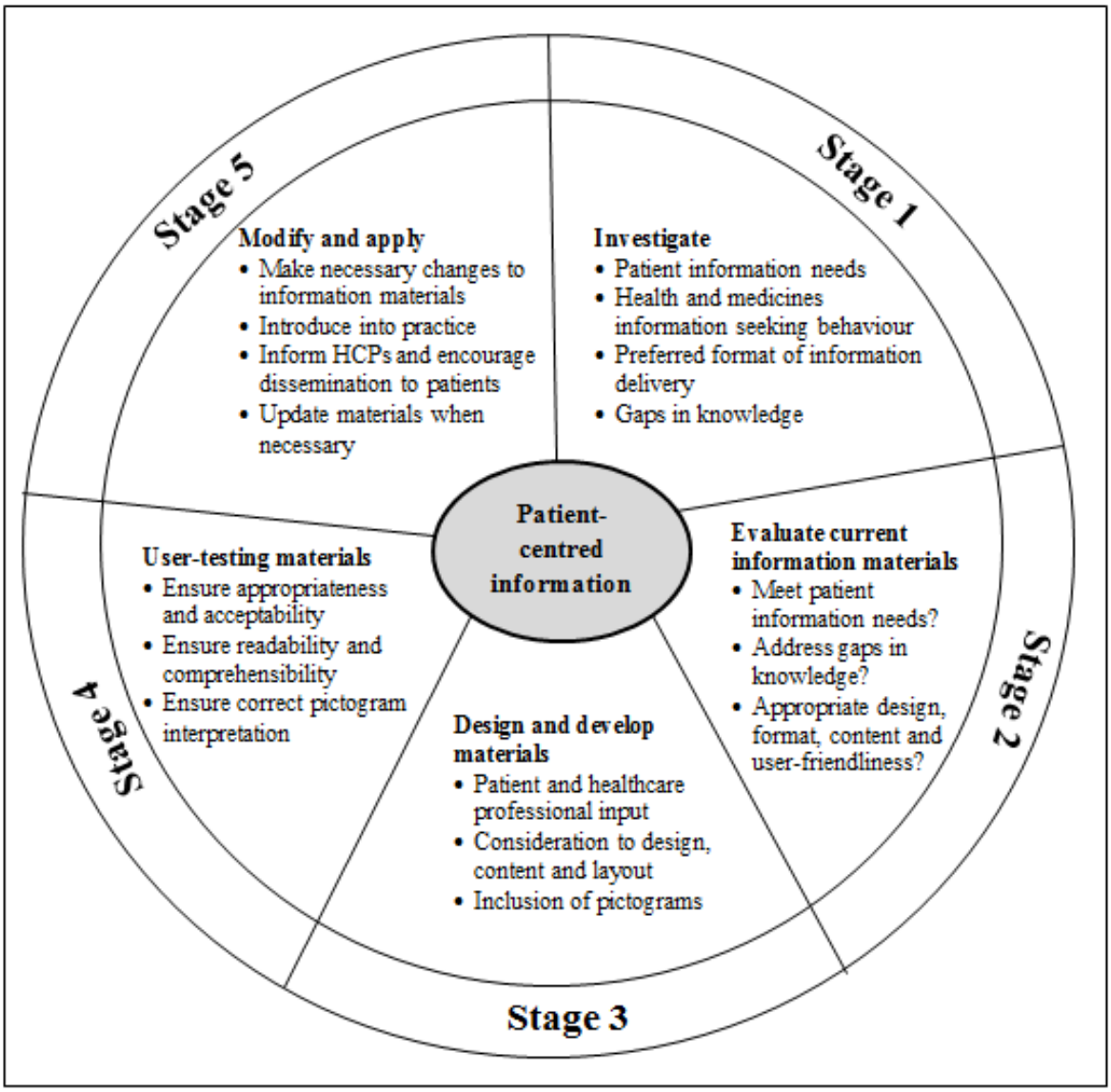


Figure 7.1: Proposed framework for the development of patient-centred health information materials targeted at limited literacy patients

A circular representation was chosen for the framework as the development process is continuous and each stage forms part of the process with patients at the centre. The main purpose of this proposed model is to map a logical sequence of stages that can be implemented by HCPs to promote the development and sustained use of patient-centred health information materials that cater to the needs of patients with limited literacy.

7.7 Measuring limited health literacy in South Africa

Existing validated health literacy tests that have emanated largely from developed countries are inappropriate for assessing the health literacy of populations with different understandings of health and disease, have diverse health beliefs, are of different cultures and include a large proportion of individuals with limited education and general literacy skills. In the only published South African study that used an existing tool in its original form, Dowse *et al.* [130] established that both the word recognition testing strategy as well as the majority of the test words were inappropriate for the study population of public sector patients, and comprehension was poorly associated with pronunciation ability.

In developing a health literacy test for my study the local burden of disease was considered, with infectious diseases currently dominating healthcare and demanding high adherence to pharmacotherapy. As my study focused on improving medicine knowledge, a medicine literacy test, the MLT, was developed based on both numerical and reading comprehension. It is the first health literacy tool that has been developed and validated in South Africa and has demonstrated its ability to identify patients who have inadequate medicine literacy.

In developed countries, several studies using the TOFHLA or S-TOFHLA have reported limited health literacy rates ranging from 7% in Australia [131] to 20% in Switzerland [132]. In contrast, a developing country such as Brazil has reported 32% of the population as having limited functional health literacy [129]. In my MLT validation study population, a higher percentage of 38% of the study population was categorised as having inadequate health literacy. Interestingly, only 20% of the RCT patients had inadequate health literacy. These TB patients are followed-up intensively at the clinic and have to present regularly each month for their medicine. It should also be noted that a third of the TB study patients were HIV positive, and in South Africa HIV patients receive greater focused counselling on a range of health-related issues such as nutrition and exercise, as well as about the disease and ARVs. It is possible that this translates into improved health literacy skills. However, the individuals who participated in the MLT study were drawn from the community rather than from clinics, with only just over half regularly presenting to a healthcare facility on a monthly basis. A large proportion of this population was therefore less familiar with accessing healthcare and with the range of issues associated with taking medicine on a routine basis. Further

investigation of factors associated with MLT score, including frequency of interactions with HCPs, could provide greater insight on this discrepancy and should constitute further research.

In practice health literacy assessment tools are not widely used due to both the time it takes to administer them and with some tools they require prior training [115]. The commonly used S-TOFHLA which is also based on numerical and reading comprehension takes up to 12 minutes to administer, whereas the MLT takes under five minutes and is therefore a quick assessment tool requiring only minimal user training prior to administration.

The use of screening questions to identify patients with limited health literacy is still being debated in the literature [106]. Previous studies from the USA [124,425] found the single item SILS to be a useful tool for identifying inadequate health literacy. This screening question was included in my RCT questionnaire as a self-reported measure of health literacy and was found to have a significant association with health literacy as measured by the MLT. Patients who reported that they "never" or "do not often" need help with reading health information had a greater MLT score than patients who "often" or "always" required help. Given the time-efficient nature of the SILs and the simplicity of asking only a single question, this seems a promising strategy to adopt in the under-resourced health system prevalent in developing countries such as South Africa.

A different testing strategy adopted in the Brazilian health literacy test, the MSFHL, combined three demographic characteristics with three screening questions to predict health literacy [129]. The MSFHL was reported to be a more accurate measure of health literacy rather than the frequently used indicator of educational attainment. Investigation into the application of this tool in the South African setting may provide further understanding of the applicability of this combination health literacy measurement tool.

In my study a relationship between educational attainment and health literacy was identified where an increase in the number of years of formal education resulted in an increase in MLT score. These findings are consistent with a review by Paasche-Orlow *et al.* [426] that reported significantly higher health literacy rates amongst individuals who had completed high school education. Apartheid era inequalities in access to formal education has decreased over the last

decade, however the bench-mark pass rate is set at only 30% thus many scholars achieve secondary education but may lack certain reading and numerical competencies. Having completed the same number of years of formal schooling does not translate into the same level of health literacy due to individual differences in reading and writing abilities. Therefore despite my study indicating a relationship between educational attainment and MLT score, caution should be exercised when using education as a rough surrogate measure of health literacy in the South African population.

7.8 Approaches to understanding and improving health literacy in South Africa

Poor health literacy can have substantial negative effects on patient health-related behaviour [427]. The first stage of this study (Chapter 3) explored the gaps in medicine-related knowledge as well as barriers to health information acquisition and its application in patients taking long-term medicines, including TB medicines. It was evident that most patients lacked the ability to obtain and use the necessary information to make informed health decisions. The majority adopted a passive approach and were disempowered in their encounters with HCPs, typical of patients with limited health literacy. These findings are similar to those reported by Williams *et al.* [428] in their review of the impact of poor health literacy on patient-physician communication and also support the model of causal pathways linking health literacy and health outcomes by Paasche-Orlow *et al.* [427] that highlights the effect of limited health literacy on access and utilization of healthcare, patient-provider-relationship and self-care. The widespread prevalence of limited health literacy found amongst local patients could certainly be described as a 'silent epidemic' in South Africa.

Very few interventions targeted at improving patient health literacy have been conducted in sub-Saharan Africa, including South Africa. In fact, the term health literacy is not a commonly used term and there have been no attempts to formally define health literacy in the South African setting [111]. Most health communication interventions by local government and NGOs do not take into account health literacy and health communication theories or the conceptual underpinnings relating to strategies that can potentially result in positive outcomes including patient empowerment, satisfaction and shared decision-making.

In Section 2.2.4, two conceptual approaches to understanding and improving health literacy as proposed by Nutbeam [13] were described; health literacy as a "risk", and health literacy as an "asset". The strategies adopted in my study and its various phases can be situated within Nutbeam's conceptual model of health literacy as a "risk". According to this model, the first important aspect is to identify patients with limited literacy using applicable health literacy tools and, in accordance with this, the MLT was developed and validated for use in the South African context. The model then highlights the importance of the provision of appropriate services that are sensitive to patients with limited literacy. The experimental PIL designed for our limited literacy patients contained pictograms and simple text and was used as a tool to counsel patients. Consistent with the need to enhance the HCP-patient relationship emphasised in the model, my study reported patient enthusiasm and satisfaction with the use of the take-home PIL as a tool to facilitate understanding of complex TB medicine information, although it did not specifically measure the effect on the HCP-patient relationship. The use of the leaflet to briefly counsel patients in the experimental group resulted in a significant increase in patient knowledge and self-efficacy which is well-matched with the model that also reports improved outcomes when information materials are tailored to meet patient needs and HCPs are sensitive to the limited HL of the population.

Most of the studies that form the basis of the conceptual model of health literacy as an "asset" have been conducted in developed countries and based on the fact that the majority of local patients are disempowered and passive in their interactions with the healthcare system, there is definitely a need to adopt this approach to encourage patient empowerment and engagement with the healthcare system. However, according to my study, the immediate concern is to improve functional health literacy skills by adopting strategies that improve basic literacy and numeracy, such as improving the quality of formal education and increased access to adult education. Achieving adequate functional health literacy can then allow patients to acquire interactive and critical health literacy skills and abilities that are needed when adopting health literacy as an "asset" as indicated in the second model proposed by Nutbeam [13].

7.9 Limitations of the study

The study was conducted in two small semi-rural towns in the Eastern Cape Province which are characterised by high levels of unemployment, poverty and most residents are from the lower end of the socio-economic scale. South Africa has 11 official languages and the PIL was only tested in isiXhosa, Afrikaans and English which are the three commonly spoken languages in the Eastern Cape Province. As a result, caution should be taken when extrapolating these results to other populations in South Africa.

The interviewer is originally from Zimbabwe and is unable to speak either Afrikaans or isiXhosa thus all interactions with patients were conducted via an interpreter. The use of an interpreter has its own limitations [429], of which loss of information during the translation process is a major concern. This tends to occur when patients make use of common phrases used in their home language or quotations [430]. The interpreter was encouraged to translate verbatim and, where necessary, explain the meaning of phrases and quotes to establish clarity.

The HISB study utilised a qualitative approach consisting of FGDs and one of the major limitations of this approach is that knowledge produced may be unique to the population included in the study.

No applicable tools to measure self-efficacy and self-reported adherence amongst South African TB patients were available. Two existing tools that have previously been used to assess these medicine-taking behaviours amongst local patient taking ARVs [37] were modified but neither has been formally validated.

Use of self-reported measures can result in overestimation and this was identified as a major limitation when measuring patient adherence. The use of both a self-reported measure and pill count could produce a more accurate measure of patient adherence.

CHAPTER 8
CONCLUSIONS AND RECOMMENDATIONS

This research study was the first study to address the lack of available TB medicine information for patients in a country where TB has increased to epidemic proportions. The simple illustrated PIL containing information about TB medicines developed for this study as a tool for brief patient counselling increased TB medicines knowledge and improved self-efficacy, but had no effect on self-reported adherence. Neither self-efficacy nor adherence was influenced by gender, age or education, and an education effect on knowledge was only observed in the control group at baseline. As there is a paucity of studies investigating the influence of take-home written leaflets on TB medicine knowledge and on patient behaviour, this study contributes significantly to the area. The modified MMAS-8 and HIV-ASES were simple and easily understood by the target population and validation of these tools could provide further insight on their applicability in the target population.

The initial HISB study identified the typical South African public sector patient as being disempowered, passive, uninformed and unable to independently seek for health and medicine information. Patients relied on the basic verbal dosing instructions from HCPs and were incapable of engaging in discussion that typically result in informed medicine-taking practices. Outcomes of health information-seeking include empowerment and satisfaction, as well as improved locus of control, HCP-patient interaction and shared-decision making, all of which were lacking in the study population. These unique findings draw attention to the high prevalence of inadequate health literacy that prevents patient involvement in the healthcare continuum.

Educating and counselling patients empowers them to engage with their HCPs and make more informed health-related decisions. A significant gap in knowledge was noted both in the type of medicine information that patients should know, as well as the range of sources offering such information. The examples of illustrated leaflets and posters that were shown to patients during the discussions generated much enthusiasm and resulted in a unanimous desire for information in this format. The urgent need to increase patient empowerment within the South African public healthcare setting should be addressed by both public health strategies and initiatives, and from within the healthcare system with HCPs being encouraged

to adopt a more patient-centered approach, improve the patient education process and actively encourage patients to ask questions. Increased active patient involvement in the healthcare system could potentially result in an increase in health literacy.

Limited health and medicine literacy research from sub-Saharan Africa has been published, with the consequence that health literacy has not been or quantified and cannot be compared to findings in other countries. The newly developed test designed to evaluate medicine literacy (the MLT) was shown to be a valid and reliable tool to assess health literacy, with a particular focus on medicine literacy, and was able to demonstrate the ability to differentiate between participants of varying health literacy skills. A significant and moderate correlation was shown between the MLT score and baseline TB knowledge, supporting the ability of the MLT to identify patients with limited health-related knowledge. As it takes on average less than five minutes to complete, as well as being a promising research tool the MLT could be used in practice to identify high risk patients where adherence is essential and where low health literacy is suspected and to offer focused counselling and support.

General disease-related knowledge of TB was good, but knowledge about medicine-taking, side effects and MDR/XDR TB was poor. Interventions targeted at improving patient knowledge should focus on these key knowledge areas. Most written information available at public healthcare clinics focused on the disease, with limited understandable information available about TB medicines and drug-resistant TB. Patients clearly preferred reading the PIL in their home language, a finding that supports the need to consider the language desires of the target population when developing and disseminating information materials.

Patients embraced the inclusion of pictograms in the PIL, commenting that they assisted with understanding. Both an age and education effect on pictogram interpretation was seen in the experimental group; older age and lower education adversely influenced pictogram interpretation. These pictograms underwent a rigorous iterative design process with careful consideration of target population characteristics, an approach which optimised their success in conveying the intended message. Most patients preferred the version of side effect information that had been illustrated, a finding that may cause HCPs some concern. Limited research has been conducted on provision of side effect information through pictograms thus

further studies are warranted to understand both patient and HCP opinion about side effect information in this format.

Almost all patients in the experimental group used the PIL to inform their medicine-taking practices and indicated their desire for medicine information in this format. A large proportion also indicated that they showed the take-home PIL to a family member or friend. This sharing of information amongst a close-knit community with largely inadequate health-related knowledge has the capacity to improve health literacy and possibly reduce the stigma of diseases such as TB and HIV.

Targeted user-friendly, illustrated information leaflets can be a valuable counselling aid to improve patient knowledge and self-efficacy, particularly among patients with limited literacy. However, careful consideration to the design and content, with input from the end-users at all stages of the process, can optimise its effectiveness. Local patients taking TB medicines want to know more about the medicines they are taking and have identified nurses, WMI and media as their key sources of information consulted. To empower patients in their medicine-taking practices and improve health literacy of the South African population, health policy makers and HCPs need to develop suitable targeted educational interventions. The provision of WMI to complement verbal information provided by HCPs has the potential to improve patient knowledge and self-efficacy.

Recommendations for future research:

- Given that nurses form the mainstay of primary healthcare in South Africa, future research should investigate nursing staff perceptions of the provision of medicine information to patients, including side effect information. Nurses tend to adopt an authoritative one-way interaction when counselling patients and make limited use of communication strategies that encourage patient autonomy. Further research is needed to understand nurse's perceived role in health communication as well as awareness of strategies to improve communication with patients, particularly those with limited literacy.
- Our study found that patients want side effect information and did not perceive the presentation of side effects in pictorial form to constitute a risk factor for nonadherence. Presentation of side effect information to patients with limited literacy

is an area that requires further investigation, including patient preferences for the format of side effect risk information.

- Pictograms were well received by the limited literacy patient population; however the influence of pictograms on HCP workload in the South African public healthcare setting has not been researched. HCP opinions and preferences in relation to the introduction of pictograms in health and medicine information materials should be investigated.
- Conducting a similar RCT with a larger sample size and a more diverse patient population could provide greater understanding on the applicability and usefulness of the PIL in other populations groups in South Africa.
- The MSFHL tool that consists of a combination of demographic and screening questions was established in a developing country (Brazil) and should be tested amongst local patients to determine its applicability. Further research is required to compare the MLT with a broader range of currently used health and medicine literacy tests. The MLT should also be applied to a broader South African population to include individuals representing the entire range of educational levels, cultural and language groups, socioeconomic groups and patients who do not rely on the public health sector as they have access to private healthcare.
- The legal requirements for producing PILs in South Africa could be compared with other countries or regions such as the USA, Australia and the EU. PILs from each country/region generated in compliance with these requirements could be compared and could focus on selected medicines commonly prescribed in South Africa. This will provide insight on ways to improve the regulation criteria of PILs in South Africa.
- The application of the proposed framework to the development and evaluation of WMI in other high-burden disease states in South Africa such as diabetes and hypertension should be explored in further studies. Greater insight into the need for a more comprehensive development process, followed by end-user evaluation, could assist potential developers of information (governmental, non-governmental, pharmaceutical manufacturers) in developing better quality patient-centred information materials.

Practical implications of the study:

- Due to the scarcity of simple targeted TB medicine information for patients with limited literacy skills, the PIL designed in this study could be made available to both HCPs and patients. Prior to the dissemination of the PIL in clinics affiliated with USAID, the PIL should be translated into the most commonly spoken languages in the area surrounding the clinic, with the translated version ideally being tested amongst patients attending the clinics.
- The proposed framework for the development and implementation of health and medicine information could be used to compile patient-centred information materials and through this process of involving the patient at all stages, resultant optimised materials are more likely to meet patient needs along with a more interactive patient role in the healthcare system.
- Design, content, format and language considerations should be a huge focus when developing health and medicine information materials and the use of pharmaceutical pictograms should be promoted, particularly with limited literacy patients. These considerations along with the need for user-testing could also be included in the legislation and guidelines for the development of PILs by industry manufacturers and government organisations.
- HCPs need to be mindful of patient health literacy and can use the MLT as a quick tool to identify individuals with limited literacy who are taking medicines requiring high adherence and provide them with suitable counselling.

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APPENDICES

APPENDIX A

ETHICAL APPROVAL DOCUMENTS

Eastern Cape Department of Health

Enquiries	Zonwabele Merile	Tel No	040 608 0830
Date	04th October 2011	Fax No	043 642 1409
e-mail address.	zonwabele.merile@impilo.ecprov.gov.za		

Dear Ms Sonal Patel

Re: Health information to improve knowledge and understanding of tuberculosis and tuberculosis treatment amongst low-literate tuberculosis patients: design, development and evaluation

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from the date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

DEPUTY DIRECTOR: EPIDEMIOLOGICAL RESEARCH & SURVEILLANCE MANAGEMENT

Ikamva eliqaqambileyo!

RHODES UNIVERSITY
Grahamstown • 6140 • South Africa

FACULTY OF PHARMACY
Tel: 046 603 8381 • Fax: 046 636 1205
P O Box 94, Grahamstown, 6140
e-mail: dean.pharmacy@ru.ac.za

7 September 2011

Dear Sonal Patel

RE: Ethical approval by the Faculty of Pharmacy's Ethics Committee

(Tracking number PHARM 2011 - 30)

As a registered student in the Faculty of Pharmacy, with student number 07P4640, I am pleased to inform you that the Faculty of Pharmacy's Ethics Committee grants you ethical approval for your research entitled:

Health Information to Improve Knowledge and Understanding of Tuberculosis and Tuberculosis Treatment amongst Low-Literate Tuberculosis Patients: Design, Development and Evaluation.

Please ensure that the Faculty of Pharmacy's Ethics Committee is notified should any substantive change(s) be made, for whatever reason, during the research process.

Sincerely

C. Oltmann

Carmen Oltmann, PhD

Chairperson of the Faculty of Pharmacy's Ethics Committee

RHODES UNIVERSITY
Grahamstown • 6140 • South Africa

FACULTY OF PHARMACY
Tel: 046 603 8381 • Fax: 046 636 1205
P O Box 94, Grahamstown, 6140
e-mail: dean.pharmacy@ru.ac.za

28 May 2012

Dear Prof Ros Dowse and Ms Sonal Patel

RE: Ethical approval by the Faculty of Pharmacy's Ethics Committee

(Tracking number PHARM 2012 - 25)

Your letter informing the Faculty of Pharmacy's Ethics Committee about the proposed changes to the research proposal you submitted last year (PHARM 2011 – 30, approved on 7 September 2011) refers. I am pleased to inform you that the committee grants you ethical approval for this research entitled:

Health Information to Improve Knowledge and Understanding of Tuberculosis (TB) and TB Treatment amongst Low-literate TB Patients: Design, Development and Evaluation.

Please ensure that the Faculty of Pharmacy's Ethics Committee is notified should any further substantive change(s) be made, for whatever reason.

Sincerely

C. Oltmann

Carmen Oltmann, PhD
Chairperson

RHODES UNIVERSITY
Grahamstown • 6140 • South Africa

FACULTY OF PHARMACY
Tel: +27 (0)46 603 8381 • Fax: +27 (0)46 603 7506 • E-mail: dean.pharmacy@ru.ac.za • PO Box 94, Grahamstown, 6140, South Africa

22 May 2014

Dear Chipiwe Marimwe (11M0629) and Sarah Gray (09G2897)

RE: Ethical approval by the Faculty of Pharmacy's Ethics Committee
(Tracking number PHARM 2014 - 5)

As registered students in the Faculty of Pharmacy, with student numbers 11M0629 and 09G2897 respectively, I am pleased to inform you that the Faculty of Pharmacy's Ethics Committee grants you ethical approval for your research entitled:

Validation of a Health Literacy Test in Public Sector Patients in South Africa,

Provided you address the following issues:

Regarding the information brochure (applies to both):
1. The sentence "Those patients can then be helped to look after themselves what is not all that good about their health and their medicines" is not clear. Please correct.
2. The sentence "you would like to part in the study" should be corrected.
3. A sentence clarifying that there will be no negative effects in the treatment the patients receive from the clinic/Settlers Day Hospital if they refuse to take part in this study (or something similar) would be appropriate.

Regarding the consent form (applies to both):
1. A sentence (in the 1st person) should be included stating that the participant has been provided with and understands the information about the study.
2. A sentence (in the 1st person) should be included stating that the participant understands that they can withdraw from the study at any time if they wish.

Please ensure that the Faculty of Pharmacy's Ethics Committee is notified should any substantive change(s) be made, for whatever reason, during the research process.

Sincerely

C. Oltmann

Carmen Oltmann, PhD
Chairperson

RHODES UNIVERSITY
Where leaders learn

Rhodes University Ethical Standards Committee, Rhodes University, P O Box 94, Grahamstown, 6140
Tel: +27 46 603 7366 • Fax: +27 46 603 8934 • email: M.Goebel@ru.ac.za

10 Aug 2013

Ethics Clearance: 2013Q3-4
Principal Investigator: Sonal Patel

Dear Ms Patel,

This letter confirms that a research proposal with tracking number 2013Q3-4 and title: '**Development of patient-centred tuberculosis medicines information to educate and empower patients with limited literacy skills in their medicine-taking practices: linking theory and practice**', including the supplementary documentation from 8 Aug 2013, was given ethics clearance by the Rhodes University Ethical Standards Committee.

Please ensure that the ethical standards committee is notified should any substantive change(s) be made, for whatever reason, during the research process. This includes changes in investigators. Please also ensure that a brief report is submitted to the ethics committee on completion of the research. The purpose of this report is to indicate whether or not the research was conducted successfully, if any aspects could not be completed, or if any problems arose that the ethical standards committee should be aware of. If a thesis or dissertation arising from this research is submitted to the library's electronic theses and dissertations (ETD) repository, please notify the committee of the date of submission and/or any reference or cataloguing number allocated.

Yours sincerely

Professor M. Göbel: Chairperson RUESC.

Note:

1. This clearance is valid from the date on this letter to the time of completion of data collection.
2. The ethics committee cannot grant retrospective ethics clearance.
3. Progress reports should be submitted annually unless otherwise specified in the clearance letter.

Eastern Cape Department of Health

Enquiries:	Zonwabele Merile	Tel No:	040 608 0830
Date:	27th September 2013	Fax No:	043 642 1409
e-mail address:	zonwabele.merile@impilo.ecprov.gov.za		

Dear Ms S Patel

Re: Development of patient-centered tuberculosis medicines information to educate and empower patients with limited literacy skills in their medicine taking practices: linking theory and practice

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress on your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

DEPUTY DIRECTOR: EPIDEMIOLOGICAL RESEARCH & SURVEILLANCE MANAGEMENT

APPENDIX B

DATA COLLECTION TOOLS AND CONSENT FORMS FOR HISB STUDY

QUESTIONNAIRE

UNDERSTANDING INFORMATION NEEDS AND HEALTH INFORMATION SEEKING BEHAVIOUR OF TB PATIENTS (PILOT)

SONAL PATEL: 2011

Interviewer: _____ Date: _____

Interpreter: _____

Respondent Name: _____ Interview site: _____

DEMOGRAPHICS ***(Completed on individual sheets by all patients with assistance from interpreter)***

Focus Group Discussion Guide- Understanding Information Needs and Health Information Seeking Behavior of TB Patients

OVERALL QUESTIONS TO ADDRESS IN FOCUS GROUP DISCUSSION:

(Reminder to facilitator)

- What TB-related health information is currently available for TB patients?
- Do patients actively look for information?
- What are patients' opinions towards the information available and are they satisfied with the information?
- Do they use the information to inform their medicine-taking practices?
- What are the information needs local TB patients with limited health literacy?
- What is the preferred format of health and medicine information delivery?
- What are patients' views about the provision of services and health communication via

Part 1:
Introduction:

Good Afternoon. My name is **Sonal Patel**. I am a pharmacy student from Rhodes University. I would like to thank you all for taking the time to be with us today.

We shall be discussing your thoughts and ideas about tuberculosis (TB) and the information that is available to you as a patient. The purpose of this research study is to find out the type of information you need, how you go about getting information and how you prefer to get the information you need?

The responses you give me will help me develop TB medicines information that will help TB patients understand their treatment and assist them with possible problems they may have while taking their treatment. There are no right or wrong answers. We are interested in hearing what you think and feel about each topic.

The discussion will take between 45 minutes and an hour. You can raise your hand when you have a response to the questions. If you don't understand a question, please let me know and I will explain it. I am here to ask questions, listen and make sure you all have a chance to share your ideas. Feel free to speak openly and honestly, as everything said in this discussion will be kept completely confidential.

We will be tape recording the session because we don't want to miss any of your comments. Only my supervisor and I will have access to these tapes. No names will be included in any reports and your comments will be kept confidential.

I would like to introduce you all to the interpreter _____, who is here to translate so that we are able to conduct the discussion in isiXhosa. I would also like to introduce you to my colleague _____ who shall be observing, taking notes and assisting me with the discussion.

May we turn on the tape recorder?

Okay, to start off, we are going to do a short fun activity. (ICEBREAKER EXERCISE) [5mins]

Part 2: Questions for discussion

Health information needs regarding TB treatment

1) What is your biggest health concern?
2) What do you think is the biggest health concern in your community?
3) Is there another word people used for tuberculosis besides TB?
4) When I say Tuberculosis, what is the first thing you think about?
5) How do you think people get TB?

   Probe: If through the air, ask if there are any other ways?
6) Do you think TB is a serious condition?

   Probe: Why?
7) Do you think TB can be cured?
8) I want you to think back to the time when you found out you were infected with TB germs. Briefly tell us what happened and what you did about it?

   Probe: Was there anything you did not like or did not understand?

   Probe: Did you ask anyone for advice about what to do?

   Probe: Did you go to someone besides a medical doctor for treatment or advice? (healer,family,friend)?

9) What are your feelings towards taking medicines to treat TB?
10) Was there anything about your medication that you did not understand and needed help with?
11) Generally, how long should you take TB treatment for?
12) Is it necessary to continue taking the TB medication even if you get better?
Probe: Why?
13) What convinced you that it is important to take you medicines?
Probe: Who explained to you that it is important to take your medication?
Probe: What explanations did you receive?
Probe: What instructions did you receive about how to take you medication?
Probe: What are some of the reasons people stop taking their medication?
14) What are the most important results you hope to get from the TB treatment you are taking?
15) What are some difficulties you have taking medicine?
Probe: Where did you go get help with these problems?
Probe: Did you stop taking your medication?
16) Can you think of anything that would convince people that it is important to take their medication?
17) How do you remind yourself to take your medicines?
Probe: Reminders from healthcare workers, family, friends, calendar?
18) Is it okay to smoke whilst on TB treatment?
Probe: Why?
19) Is it okay to drink whilst on TB treatment?
Probe: Why?
Probe: How do you feel about not drinking alcohol while you on treatment?
20) Do you ever feel that taking your medication stops you from doing things in your life you normally do?
Probe: What kind of things?
21) As a TB patient what information do you want about your condition and its treatment?
Probe: Information about your medication, side-effects, what to avoid when on the medication, information about TB?

[30minutes]

Health Information Seeking Behaviour

1) How do you prefer to receive information about your health and your medication?
   Probe: Written materials such as (Leaflets, posters, booklets), sms, phone call, television, radio, newspapers or internet?
2) Have you heard about using your cell phone to help with your health or the health of your family? (for example, setting a reminder for a clinic appointment or to remember to take medication, or sending an SMS to someone to remind them to take medication, or looking for health information)
3) Have you ever used your cell phone for health?
4) Would it be helpful to you to be able to use your cell phone for health?
5) What problems do you think you may have when you use your cell phone for accessing health information and keeping reminders?
6) Tell me about the different ways in which you have received information about TB?
   Probe: Of all the ways you have received information, which was the most helpful?
7) Are you happy with the information that is currently available or do you feel there is room for improvement?
8) Do you use the information to make decisions about your health?
9) Do you look for information about your condition before you visit a TB clinic?
10) After you were diagnosed with TB, did you want to know more about your condition?
    Probe: Where do you go or what do you do to get more information about your condition?
11) What factors affect how you get information about your condition?
12) What makes you want to look for information about and its treatment?

[25minutes]

Summary

Is there anything else you would like to discuss or add to the discussion? Is there anything else you feel we should know?

I would like to thank you all for coming here today. We really appreciate your thoughts and ideas and I am sure they will help us develop information that will help TB patients understand their condition and its treatment.

RHODES UNIVERSITY

INFORMATION NEEDS AND HEALTH SEEKING BEHAVIOUR OF TB PATIENTS

My name is **Sonal Patel** and I am a Postgraduate Student from the Faculty of Pharmacy, Rhodes University, South Africa. I would like to invite you to take part in a research study which involves developing health information for TB patients currently taking TB medication. I intend to develop health information to help TB patients understand their condition and its treatment. This consent form gives detailed information about the research study. Once you have read and understood the information contained in this form, you may ask me any questions. I will then ask you to sign this form if you wish to take part.

WHY ARE WE DOING THIS RESEARCH?

The purpose of my research is to develop simple, easily understood, attractive and user-friendly health information for TB patients. My aim is to determine the type of information TB patient's need, their health information seeking activities and the preferred format of the information. Thereafter, I shall develop health information suited to the needs of TB patients and shall test whether it helps patients understand their TB treatment.

I am looking for patients visiting the clinic who are isiXhosa-speaking and are taking TB medication for at least one month. You should be able to read at least some English or isiXhosa.

WHAT WILL YOU DO IF YOU TAKE PART IN THIS STUDY?

You will take part in a short discussion about TB, TB treatment and the health information available to assist patients on TB treatment. An interpreter will be present to translate so that you can speak in isiXhosa. The discussion will be recorded on a tape recorder however only the interviewer (myself) and my supervisor will have access to this recording.

The discussion will take between 45 and 60 minutes. In the discussion I shall ask you questions about TB, its treatment and the health information that is currently given to you. You can raise your hand when you have a response to the questions. You will be given R40 worth food stamps to thank you for your time and for helping us with this study.

HOW WILL THIS STUDY HELP YOU?

After the discussion, I shall understand the type of information and format of information you as a TB patient require. I shall then develop health information to improve your understanding and knowledge about TB and TB treatment. This information will be made available to you. The more you understand the better care you can take of yourself. We would like to have this health information given at other clinics and hospitals so that TB patients like you can learn and understand their treatment.

All your details will be kept confidential – this means that I will not tell anyone your name or personal details, and none of this information will appear in the published results from this study.

DO YOU HAVE THE RIGHT TO REFUSE OR LEAVE THE DISCUSSION?

If you do not wish to take part in the discussion you have the right to refuse. If you take part in the discussion, you have the right to leave the discussion at any time.

FINAL STEP

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

RESEARCH SUPERVISOR

Professor R Dowse, Faculty of Pharmacy, Rhodes University

Tel: +27 46 603-8071

CONSENT

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

Signature: …….(researcher)

Signature: ……(interpreter)

PARTICIPANT TO BE INTERVIEWED:

I, …… would like to take part in this research study. I give permission to **Sonal Patel** (the researcher) and..... (the interpreter) to ask the necessary questions.
I understand that all information gathered from this research study will be kept private.

Signature: …….

Witness: …….

Date: …….

FOCUS GROUP DISCUSSION GUIDE- UNDERSTANDING INFORMATION NEEDS AND HEALTH INFORMATION SEEKING BEHAVIOR OF TB PATIENTS

SONAL PATEL: 2011

Part 1:

Introduction

Good Afternoon. My name is **Sonal Patel**. I am a pharmacy student from Rhodes University. I would like to thank you all for taking the time to be with us today.

We shall be discussing your thoughts and ideas about tuberculosis (TB) and the information that is available to you as a patient. The purpose of this research study is to find out the type of information you need, how you go about getting information and how you prefer to get the information you need?

The responses you give me will help me develop TB medicines information that will help TB patients understand their treatment and assist them with possible problems they may have while taking their treatment. There are no right or wrong answers. We are interested in hearing what you think and feel about each topic.

The discussion will take between 45 minutes and an hour. You can raise your hand when you have a response to the questions. If you don't understand a question, please let me know and I will explain it. I am here to ask questions, listen and make sure you all have a chance to share your ideas. Feel free to speak openly and honestly, as everything said in this discussion will be kept completely confidential. A sheet of paper will be passed around for you to fill in details regarding your gender, age, education, employment and the current medication you are taking. If you have any difficulties filling out this form you may come after the discussion and we shall assist you with it.

We will be tape recording the session because we don't want to miss any of your comments. Only my supervisor and I will have access to these tapes. No names will be included in any reports and your comments will be kept confidential.

I would like to introduce you all to the interpreter _____, who is here to translate so that we are able to conduct the discussion in isiXhosa. I would also like to introduce you to my colleague _____ who shall be observing, taking notes and assisting me with the discussion.

May we turn on the tape recorder?

Okay, to start off, we are going to do a short fun activity. (ICEBREAKER EXERCISE)

[5mins]

Part 2: Questions for discussion

Health information needs regarding TB treatment

1) Is there another word people use for tuberculosis besides TB?
2) When I say Tuberculosis, what is the first thing you think about?
3) How do you think people get TB?

   Probe: If through the air, ask if there are any other ways?
4) Do you think TB is a serious condition?

   Probe: Why?

   Probe: Do you think TB can be cured?
5) I want you to think back to the time when you found out you were infected with TB germs. Briefly tell me what happened and what you did about it?

   Probe: Was there anything you did not like or did not understand?

   Probe: Did you ask anyone for advice about what to do?

   Probe: Did you go to someone besides a doctor for treatment or advice? (healer,family,friend)?
6) What are your feelings towards taking medicines to treat TB?

   Probe: Was there anything about your medication that you did not understand and needed help with? **Probe:** Who helped you? What advice did they give you?
7) Is it necessary to continue taking the TB medication even if you get better?

   Probe: Why?

   Probe: What are some of the reasons people stop taking their medication?
8) What are some difficulties you have taking medicine?

   Probe: Where did you go get help with these problems?

   Probe: Did you stop taking your medication?
9) Can you think of anything that would convince people that it is important to take their medication?
10) Is it okay to smoke and drink whilst on TB treatment?

    Probe: Why?

    Probe: How do you feel about not drinking alcohol while you on treatment?
11) Do you ever feel that taking your medication stops you from doing things in your life you normally do?

    Probe: What kind of things?
12) As a TB patient what information do you want about your condition and its treatment?

Probe: Information about your medication, side-effects, what to avoid when on the medication, information about TB?

[25minutes]

Health Information Seeking Behaviour

13) How do you prefer to receive information about your health and your medication?

Probe: Written materials such as (Leaflets, posters, booklets, labels), sms, phone call, television, radio, newspapers or internet?

14) Have you heard about using your cell phone to help with your health or the health of your family? (for example, setting a reminder for a clinic appointment or to remember to take medication, or sending an SMS to someone to remind them to take medication, or looking for health information on the internet)

Probe: Have you ever used your cell phone for health?

Probe: Would it be helpful to you to be able to use your cell phone for health?

Probe: What problems do you think you may have when you use your cell phone for accessing health information and keeping reminders?

15) Tell me about the different ways in which you have received information about TB?

Probe: Of all the ways you have received information, which was the most helpful?

Probe: Are you happy with the information that is currently available or do you feel there is room for improvement?

Probe: Do you use the information to make decisions about your health?

16) After you were diagnosed with TB, did you want to know more about your condition and medicines?

Probe: Where do you go or what do you do to get more information about your condition and medicines?

Probe: Is there anything that prevents you or stops you for getting information?

[20minutes]

Summary

Is there anything else you would like to discuss or add to the discussion? Is there anything else you feel we should know?

I would like to thank you all for coming here today. We really appreciate your thoughts and ideas and I am sure they will help us develop information that will help TB patients understand their condition and its treatment.

RHODES UNIVERSITY

INFORMATION NEEDS AND HEALTH INFORMATION SEEKING BEHAVIOUR OF TB

My name is **Sonal Patel** and I am a Postgraduate Student from the Faculty of Pharmacy, Rhodes University, South Africa. I would like to invite you to take part in a research study which involves developing health information for TB patients currently taking TB medication. I intend to develop information to help TB patients understand their condition and its treatment. This consent form gives detailed information about the research study. Once I have explained the information contained in this form, you may ask me any questions. I will then ask you to sign this form if you wish to take part.

WHY ARE WE DOING THIS RESEARCH?

The purpose of my research is to develop simple, easily understood, attractive and user- friendly health information for TB patients. My aim is to determine the type of information TB patient's need, their health information seeking activities and the preferred format of the information. Thereafter, I shall develop health information suited to the needs of TB patients and shall test whether it helps patients understand their TB treatment.

I am looking for patients aged 18 years or above, that go to Temba TB Hospital who are isiXhosa-speaking and who have been taking TB medication for at least one month. You should be able to read at least some English or isiXhosa.

WHAT WILL YOU DO IF YOU TAKE PART IN THIS STUDY?

You will take part in a discussion about TB heath information with me and 5-6 other TB patients. An interpreter will be present to translate so that you can speak in isiXhosa. The discussion will be recorded on a tape recorder, however only the interviewer (myself) will have access to this recording.

The discussion will take between 45 minutes and an hour. In the discussion I shall ask you questions about TB, its treatment and the health information that is currently given to you. You can raise your hand when you have a response to the questions. You will be given food stamps worth R40 to thank you for your time and for helping us with this study.

HOW WILL THIS STUDY HELP TB PATIENTS?

Your opinions will help me develop health information for TB patients. We would like to have this health information given at other clinics and hospitals so that TB patients like you can learn and understand their treatment.

All your details will be kept confidential – this means that I will not tell anyone your name or personal details, and none of this information will appear in the published results from this study.

DO YOU HAVE THE RIGHT TO REFUSE OR LEAVE THE DISCUSSION?

If you do not wish to take part in the discussion you have the right to refuse. If you take part in the discussion, you have the right to leave the discussion at any time.

FINAL STEP

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

CONTACT DETAILS:

Researcher: Ms Sonal Patel Cellphone: 072 696 1612
Supervisor: Prof Ros Dowse Tel (w): 046 603-8071

CONSENT

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

Signature: …….(researcher)

Signature: ……(interpreter)

PARTICIPANT TO BE INTERVIEWED:

I, …… would like to take part in this research study. I give permission to **Sonal Patel** (the researcher) and..... (the interpreter) to ask the necessary questions.
I understand that all information gathered from this research study will be kept private.

Signature: …….

Witness: …….

Date: …….

RHODES UNIVERSITY

INFORMATION NEEDS AND HEALTH INFORMATION SEEKING BEHAVIOUR OF PATIENTS TAKING LONG-TERM MEDICATION

My name is **Sonal Patel** and I am a Postgraduate Student from the Faculty of Pharmacy, Rhodes University, South Africa. I would like to invite you to take part in a research study which involves understanding the information needs and health information seeking practices of patients taking long-term medication. This consent form gives detailed information about the research study. Once you have read and understood the information contained in this form, you may ask me any questions. I will then ask you to sign this form if you wish to take part.

WHY ARE WE DOING THIS RESEARCH?

The purpose of my research is to determine the health information seeking activities and information needs of patients taking chronic medication. Additionally, to investigate the type of information currently available to patients and determine what barriers patients may encounter when trying to get information about their medication.

I am looking for patients aged 18 years or above, that go to Raglan Road Clinic who are isiXhosa-speaking and who are currently taking chronic medication for the following conditions: diabetes mellitus, hypertension, asthma, epilepsy,HIV/AIDS and tuberculosis. You should be able to read at least some English or isiXhosa.

WHAT WILL YOU DO IF YOU TAKE PART IN THIS STUDY?

You will take part in a discussion about medicines information with me and 5 other patients. An interpreter will be present to translate so that you can speak in isiXhosa. The discussion will be recorded on a tape recorder, however only the interviewer (myself) will have access to this recording.

The discussion will take between 45minutes and an hour. In the discussion I shall ask you questions about the medicines information that is currently offered to you. You can raise your hand when you have a response to the questions. You will be given food stamps to thank you for your time and for helping us with this study.

HOW WILL THIS STUDY HELP PATIENTS TAKING CHRONIC MEDICINES?

Your opinions will help inform the development of patient-centred information and help to identify potential gaps in knowledge and barriers to getting medicines information.

All your details will be kept confidential – this means that I will not tell anyone your name or personal details, and none of this information will appear in the published results from this study.

DO YOU HAVE THE RIGHT TO REFUSE OR LEAVE THE DISCUSSION?

If you do not wish to take part in the discussion you have the right to refuse. If you take part in the discussion, you have the right to leave the discussion at any time.

FINAL STEP

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

CONTACT DETAILS:

Researcher: Ms Sonal Patel Cellphone: 072 696 1612
Supervisor: Prof Ros Dowse Tel (w): 046 603-8071

CONSENT

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

Signature: …….(researcher)

Signature: ……(interpreter)

PARTICIPANT TO BE INTERVIEWED:

I, …… would like to take part in this research study. I give permission to **Sonal Patel** (the researcher) and..... (the interpreter) to ask the necessary questions. I understand that all information gathered from this research study will be kept private.

Signature: ……

Witness: …….

Date: …….

FOCUS GROUP DISCUSSION GUIDE- UNDERSTANDING INFORMATION NEEDS AND HEALTH INFORMATION SEEKING BEHAVIOR OF PATIENTS TAKING LONG-TERM MEDICATION

SONAL PATEL: 2012

Part 1:

Introduction:

Hello everyone. My name is **Sonal Patel**. I am a postgraduate student from Rhodes University. I would like to thank you all for taking part in this research. I would like to introduce you all to **Thozama Mzangwa**, who is here to translate so that we can do our discussion in isiXhosa. I would also like to introduce you to **……**who will be observing, taking notes and helping us with the discussion.

We shall be talking about your medicines and what information there is to help you take it.

The reason why I am doing this research is to find out what type of information patients need and how they want to get it. The answers you give me will help me make information to help patients like you. There is no right or wrong answers. We just want to hear what you think and feel is important.

The discussion will take between 45 minutes and an hour.

If you don't understand a question, please let me know and I can explain it. Feel free to speak openly and honestly because everything said in this discussion will be kept completely confidential.

After the discussion we will give you a gift in the form of food stamps/money worth R40 to thank you for your time. For the study we need to know something about you. Please could you give us these details at the end of the discussion? I will remind you about it at the end.

We will be tape recording the discussion because we don't want to miss any of your comments. Only my supervisor and I will use these tapes. No names will be used in any reports and your comments will be kept confidential.

PASS AROUND CONSENT FORMS

You have each been given a consent form. We have already gone over the first page explaining who we are and why we are doing this research. Please could you turn to the next page? Now that you know what our research is all about, if you would like to take part please write your name on the dotted line with the happy face next to it

And please sign on the dotted line with 2 stars next to it. If you need help please let me know.

May we turn on the tape recorder?

Okay, to start off, we are going to do a short fun activity.

[5mins]

ICE BREAKER EXERCISE

Give each participant a piece of paper (facilitator, observer and interpreter to do as well)

I will be giving you some steps to follow. It is not a test, it is more like a game… so there are no right or wrong ways of doing the steps. Fold the paper in half; tear off one corner of the paper. Fold the paper in half again and tear another corner. Now fold the paper in half again and tear the corner. Unfold the paper. Can you all hold it up? Can you see all the different patterns you have made☺☺. This is the same thing we hope to get from the discussion. We want to get al.l your ideas and opinions… Okay so let us get started…

Just a reminder: I will speak in English, Thozama **will translate into isiXhosa and you can answer in isiXhosa.** Thozama **will then translate your answer into English. Alright let's start….**

Part 2: Questions for discussion

1. When you go to the clinic to get your medicines, you are told by the nurse or the pharmacist how to take it. Right? Can you tell me what else you are told about your medicines?

2. How important is it to have some information about your medicines?

   Probe: Do you all feel this way?

   Probe: Why?

3. Can you describe **WHAT** information is important for you to have about your medicines?

How to take your medicine When you collect your medicines from the clinic, how important is it to be told when and how to take the medication?
How long to take your medicines for Some medicines, like in hypertension and diabetes, you take forever whereas if you fall down and get hurt you are usually given medicine for a few days. Do you think it is important to know how long you should be taking a certain medicine for? Why? Were you told or given information on how long you are expected to take your 'high high' or asthma or 'sugar' medicines?
What your medicine is for How important is it for you to know the names of the medicines you are taking?

Probe: Do you all agree?**Probe:** Why do you feel this way?

What will happen if you don't take your medicines

If you were to stop taking your medicines for a few days, have you been told what might happen?

Probe: Can you explain what you were told?

Probe: If you knew what would happen if you stopped taking your medicines (for example in asthma/hypertension/TB...), how would that affect the way you take your medicines?

Side-effects

All medications are given to you to make you feel better but sometimes the medicines can have some bad effects, this is also called side-effects.

Have you ever been told or given information about the possible side-effects you may have when you take your medicines?

IF Yes:

Probe: How did the information help you?

Probe: Were you all given information on the side-effects of your medication?

IF No:

Probe: Do you think knowing information about side effects will help you?

Will knowing information about the possible side-effects of the medication stop you from taking it? Or do you prefer to be prepared and know what to expect when you take your medication?

Can you tell me more about what you do when you have side-effects?

Medicine-food interactions

What about food and medicines?

Probe: How do you feel about having food and taking your medicines? Can the food you eat have an effect on your medications?

Probe: Do you have your medicines after you have eaten food or when your stomach is empty?

Probe: What would you do if you were told to have your medication after food and there was no food in the house? Can you still take the medicines even if you haven't eaten?

Medicine-medicine interactions + sharing medicines

If you were given medicine from the clinic to help you sleep and your uncle/aunt is not able to sleep. How would you help him/her? Can you give him some of your tablets to help him/her sleep?

Have you ever been told what to do if you are taking medicines that the clinic has not given you? For example medicines from the sangoma or medicines from family members or friends?

How important do you feel it is to know whether it is safe to take medicines from the sangoma with medicines from the clinic?

Forget to take your medication

How many of you forget to take your medicines?

Has anyone ever told you what to do if you forget to take your medication?

If you were told to take your medication three times a day and you forget to take it at lunch time, what would you do?

Probe: have you ever been told what to do?

Storage of medicines

Have you ever been told how to store your medicines?

Probe: How did the information help you? **Probe:** How helpful do you feel it is to have information on how to store medicines?
How to dispose medicines What do you do with the old medicines that you are not using? Have you ever been told or given information on how to get rid of your old or unwanted medicines? **Probe:** How did the information help you? **Probe:** Would you want information like this? Why?

4. When you were told by the doctor that you have asthma, diabetes or hypertension did you look for information about your condition or the medicines you were taking?

   If yes: Where did you get this information? How did the information help? Did you all look for information?
   If no: Can you explain what you feel might stop people from trying to get information about their medication?

   Can you describe some problems people may have when trying to get information about their medicines? What do you feel could be done to make medicines information more available?

5. Who do you think should give you information about your treatment?

Doctor	Pharmacist	Nurse	Social Worker	Traditional healer

6. If you wanted information about your medication how would you like to get it?

   Probe: Let's discuss a few options and how useful they may be… (How helpful do you think it is? Would you use it? What problems may you have when trying to use this type of information?)

Verbal or spoken information from nurses, doctors or pharmacists
Written information leaflet that you can take home (show example)
Posters to stick on walls at home (show example)
Labels on medicines
An sms on your phone (show example)
On television or radio

SWALLOWING TABLETS + FOOD TO MIX CRUSH TABLETS WITH:

- For one of our similar projects we would like to find out how common it is for patients to have difficulty swallowing their medicines.
- Do any of you have difficulty swallowing your tablets?
- This is a tablet that is given patients to swallow with a glass of water. How difficult would it be to swallow this tablet?
- Have you ever been told what to do if the tablet is too big and you have problems swallowing it?
- If you were told by the pharmacist or nurse to crush the tablet and take it, what would you use to crush the tablet?
- And what would you mix the tablet with? (What food or drink do you usually have at home to mix the crushed tablet with?)

Summary

- Is there anything else you would like to discuss or add to the discussion? I would like to thank you all. We really appreciate your ideas and I am sure they will help us make information that will help patients.

- Please could you each come and collect a token of appreciation for your participation in the study and please could you fill in the details required? Thank you ☺

- (Sign for token and fill in demographic form)

- **Turn off tape recorder**

APPENDIX C

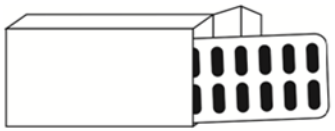
FIRST-LINE TB MEDICINE PATIENT INFORMATION LEAFLET

USAID FROM THE AMERICAN PEOPLE | TUBERCULOSIS PROGRAM SOUTH AFRICA

FIRST-LINE TB MEDICINES

RHODES UNIVERSITY
Faculty of Pharmacy, Rhodes University, Grahamstown 6139.
Tel : 046 603 8381.

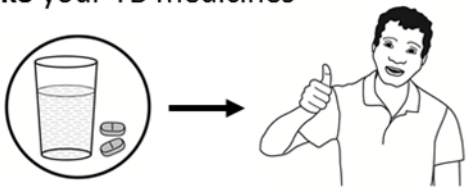
Name of your TB medicine



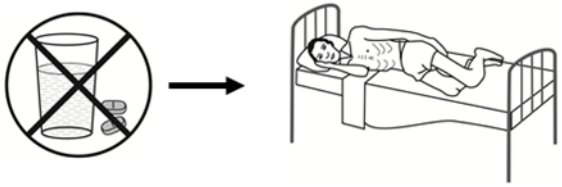
Rifafour® - First 2-3 months
Rifinah® - Next 4 months

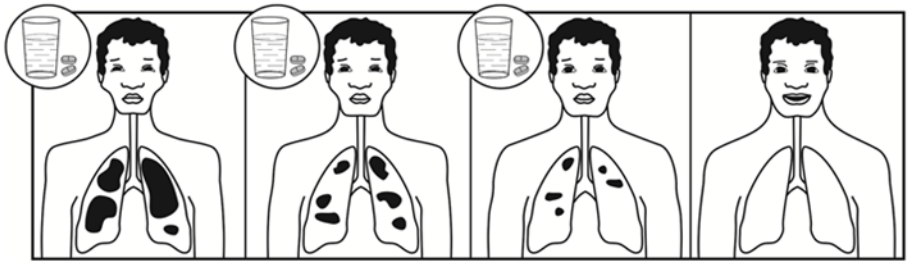
Why you must take your TB medicines

If you **take** your TB medicines



If you **do not** take your TB medicines





0 months | 2 months | 4 months | Cured

Take your TB medicine for 6 months or as long as you are told to, so that your TB can be cured

Do not stop taking your TB medicines even if you feel better

Before starting your TB medicines

Tell your healthcare provider if you:

- are taking any other medicines
- have any allergies
- are pregnant, breast feeding or trying to fall pregnant
- are on a oral contraceptive or injectable contraceptive
- if you are HIV positive

How to take your TB medicine

Take your medicine at the **same time** every day

You can take your TB medicine...

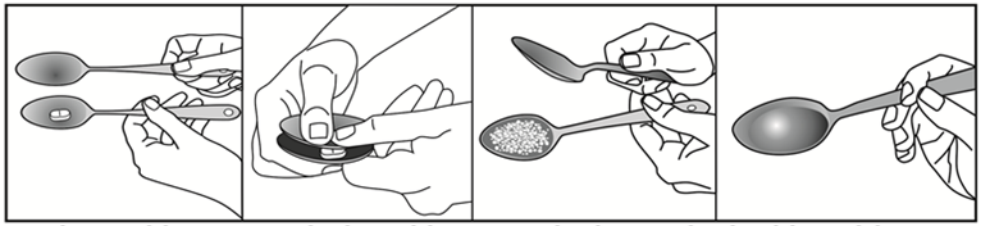
With food

OR

Without food

If you **forget to take** your TB medicine, take it as soon as you remember

If you find it difficult to swallow your tablets



Place tablet on a spoon | **Crush the tablet between the spoons** | **Mix the crushed tablet with a small amount of water, juice, jam or yoghurt before you take it**

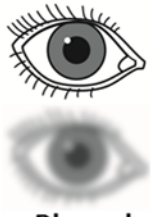
Side-effects

Side-effects are unusual effects that may appear when you are taking medicines, but they can be managed and treated

If you experience any of these side-effects tell the healthcare provider at the clinic:

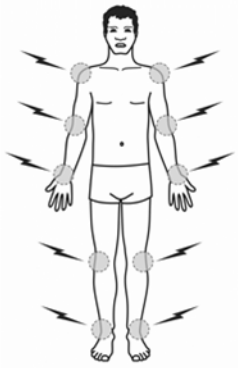
Vomiting

Skin rash



Blurred vision

Tingling, burning or pain in the hands and the feet (pins and needles)



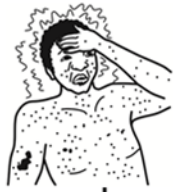
Joint pain

Dizziness

Muscle weakness

Go to the clinic as soon as you can if you have:

Stomach pain, nausea and vomiting



Severe rash on your body and a fever

You must not do the following when taking TB treatment

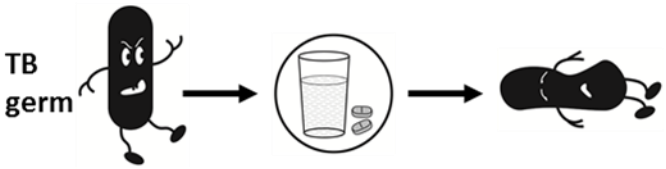
Do not share medicines

Do not smoke

Do not drink alcohol

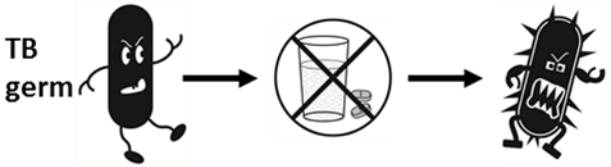
MDR-TB and XDR-TB

If you **take** your medicine **correctly**...

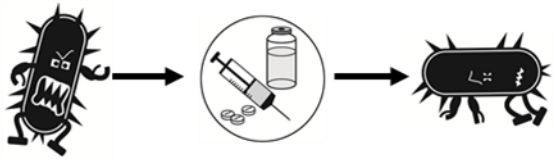


TB germ dies

If you **do not take** your medicine correctly...



TB germ becomes stronger causing MDR-TB or XDR-TB



Special TB medicines must be taken for about **18 months** to kill all the MDR-TB or XDR-TB germs

TB and HIV

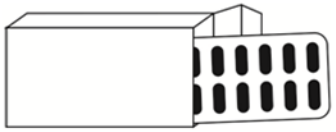
- Having TB does not mean that you will test HIV-positive
- Even if you are HIV positive, TB can be cured
- All HIV-infected people should get tested for TB on a regular basis
- If you take medicines for HIV and TB, tell your healthcare provider so that they can help you manage side-effects

USAID FROM THE AMERICAN PEOPLE | TUBERCULOSIS PROGRAM SOUTH AFRICA

IIPILISI ZOKUQALA E-TB

RHODES UNIVERSITY
Faculty of Pharmacy, Rhodes University, Grahamstown 6139. Tel : 046 603 8381.

Igama leyeza zakho leTB

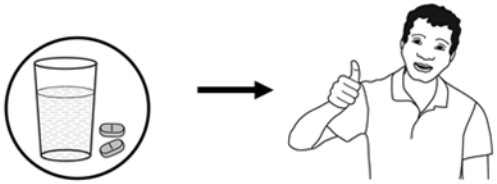


Rifafour® - iinyanga zokuqala ezi-2
ukuya kwezi-3

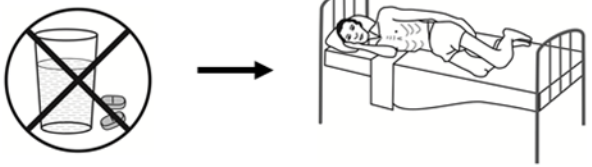
Rifinah® - iinyanga ezi-4 ezilandelayo

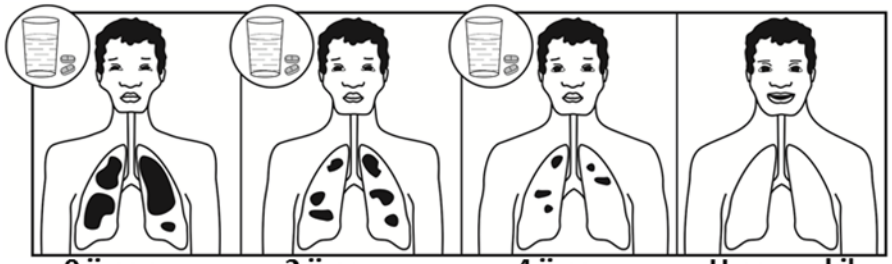
Kutheni le nto kufuneka uthathe iipilisi zeTB?

Ukuba uya **zithatha** iipilisi zakho zeTB



Ukuba **akuzithathi** iipilisi zakho zeTB





0 iinyanga | 2 iinyanga | 4 iinyanga | Unyangekile

Thatha iipilisi zakho eTB iinyanga ezi-6, okanye kangongakuba uxelelwa, ukuze iTB inyangeke
Musa ukuyeka ukuzithatha iipilisi zakho zeTB nokuba sele uziva ngcono

Phambi kokuba uqale ukusebenzisa iipilisi zakho zeTB

Xelela unompilo wakho ukuba:

- kukho ezinye iipilisi ozisebenzisayo
- kukho iipilisi ezingavani nomzimba wakho
- ukhulelwe, uyancancisa okanye uzama ukukhulelwa
- usebenzisa iipilisi okanye isitofu ukucwangcisa
- ukuba uHIV

Indlela yokuthatha iipilisi zakho zeTB

Zithathe iipilisi zakho **ngexesha elinye** yonke imihla

Ungazithatha iipilisi zakho zeTB...

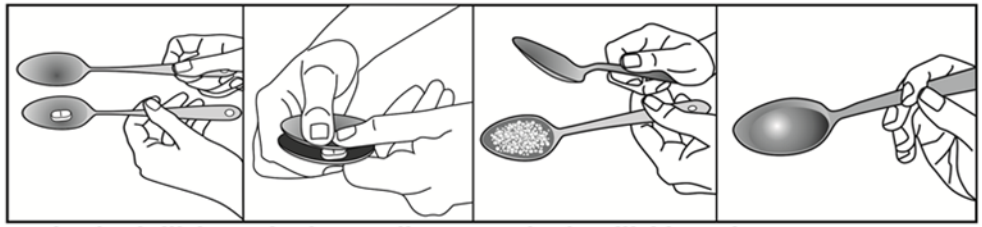
Emva kokutya

OKANYE

Ngaphandle kokutya

Ukuba **uye walibala** ukuzithatha ipilisi zakho zeTB, zithathe ngokukhawulez a wakube ukhumbule

Ukuba ufumanisa kunzima ukuzisela ipilisi



Thatha ipilisi uyibeke ecepheni | **Yigube ngelinye icephe** | **Xuba le pilisi igutyiweyo nentwana yamanzi, ijusi, ijemu okanye neyogathi phambi kokuba uyisele**

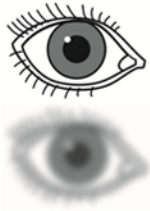
Izinto ezinokubangwa zipilisi

Amangenelela angaqhelekanga kunokwenzeka avele xa usebenzisa iipilisi kodwa ke ayalawuleka kwaye ayanyangeka

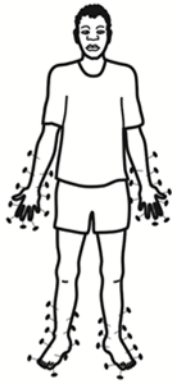
Ukuba uthi ufumane ezi zinto zisecaleni, mxelele unompilo wakho ekliniki:

Ukugabha

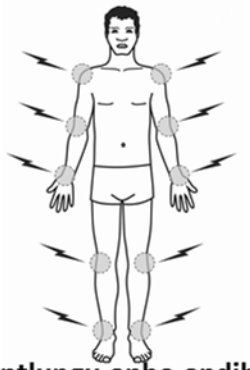
Irhashalala



Ukubona luzizi



Ukuntlontlozela, ukutshisa okanye iintlungu ezandleni nasezinyaweni



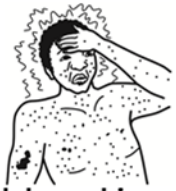
Iintlungu apho andibana khona amalungu omzimba

Isiyezi

Ukutyhafa kwezihlunu

Yiya ekliniki ngokukhawuleza xa unezi zinto zilandelayo:

Isisu esilumayo, isicaphu-caphu nokugabha



Irhashalala embi emzimbeni, kunye nomkhuhlane

Kufuneka ungazenzi ezi zinto zilandelayo xa uthatha iipilisi zeTB

Musa ukunikisa ngepilisi zakho kwabanye abantu

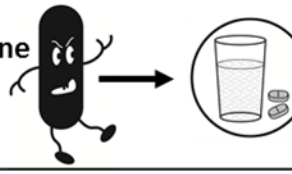
Musa ukutshaya

Musa ukusela utywala

I-MDR-TB ne-XDR-TB

Xa uzithatha iipilisi zakho **ngokufanelekileyo…**

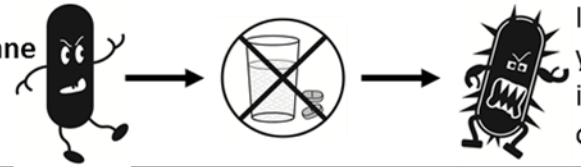
Intsholongwane yeTB



Intsholongwane yeTB iyafa

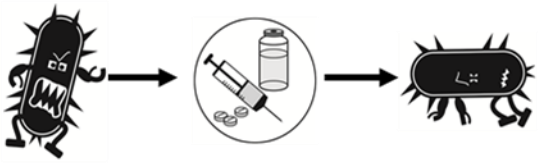
Ukuba **akuzithathi** ngokufanelekileyo iipilisi zakho…

Intsholongwane yeTB



Intsholongwane yeTB iyomelela, ibange iMDR-TB okanye iXDR-TB

Intsholongwane yeMDR-TB okanye yeXDR-TB



Amayeza awodwa eTB kufanele ukuba athathwe ixesha elimalunga **neenyanga ezili-18** ukwenzela ukubulala ezintsholongwane

I-TB ne-HIV

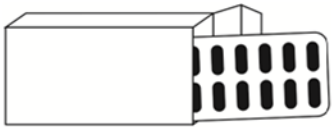
- Xa uneTB loo nto ayithethi ukuba uya kuba neHIV xa uthe wahlolelwa yona
- Nokuba unayo iHIV, iTB inako ukunyangeka
- Bonke abantu abosuleleke yiHIV kumele bayokwenza uvavanyo lwe TB rhoqo
- Ukuba uthatha amayeza eHIV neTB kuyakufuneka umazise unompilo wakho ukwenzela akuncede ukulawula amangenelela anokuthi avele

USAID FROM THE AMERICAN PEOPLE | TUBERCULOSIS PROGRAM SOUTH AFRICA

EERSTE LINIE TB MEDISYNE

RHODES UNIVERSITY
Faculty of Pharmacy, Rhodes University, Grahamstown 6139. Tel: 046 603 8381.

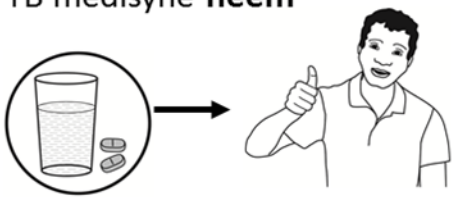
Die naam van jou TB medisyne



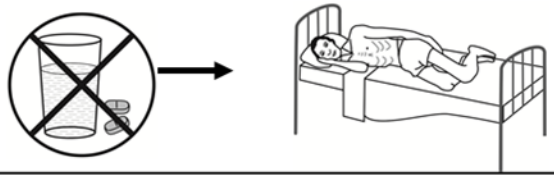
Rifafour® - Die eerste 2-3 maande
Rifinah® - Die volgende 4 maande

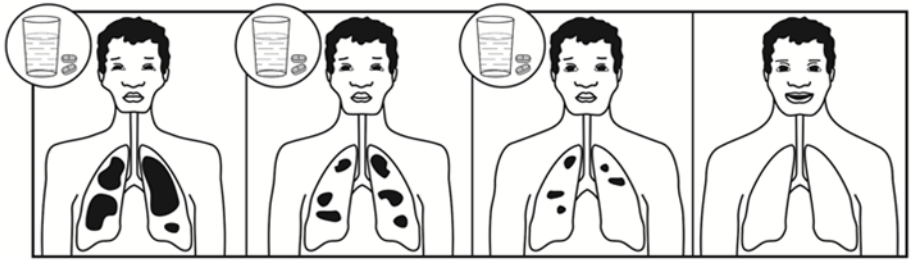
Hoekom jy jou TB medisyne moet neem

As jy jou TB medisyne **neem**



As jy **nie** jou TB medisyne neem nie





0 maande | 2 maande | 4 maande | Gesond

Neem jou TB medisyne vir 6 maande of vir so lank as wat daar vir jou gesê word om dit te neem sodat jou TB gesond gemaak kan word

Moenie ophou om jou TB medisyne te gebruik nie, selfs al begin jy beter voel

Voordat jy begin om jou TB medisyne te gebruik

Vertel vir jou gesondheidswerker indien jy:

- ander medisynes gebruik
- allergies is vir enigiets
- swanger is, op die oomblik probeer om swanger te word of besig is om jou baba met die bors te voed
- besig is om die geboorte beperkings pil te gebruik of vir inspuitings gaan om nie swanger te raak nie
- indien jy MIV positief is

Hoe om jou TB medisyne te neem

Neem jou medisyne elke dag op **dieselfde tyd**

Jy kan jou TB medisyne neem...

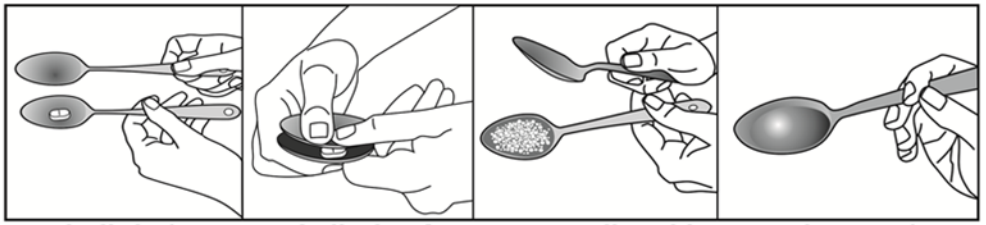
Met kos

OF

Sonder kos

Indien jy **vergeet** om jou TB medisyne te neem, doen dit so gou as wat jy daarvan

Indien dit moeilik is om die tablette in te sluk



Sit dit in 'n teelepel | **Druk dit dan fyn met 'n ander teelepel** | **Meng die table se poeier met 'n bietjie water, sap, konfyt of jogurt voor jy dit eet**

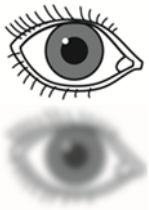
Newe effekte

Newe effekte is ongewone reaksies wat met jou kan gebeur terwyl jy medisyne gebruik, maar dit kan behandel word

Vertel 'n gesondheidswerker by die kliniek indien jy enige van die volgende newe effekte kry:

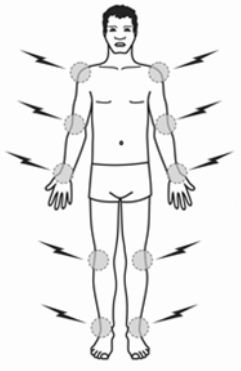
Opgooi

Veluitslag



Nie meer helder kan sien nie

Hande en voete wat jeuk, brand of seer is (soos naalde en spelde)



Seer gewrigte

Dronk voel of duiselig

Jou spiere swak voel

Gaan so gou moontlik kliniek toe indien die volgende met jou gebeur:

Maagpyn, naar voel en opgooi

Koors en 'n erge uitslag op jou lyf

Terwyl jy TB medisyne gebruik, mag jy nie die volgende doen nie

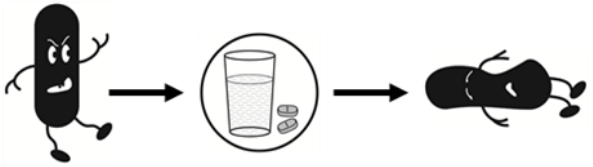
Moenie jou medisyne met iemand anders deel nie

Moenie rook nie

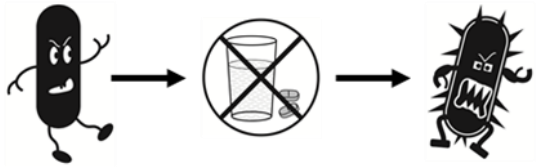
Moenie alkohol gebruik nie

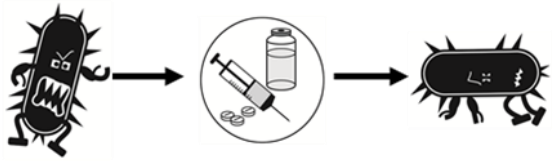
MDR-TB en XDR-TB

Wanneer jy jou medisyne op die **regter manier** gebruik…



Wanneer jy **nie** jou medisyne op die **regte manier gebruik nie**…





TB en MIV

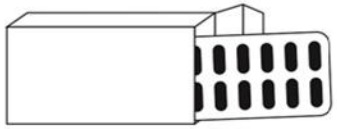
- As jy TB het, beteken dit nie dat jy MIV positief is nie
- Selfs al is jy MIV positief, kan TB gesond gemaak word
- Almal wat MIV positief is moet gereeld getoets word vir TB
- Vertel jou gesondheidswerker as jy medisyne teen MIV en teen TB gebruik, hulle sal jou kan help om die newe-effekte te behandel

USAID FROM THE AMERICAN PEOPLE | TUBERCULOSIS PROGRAM SOUTH AFRICA

FIRST-LINE TB MEDICINES

RHODES UNIVERSITY
Faculty of Pharmacy, Rhodes University, Grahamstown 6139. Tel : 046 603 8381.

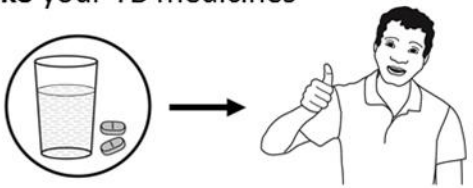
Name of your TB medicine



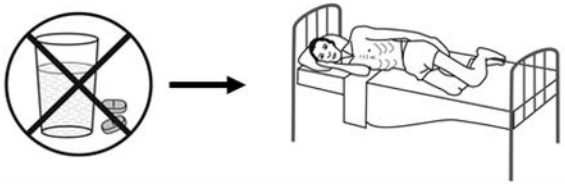
Rifafour® - First 2-3 months
Rifinah® - Next 4 months

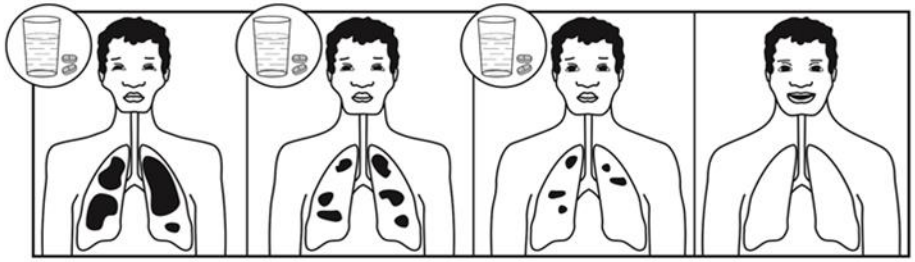
Why you must take your TB medicines

If you **take** your TB medicines



If you **do not** take your TB medicines





0 months | 2 months | 4 months | Cured

Take your TB medicine for 6 months or as long as you are told to, so that your TB can be cured

Do not stop taking your TB medicines even if you feel better

Before starting your TB medicines

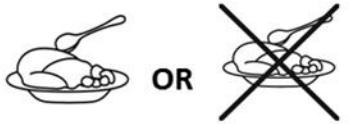
Tell your healthcare provider if you:

- are taking any other medicines
- have any allergies
- are pregnant, breast feeding or trying to fall pregnant
- are on a oral contraceptive or injectable contraceptive
- if you are HIV positive

How to take your TB medicine

Take your medicine at the **same time** every day

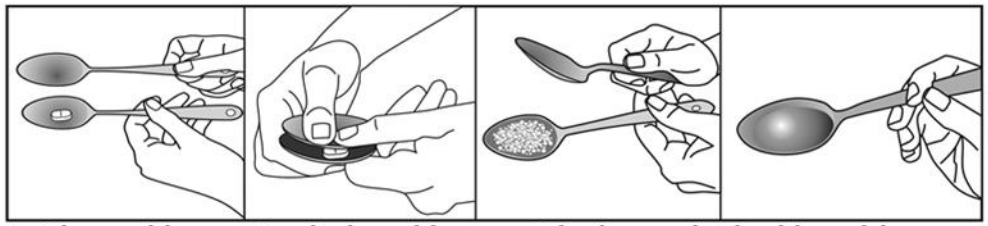
You can take your TB medicine...



With food **OR** **Without food**

If you **forget to take** your TB medicine, take it as soon as you remember

If you find it difficult to swallow your tablets



Place tablet on a spoon | **Crush the tablet between the spoons** | **Mix the crushed tablet with a small amount of water, juice, jam or yoghurt before you take it**

Side-effects

Side-effects are unusual effects that may appear when you are taking medicines, but they can be managed and treated

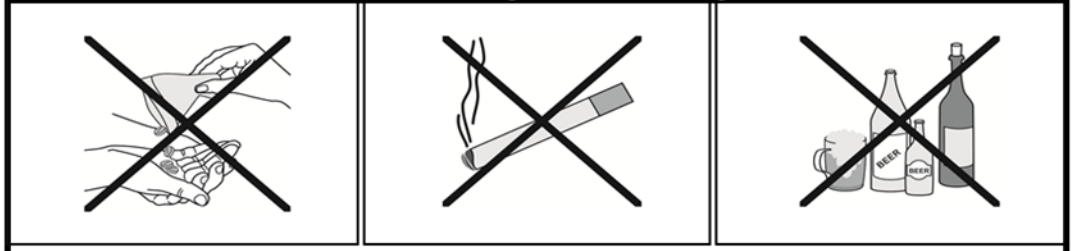
If you experience any of these side-effects tell the healthcare provider at the clinic:

- Vomiting
- Skin rash
- Blurred vision
- Tingling, burning or pain in the hands and feet (pins and needles)
- Joint pain
- Dizziness
- Muscle weakness

Go to the clinic as soon as you can if you have:

- Stomach pain, nausea and vomiting
- Severe rash on your body and a fever

You must not do the following when taking TB treatment

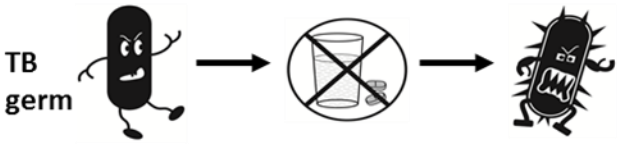


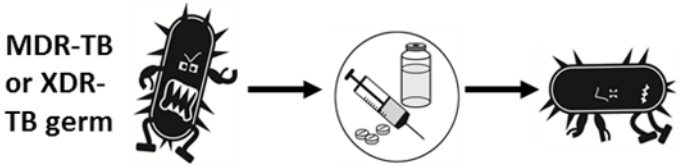
Do not share medicines | **Do not smoke** | **Do not drink alcohol**

MDR-TB and XDR-TB

If you take your medicine **correctly**...

If you **do not take** your medicine correctly...





TB and HIV

- Having TB does not mean that you will test HIV-positive
- Even if you are HIV positive, TB can be cured
- All HIV-infected people should get tested for TB on a regular basis
- If you take medicines for HIV and TB, tell your healthcare provider so that they can help you manage side-effects

TB can be cured if you take your TB medicines correctly

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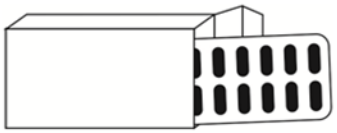
IIPILISI ZOKUQALA E-TB

RHODES UNIVERSITY
Faculty of Pharmacy, Rhodes University, Grahamstown 6139. Tel : 046 603 8381.

Igama leyeza zakho leTB

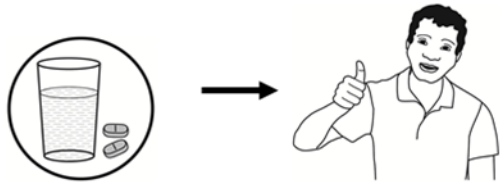


Rifafour® - iinyanga zokuqala ezi-2
ukuya kwezi-3

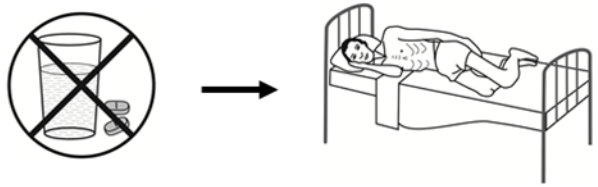
Rifinah® - iinyanga ezi-4 ezilandelayo

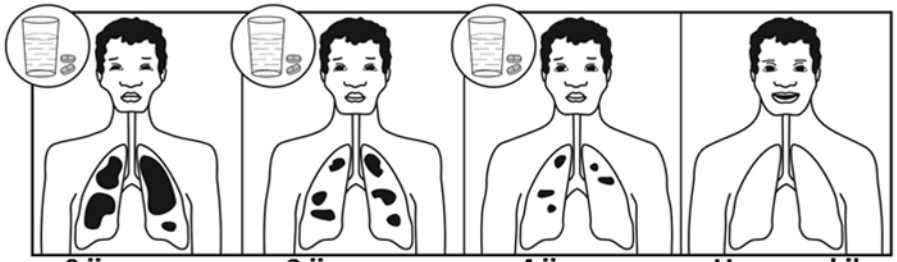
Kutheni le nto kufuneka uthathe iipilisi zeTB?

Ukuba uya **zithatha** iipilisi zakho zeTB



Ukuba **akuzithathi** iipilisi zakho zeTB





0 iinyanga | 2 iinyanga | 4 iinyanga | Unyangekile

Thatha iipilisi zakho eTB iinyanga ezi-6, okanye kangongakuba uxelelwa, ukuze iTB inyangeke
Musa ukuyeka ukuzithatha iipilisi zakho zeTB nokuba sele uziva ngcono

Phambi kokuba uqale ukusebenzisa iipilisi zakho zeTB

Xelela unompilo wakho ukuba:

- kukho ezinye iipilisi ozisebenzisayo
- kukho iipilisi ezingavani nomzimba wakho
- ukhulelwe, uyancancisa okanye uzama ukukhulelwa
- usebenzisa iipilisi okanye isitofu ukucwangcisa
- ukuba uHIV

Indlela yokuthatha iipilisi zakho zeTB

Zithathe iipilisi zakho **ngexesha elinye** yonke imihla

Ungazithatha iipilisi zakho zeTB...

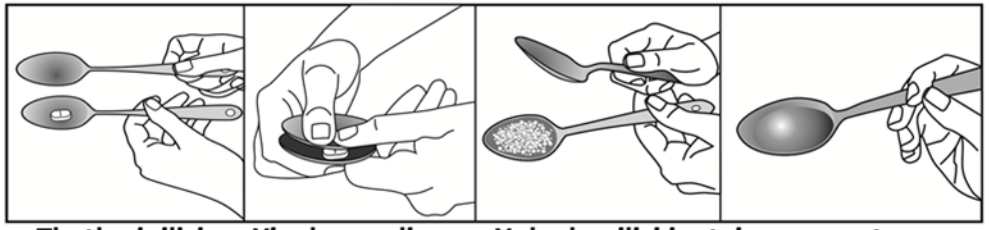
Emva kokutya

OKANYE

Ngaphandle kokutya

Ukuba **uye walibala** ukuzithatha ipilisi zakho zeTB, zithathe ngokukhawulez a wakube ukhumbule

Ukuba ufumanisa kunzima ukuzisela ipilisi



Thatha ipilisi uyibeke ecepheni | **Yigube ngelinye icephe** | **Xuba le pilisi igutyiweyo nentwana yamanzi, ijusi, ijemu okanye neyogathi phambi kokuba uyisele**

Izinto ezinokubangwa zipilisi

Amangenelela angaqhelekanga kunokwenzeka avele xa usebenzisa iipilisi kodwa ke ayalawuleka kwaye ayanyangeka

Ukuba uthi ufumane ezi zinto zisecaleni, mxelele unompilo wakho ekliniki:

- Ukugabha
- Irhashalala
- Ukubona luzizi
- Ukuntlontlozela, ukutshisa okanye iintlungu ezandleni nasezinyaweni
- Iintlungu apho andibana khona amalungu omzimba
- Isiyezi
- Ukutyhafa kwezihlunu

Yiya ekliniki ngokukhawuleza xa unezi zinto zilandelayo:

- Isisu esilumayo, isicaphu-caphu nokugabha
- Irhashalala embi emzimbeni, kunye nomkhuhlane

Kufuneka ungazenzi ezi zinto zilandelayo xa uthatha iipilisi zeTB

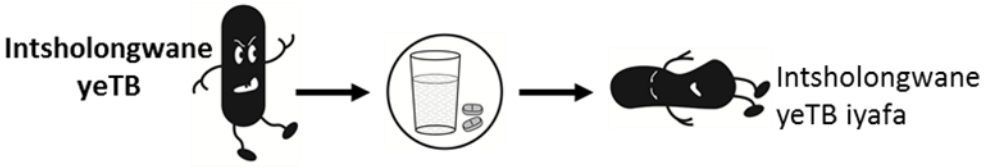
Musa ukunikisa ngepilisi zakho kwabanye abantu

Musa ukutshaya

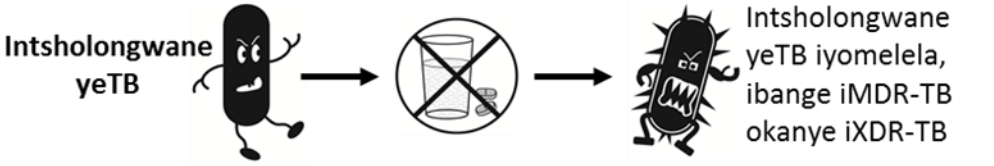
Musa ukusela utywala

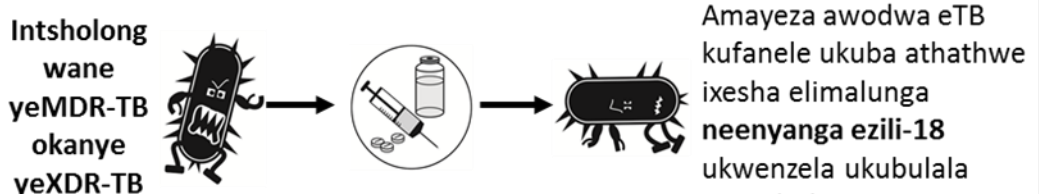
I-MDR-TB ne-XDR-TB

Xa uzithatha iipilisi zakho **ngokufanelekileyo…**



Ukuba **akuzithathi** ngokufanelekileyo iipilisi zakho…





I-TB ne-HIV

- Xa uneTB loo nto ayithethi ukuba uya kuba neHIV xa uthe wahlolelwa yona
- Nokuba unayo iHIV, iTB inako ukunyangeka
- Bonke abantu abosuleleke yiHIV kumele bayokwenza uvavanyo lwe TB rhoqo
- Ukuba uthatha amayeza eHIV neTB kuyakufuneka umazise unompilo wakho ukwenzela akuncede ukulawula amangenelela anokuthi avele

iTB iyanyangeka ukuba usebenzisa iipilisi zakho ngendlela

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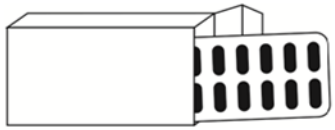
EERSTE LINIE TB MEDISYNE

RHODES UNIVERSITY
Faculty of Pharmacy, Rhodes University, Grahamstown 6139. Tel : 046 603 8381.

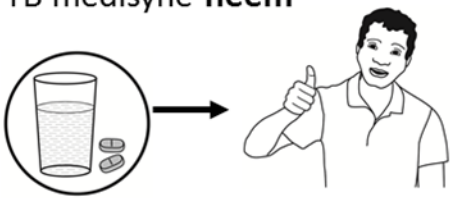
Die naam van jou TB medisyne



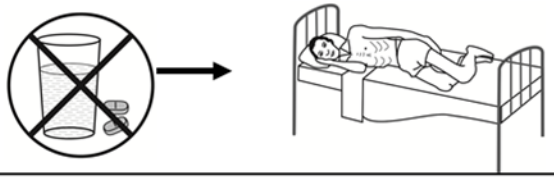
Rifafour® - Die eerste 2-3 maande
Rifinah® - Die volgende 4 maande

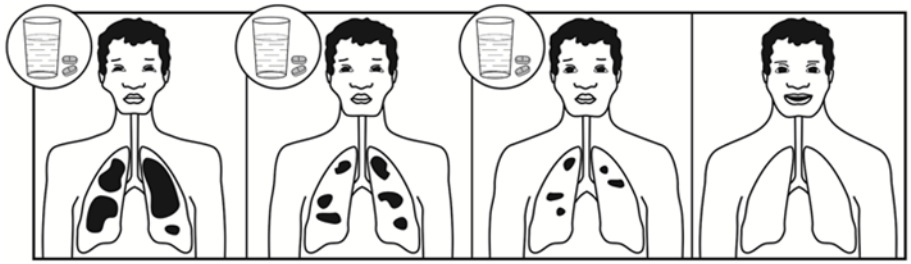
Hoekom jy jou TB medisyne moet neem

As jy jou TB medisyne **neem**



As jy **nie** jou TB medisyne neem nie





0 maande | 2 maande | 4 maande | Gesond

Neem jou TB medisyne vir 6 maande of vir so lank as wat daar vir jou gesê word om dit te neem sodat jou TB gesond gemaak kan word

Moenie ophou om jou TB medisyne te gebruik nie, selfs al begin jy beter voel

Voordat jy begin om jou TB medisyne te gebruik

Vertel vir jou gesondheidswerker indien jy:

- ander medisynes gebruik
- allergies is vir enigiets
- swanger is, op die oomblik probeer om swanger te word of besig is om jou baba met die bors te voed
- besig is om die geboorte beperkings pil te gebruik of vir inspuitings gaan om nie swanger te raak nie
- indien jy MIV positief is

Hoe om jou TB medisyne te neem

Neem jou medisyne elke dag op **dieselfde tyd**

Jy kan jou TB medisyne neem...

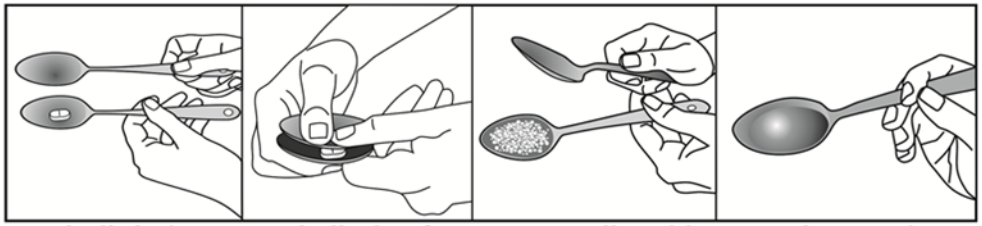
Met kos

OF

Sonder kos

Indien jy **vergeet** om jou TB medisyne te neem, doen dit so gou as wat jy daarvan

Indien dit moeilik is om die tablette in te sluk



Sit dit in 'n teelepel | **Druk dit dan fyn met 'n ander teelepel** | **Meng die table se poeier met 'n bietjie water, sap, konfyt of jogurt voor jy dit eet**

Newe effekte

Newe effekte is ongewone reaksies wat met jou kan gebeur terwyl jy medisyne gebruik, maar dit kan behandel word

Vertel 'n gesondheidswerker by die kliniek indien jy enige van die volgende newe effekte kry:

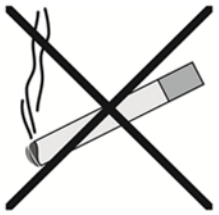
- Opgooi
- Veluitslag
- Nie meer helder kan sien nie
- Hande en voete wat jeuk, brand of seer is (soos naalde en spelde)
- Seer gewrigte
- Dronk voel of duiselig
- Jou spiere swak voel

Gaan so gou moontlik kliniek toe indien die volgende met jou gebeur:

- Maagpyn, naar voel en opgooi
- Koors en 'n erge uitslag op jou lyf

Terwyl jy TB medisyne gebruik, mag jy nie die volgende doen nie

Moenie jou medisyne met iemand anders deel

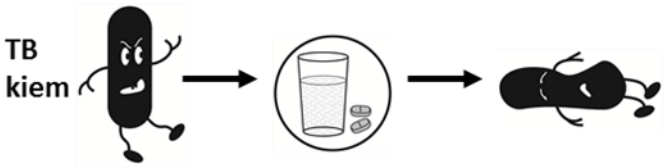


Moenie rook nie

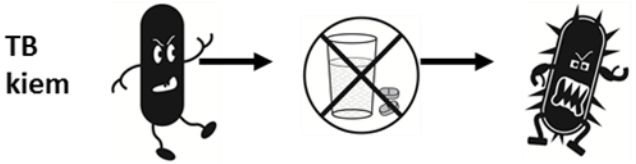
Moenie alkohol gebruik nie

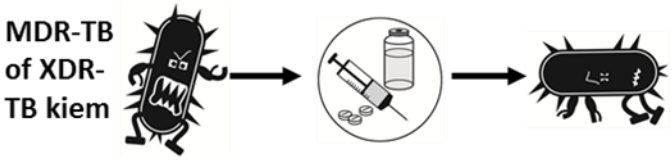
MDR-TB en XDR-TB

Wanneer jy jou medisyne op die **regter manier** gebruik…



Wanneer jy **nie** jou medisyne op die **regte manier gebruik nie**…





TB en MIV

- As jy TB het, beteken dit nie dat jy MIV positief is nie
- Selfs al is jy MIV positief, kan TB gesond gemaak word
- Almal wat MIV positief is moet gereeld getoets word vir TB
- Vertel jou gesondheidswerker as jy medisyne teen MIV en teen TB gebruik, hulle sal jou kan help om die newe-effekte te behandel

TB kan genees word as jy jou TB medisyne korrek

APPENDIX D

DATA COLLECTION TOOLS FOR MLT VALIDATION STUDY

CIPLOXX 250 (28 tablets)

Take two tablets twice a day with a full glass of water. The medicine may be taken with or without food. Take the medicine at the same time every day. Do not drink or eat dairy products or antacids less than two hours before or after taking the medicine. This medicine may lead to drowsiness, especially when taken with alcohol. Complete the course. Store in a cool place, away from children.

CIPLOXX 250 (iipilisi ezingama-28)

Thatha iipilisi zibe mbini kabini ngemini, uzisele ngeglasi yamanzi. Zingathathwa nokuba utyile okanye awutyanga. Zithathe ipilisi ngexesha elinye yonke imihla. Musa ukusela okanye utye izinto ezenziwe ngobisi okanye iyeza elinyanga isitchisa(antacids) kwiiyure ezimbini phambi okanye emva kokuzithatha iipilisi. Ezi pilisi zingabanga ukuba wozele, ingakumbi xa ziselwa kunye notywala. Zisele zide ziphele. Zigcine kwindawo eyomileyo, kude nabantwana.

CIPLOXX 250 (28 tablette)

Neem twee tablette twee maal per dag met ’n glas vol water. Die medisyne kan met of sonder kos geneem word. Neem die medisyne elke dag op dieselfde tyd. Moenie enige melkprodukte of teensuurmiddels (vir sooibrand) gebruik twee ure voor of nadat jy die tablette geneem het nie. Hierdie medisyne mag tot lomerigheid lei, veral as dit saam met al.kohol ingeneem word. Voltooi die kursus. Stoor in ‘n koel plek en hou buite bereik van kinders.

QUESTIONNAIRE – 2014

Health Literacy Testing in a Xhosa population

Sarah Gray & Chipiwa Marimwe: 4th Year project: 2014

Interviewer: _____ **Interview site:** _____

Participant: _____ **Address:** _____

Contact number: _____ _____

Date: _____ **Follow-up date:** _____

1. DEMOGRAPHICS

We would first like to ask you some questions about yourself			**Score**
1.1	**Gender**	1 = Male 2 = Female	
1.2	**Age**	1 = 18 - 29 2 = 30 - 44 3 = 45 - 59 4 = ≥60 **Number of years:**	
1.3	**Race**	1 = Black 2 = White 3 = Coloured 4 = Asian	
1.4	**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	
1.5	**Education**	1 = ≤ Grade 4 2 = Grade 5 - 7 3 = Grade 8 - 12 **Grade:** **Number of years:**	
1.6	**Are you employed?**	1 = Yes 0 = No	
1.7	**Type of employment**	1 = Not employed 2 = Predominantly manual 3 = Predominantly non-manual	
1.8	**Do you receive a government grant? If yes, what type of grant?**	1 = Yes 0 = No	
1.9	**Self-reported isiXhosa literacy**	1 = Can listen and understand 2 = Can speak 3 = Can read	
1.10	**Self-reported English literacy**	1 = Can listen and understand 2 = Can speak 3 = Can read	
1.11	**Do you have a long term health condition?**	1 = Yes 0 = No	
1.12	**How many different prescribed medicines have you taken in the past month?**		
1.13	**How often do you come to the clinic to get your medicine?**	1 = More than once a month 2 = Once a month (regular visit) 3 = Less than once a month (not regularly)	

2. MULTIDIMENSIONAL SCREENER OF FUNCTIONAL HEALTH LITERACY (MSFHL)

			Score
1.	**Educational attainment*** What grade did you complete at school? **Highest grade completed (in years)*	0 = 0–3 years 1 = 4–7 years 2 = 8–11 years 3 = ≥12 years	
2.	**Mother's educational attainment*** What grade did your mother complete at school? **Individuals who are unable to give an exact answer should be asked to make an estimation.*	0 = 0–3 years 1 = 4–7 years 2 = 8–11 years 3 = ≥12 years	
3.	**Lifetime occupation*** What sort of work/job have you done for most of your life? *******Manual occupations - do not require intensive training or supervisory elements (e.g. farming, mining, construction, manufacturing, mechanical maintenance, garden maintenance, housekeeping and cleaning). Individuals who never had a paid job score zero in this item.*	0 = Predominantly manual 1 = Predominantly non-manual	
4.	**Use of technology*** How often do you use a computer? **Desktops, laptops, and tablets should be considered computers*.	0 = Do not use computers or do it only occasionally 1 = Use computers at least once a week	
5.	**Writing** Do you have difficulties with writing that stop you from getting a better job?	0 = Difficulty with writing that have precluded participant from getting a better job 1 = No significant difficulty	
6.	**Reading*** Do you have difficulty reading the subtitles while watching a foreign movie? *NOTE: Interpreter to refer to Xhosa subtitles in English movies* **Individuals who allege they simply 'do not watch movies with subtitles' score zero in this item.*	0 = Difficulty reading the subtitles while watching a foreign movie 1= No significant difficulty	
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)			

3. MEDICINES LITERACY ASSESSMENT (MLT)

Show the medicine label and say: This is a medicine label that contains information about taking medicines. THIS IS NOT A LABEL FOR ANY MEDICINES YOU TAKE. It is a label for a medicine that some other people may take.			**Score**
	Would you like to read the label in isiXhosa or English?	0 = isiXhosa 1 = English 2 = Afrikaans	
1.	**How many tablets must be taken each time?** *Two*	0 = Incorrect 1 = Correct	
2.	**Do you have to take this medicine after eating a meal?** *No*	0 = Incorrect 1 = Correct	
3.	**What should you take this medicine with?** *A full glass of water*	0 = Incorrect 1 = Correct	
4.	**For how many days would you take this medicine?** *For seven days*	0 = Incorrect 1 = Correct	
5.	**If you take this medicine at 7pm (in the night), what times (before and after 7pm) will it be okay to drink some milk?** *5pm and 9pm*	0 = Incorrect 1 = Correct	
6.	**Would you keep any of this medicine to use if you got sick again?** *No*	0 = Incorrect 1 = Correct	
7.	**How might this medicine make you feel, especially if you take it with alcohol?** *Causes drowsiness*	0 = Incorrect 1 = Correct	
8.	**How should this medicine be stored?** *Cool place, away from children*	0 = Incorrect 1 = Correct	
	Total Score *(out of 8)* Interpretation Inadequate medicine literacy: (0-3) Marginal medicine literacy: (4-5) Adequate medicine literacy: (6-8)		
	Time taken for MLT (mins)		

4. MISCELLANEOUS QUESTIONS

			Score
1.	**How often would you need help to fill in forms like these?** *Show an example of a doctor's information form*	1 = Always 2 = Sometimes 3 = Never	
2.	**How often do you need help with reading your medicine instructions, or information leaflets about general health and medicines?** *Show 2 types of info materials and say: Here are some examples*	1 = Always 2 = Sometimes 3 = Never	
3.	**How often do you have problems learning about your medical condition because of difficulty reading information materials?**	1 = Always 2 = Sometimes 3 = Never	
Total Score *(out of 9)* Interpretation 0 - 5: Inadequate functional health literacy 6 - 7: Marginal functional health literacy 8 - 10: Adequate functional health literacy			

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 and then I will ask you some questions. You can look at the label for the answers.			**Score**
1.	**Are the pilchards (the fish) plain or is there a flavour that has been added?** *The pilchards are in a tomato sauce*	0 = Incorrect 1 = Correct	
2.	**If you eat 200g from this tin, how much of the tin will you eat?** *Half the tin*	0 = Incorrect 1 = Correct	
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?** *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 require to specify the amount of pilchards eaten)*	0 = Incorrect 1 = Correct	
4.	**Pretend that you are allergic to the following substances: penicillin, milk and gluten. Is it safe for you to eat this food?** *Yes*	0 = Incorrect 1 = Correct	
5.	**If you eat the whole can of pilchards, how many grams of carbohydrate will you eat?** *2 x 4 = 8 g*	0 = Incorrect 1 = Correct	
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?** *Because it is approved as part of the Heart and Stroke Foundation eating plan (subject must indicate text and image)*	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)	

This is the end of the first interview. I will see you again after two weeks. Thank you for your time!

TWO-WEEK FOLLOW-UP INTERVIEW

6. MEDICINES LITERACY ASSESSMENT (MLT)

Show the medicine label and say: This is a medicine label that contains information about taking medicines. THIS IS NOT A LABEL FOR ANY MEDICINES YOU TAKE. It is a label for a medicine that some other people may take.			**Score**
	Would you like to read the label in isiXhosa or English?	0 = isiXhosa 1 = English 2 = Afrikaans	
1.	**How many tablets must be taken each time?** *Two*	0 = Incorrect 1 = Correct	
2.	**Do you have to take this medicine after eating a meal?** *No*	0 = Incorrect 1 = Correct	
3.	**What should you take this medicine with?** *A full glass of water*	0 = Incorrect 1 = Correct	
4.	**For how many days would you take this medicine?** *For seven days*	0 = Incorrect 1 = Correct	
5.	**If you take this medicine at 7pm (in the night), what times (before and after 7pm) will it be okay to drink some milk?** *5pm and 9pm*	0 = Incorrect 1 = Correct	
6.	**Would you keep any of this medicine to use if you got sick again?** *No*	0 = Incorrect 1 = Correct	
7.	**How might this medicine make you feel, especially if you take it with alcohol?** *Causes drowsiness*	0 = Incorrect 1 = Correct	
8.	**How should this medicine be stored?** *Cool place, away from children*	0 = Incorrect 1 = Correct	
	Total Score *(out of 8)* Interpretation Inadequate medicine literacy: (0-3) Marginal medicine literacy: (4-5) Adequate medicine literacy: (6-8)		
	Time taken for MLT (mins)		

This is the end of the follow-up interview. Thank you for your time!

RHODES UNIVERSITY

TESTING HEALTH LITERACY IN PUBLIC SECTOR PATIENTS IN SOUTH AFRICA

My name is **Chipiwa Marimwe** and I am a 4th year pharmacy student from Rhodes University. I would like to invite you to take part in this research study. We have developed a test 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?
There will be two interviews. I will interview you with an interpreter so that you can speak in isiXhosa. This may be before you see the doctor or nurse and get your medicines, or after you have done that. The interview will last about 30-45 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. The second interview will be one week later and will only take about 15 minutes. I will ask you to read something again and ask you questions. You will be given vouchers from Shoprite to thank you for your time and for helping us, R40 – 1st interview and R20 – 2nd interview.

How will this study help patients like me?
Your answers will help us know which patients cannot understand what the doctor or nurse tells them and how to take their medicines. Once the doctor or nurse knows who these patients are, they can help those patients to look after themselves and to take medicines correctly.

Confidentiality
All the personal details you give me will be private, no-one will know your name, and I will not be able to tell anyone about information you give me 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. It will not affect the treatment you receive from the clinic or Settlers Day Hospital.

Now that you have read the information and have asked questions, and if you have decided that you would like to take 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: Chipiwa Marimwe (researcher): 078 2356859
Prof Ros Dowse (supervisor) 046 603807

RHODES UNIVERSITY

CONSENT FORM

Title of project: Testing health literacy in public sector patients in South Africa

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)

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 have been given information about the project and I understand the information. I understand that all information gathered from this research study will be kept private. I understand that I can leave the study at any time.

Signature: …….

Witness: …….

Interpreter: …….

Date: …….

APPENDIX E

DATA COLLECTION TOOLS AND CONSENT FORMS FOR RCT

QUESTIONNAIRE – 2013

TUBERCULOSIS MEDICINES: KNOWLEDGE, ATTITUDE AND PRACTICES

Sonal Patel: PhD project: 2013

Date: _____ **Interview site: _____**

Interviewer: _____ **Interpreter: _____**

Participant (surname, name): _____ **Participant number _____**

Participant address_____

Participant contact number: _____ **Follow-up date: _____**

1. DEMOGRAPHICS

We would first like to ask you some questions about yourself			***For official use only**
1.1	**Gender**	1 = Male 2 = Female	
1.2	**Age**	1=18-29 2= 30-44 3=45-59 4= ≥60 **Write number of years:**	
1.3	**Race**	1= Black 2= White 3= Coloured 4= Asian	
1.4	**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	
1.5	**Education**	1= ≤ Grade 4 2= Grade 5-7 3= Grade 8-10 **Grade: Number of yrs:**	
1.6	**Are you employed?**	1 = Yes 0 = No	
1.7	**How many people live in your house?**	Write number:	
1.8	**Is there anyone at home taking TB treatment?**	1 = Yes 0 = No	
1.9	**What is your house made of?**	1 = brick or cement block 2 = built shack (aluminium sheets) 3 = traditional mud dwelling	
1.10	**Do you have a tap with running water at your house?**	1 = Yes 0 = No	
1.11	**Do you have electricity at home?**	1 = Yes 0 = No	

1.12	**Has there ever been a time when the clinic/hospital could not supply you with your TB medicines?**	1= Yes 0= No	
1.13	**Have you ever been admitted to a hospital?** **If yes, specify why?**	1 = Yes 0 = No	

2. LITERACY ASSESSMENT

We shall give you something to read, would you prefer English or isiXhosa?				***For official use only**
2.1	**Home language**	1= Listen (verbal understanding) 2= Speak 3= Read		
2.2	**English**	1= Listen (verbal understanding) 2= Speak 3= Read		
2.3	**Can you tell me how often do you need help with reading instructions, pamphlets or other written medicines information given to you at the clinic? (Show an example)**	1= Never 2= Not often 3= Sometimes 4= Often 5= Always		
2.4	**Literacy assessment using medicine label**	0= isiXhosa 1= English 2=Afrikaans		
2.4.1	**How many tablets must be taken each time?**	0= Incorrect 1= Correct ***Two***		
2.4.2	**Do you have to take this medicine after eating a meal?**	0= Incorrect 1= Correct ***No***		
2.4.3	**What should you take this medicine with?**	0= Incorrect 1= Correct ***A FULL glass of water***		
2.4.4	**For how many days would you take this medicine?**	0= Incorrect 1= Correct ***For seven days***		
2.4.5	**If you take this medicine at 7pm (in the night), what times (before and after 7pm) will it be okay to drink some milk?**	0= Incorrect 1= Correct ***5pm and 9pm***		
2.4.6	**Would you keep any of this medicine to use if you got sick again?**	0= Incorrect 1= Correct ***No***		
2.4.7	**How might this medicine make you feel, especially if you take it with alcohol?**	0= Incorrect 1= Correct ***Causes drowsiness***		
2.4.8	**How should this medicine be stored?**	0= Incorrect 1= Correct ***Cool place, away from children***		
	LITERACY RATING		/8	%
	Interpretation: **Inadequate medicine literacy: (0-3)** **Marginal medicine literacy: (4-5)** **Adequate medicine literacy: (6-8)**			

3. CLINICAL DATA FROM HEALTH PASSPORT

3.1 Body Mass **Weight**	
3.2 Date of TB diagnosis	
3.3 Current TB medicine **Name(s):** **Daily dosage:** **Duration on medicine(s):**	
3.3 Regimen changes	
3.4 Adverse Reactions	
3.5 Chronic medication for co-morbidities or opportunistic infections **HIV + / HIV negative**	
3.6 Clinical Data (Sputum Conversion)	
3.7 Pharmacy refill dates over last 3 months **1:** **2:** **3:** **Next clinic visit:**	
Patient ability to identify tablet and specify dose (Compare with Health Passport to determine correct/incorrect)	
3.8 Can you tell me which tablet you are taking? **(Show tablets and patient to identify)**	0 = Incorrect 1 = Correct

	2= Unsure
3.9 How many tablets do you take every day?	0 = Incorrect 1 = Correct 2= Unsure

4. STIGMA AND PREVALENCE

			***For official use only**
4.1	**How do people IN YOUR FAMILY and those who live in your house treat people with TB? *(Do they speak to/ reject / avoid / support them?)***	1 = Ignored or rejected (no mention of HIV/AIDS) 2= Accepted and treated normally 3= Actively avoid them 4= Reject because person associates TB with having HIV/AIDS 5= Unsure 6= Other : _____	
4.2	**How do most people IN YOUR COMMUNITY treat people with TB? *(Do they speak to/ reject / avoid / support them?)***	1 = Ignored or rejected (no mention of HIV/AIDS) 2= Accepted and treated normally 3= Actively avoid them 4= Reject because person associates TB with having HIV/AIDS 5= Unsure 6= Other : _____	
4.3	**Who do you think can get TB? Can anybody get it or only certain people can get TB?**	0 = Anybody 1 = Unsure 2= Other: _____	
4.4	**Do you think TB is a problem and affects a lot of people in South Africa?**	1 = Yes 0 = No 2 = Unsure	
4.5	**Do you think that people can die from TB?**	1 = Yes 0 = No 2 = Unsure	

5. KNOWLEDGE ABOUT TB TREATMENT

We shall now ask you a few questions about your TB medicines. Some questions will need a yes or no response and others will require you to give the first answer that comes to your mind. If you are not sure you can say 'I am not sure'. At any point, feel free to ask us to repeat the question or to explain the question if you do not understand it.			***For official use only**
5.1	**Can TB be cured?**	0 = Incorrect 1 = Correct 2= Unsure	

		Yes	
5.2	**How can a person with TB get better?**	0 = Incorrect 1 = Correct 2= Unsure ***By taking TB medicines as they are told***	
5.3	**How long does a person with TB have to take medicines for?**	0 = Incorrect 1 = Correct 2= Unsure ***At least 6 months***	
5.4	**What is the cause of TB in the body? Is it a virus, bacteria/germ, a tokoloshe or a punishment from God?**	0 = Incorrect 1 = Correct 2= Unsure ***Germ/Bacteria***	
5.5	**What is the name/s of the medicine you are taking for TB?**	0 = Incorrect 1 = Correct 2= Unsure ****Rifafour®; Rimstar 4-FDC®, Ritib® (intensive)-*** *Rifampicin, Isoniazid, Pyrazinamide and Ethambutol* ****Rifinah® ; Rimactazid®(continuous)-****Rifampicin and Isoniazid*	
5.6	**If someone is starting to take TB medicines for the first time, what should they tell their doctor?**	0 = Incorrect 1 = Correct 2= Unsure ***Mark correct only if 2 of the options below are mentioned*** ***-are HIV positive*** ***-are taking any other medicines*** ***-have any allergies*** ***-are pregnant or trying to fall pregnant*** ***-are breastfeeding*** ***-are on an oral or injectable contraceptive***	
5.7	**If a TB patient is about to start taking TB medicines but is also taking other medicines (for example medicines to treat diabetes) what should they do?** **-Stop taking the diabetes medicines** **-Tell the HCP they are taking other medicines** **-Take the diabetes medicines only when they have finish**	0 = Incorrect 1 = Correct 2= Unsure	

	their TB medicines	***Inform their healthcare provider***			
5.8	**What serious problem (other than feeling very sick and possible death) can happen if someone does not take their TB medicine as they are supposed to?**	0 = Incorrect 1 = Correct 2= Unsure ***Development of drug resistant TB***			
5.9	**Can you take your TB medicines on an empty stomach/without food?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes*** ***If no why? Answer:***			
5.10	**When you are taking TB medicines, what things should you avoid doing?**	0 = Incorrect 1 = Correct (excessive alcohol and smoking) 2= Unsure ***Excessive alcohol and smoking***			
5.11	**TB medicines are quite big and can be difficult to swallow. If someone has difficulty swallowing their TB medicines what can they do?**	0 = Incorrect 1 = Correct 2= Unsure ***Crush them and take them with small amount of water or food***			
5.12	**Medicines help you get better. Can they sometimes have some unusual effects when you take them?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***			
	If yes: Have you had any unusual effects from taking your TB medicine?	0= No 1= Yes 2= Unsure	***If yes, what unusual effects? (Enter number allocation for question 4.14)**		
5.13	**Some people can have strange or unusual effects from taking medicines and these are called side-effects or adverse (bad) effects. Can you tell me which side-effects of TB medicines you know about?** ****Mark the mentioned options***	1= Skin rash		1= Yes	0= No
		2= Nausea		1= Yes	0= No
		3= Vomiting		1= Yes	0= No
		4= Yellow eyes or skin		1= Yes	0= No
		5= Muscle weakness		1= Yes	0= No
		6= Blurry vision		1= Yes	0= No
		7= Dizziness		1= Yes	0= No
		8= Joint pain		1= Yes	0= No
		9=Tingling, burning, numbness or pain in the hands and feet (pins and needles)		1= Yes	0= No
		10= Stomach pain		1= Yes	0= No
		11=Severe rash on body		1= Yes	0= No

		12=Fever	1= Yes	0= No	
		13= Orange urine, sweat and tears	1= Yes	0= No	
		14= Fatigue/ tiredness	1= Yes	0= No	
		Note: Mark correct only if 4 or more side effects are identified 0 = Incorrect 1 = Correct 2= Unsure			
5.14	**What should you do if you experience one or more side-effects?**	0 = Incorrect 1 = Correct 2= Unsure ***Go to the clinic and ask a health professional***			
5.15	**When should you stop taking your TB medicines?**	0 = Incorrect 1 = Correct 2= Unsure ***When you have completed your medicines and are told to stop by doctor, nurse or pharmacist at the clinic***			
5.16	**If your neighbour runs out of TB medicines, can you give him or her some of yours?**	0 = Incorrect 1 = Correct 2= Unsure ***No***			
5.17	**What should you do if you forget to take your TB medicines?**	0 = Incorrect 1 = Correct 2= Unsure ***Take it as soon as you remember***			
5.18	**Have you heard of MDR and XDR TB? What do you think MDR or XDR TB is?**	0 = Incorrect 1 = Correct 2= Unsure ***Must mention its stronger type of TB that is harder to treat***			
5.19	**Is it true that if you do not take your TB medicine correctly, you can get a stronger type of TB?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***			
5.20	**Can this stronger type of TB (MDR or XDR) be cured?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***			
5.21	**Can you use the same medicines you are taking for TB to treat this stronger type of TB (MDR and XDR TB)?**	0 = Incorrect 1 = Correct 2= Unsure ***No***			

5.22	**Do you know how long it takes to cure the stronger TB?**	0 = Incorrect 1 = Correct 2= Unsure ***18 months / 1½ years/ more than a year***	
5.23	**Does everyone who has TB also have HIV?**	0 = Incorrect 1 = Correct 2= Unsure ***No***	
5.24	**Can TB be cured if you have HIV?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***	
Total Score (out of 24)			%

6. HISB AND SOURCES OF TB MEDICINES INFORMATION

We now want to know a little bit about where you get information about your medicines and if you are happy with the information you are given?					***For official use only**
6.1	**How much do you think you know about TB? A little bit, some information, know a lot or unsure…**	1 = A little bit 2 = Do know some information 3 = Know a lot 4 = Unsure			
6.2	**Where did you get this information?**	1= Doctor	1= Yes	0= No	
		2= Nurse	1= Yes	0= No	
		3= Pharmacist	1= Yes	0= No	
		4= Religious leader	1= Yes	0= No	
		5=Tsangoma	1= Yes	0= No	
		6= Family or friends	1= Yes	0= No	
		7= School	1= Yes	0= No	
		8 =Television and radio	1= Yes	0= No	
		9 = Newspapers and magazines	1= Yes	0= No	
		10 = PILs, brochures and posters	1= Yes	0= No	
		11 = Labels on medicine containers	1= Yes	0= No	
		12 = Package insert	1= Yes	0= No	
		13= Personal experience	1= Yes	0= No	
6.3	**Do you think you know enough about your TB medicines?**	0 = No 1 = Yes 2 = Unsure 3= Other: _____			
6.4	**Do you ever ask the**	0 = No			

	nurse questions about your medicines?	1 = Yes 2 = Unsure 3= Other: _____ If yes, was this information enough? Yes/No	
6.5	**Do you know that you can ask questions about your medicines?**	0 = No 1 = Yes 2 = Unsure 3= Other: _____	
6.6	**Do the nurses ever ask you if you have any questions?**	0 = No 1 = Yes 2 = Unsure 3= Other: _____	
6.7	**Do you think that the nurses are too busy to give you answers to your questions?**	0 = No 1 = Yes 2 = Unsure 3= Other: _____	
6.8	**Would you like to learn more about TB medicines?**	0 = No 1 = Yes 2 = Unsure 3= Other: _____	
6.9	**What worries you the most when you think of taking your TB medicines?**		

7. MODIFIED VERSION OF THE 8-ITEM MORISKY SELF-REPORTED ADHERENCE SCALE

We would like to ask you some questions about the TB medicine(s) you are taking			***For official use only**
7.1	**Do you sometimes forget to take your TB medicines?**	0 = No 1 = Yes	
7.2	**Sometimes people may not forget to take their medicines but miss taking it for other reasons. Over the past month (since your last clinic visit) were there any days when you did not take your TB medicines?**	0 = No 1 = Yes	
7.3	**Have you ever reduced or stopped taking your TB medication without telling your doctor, because you felt worse when you took it?**	0 = No 1 = Yes	
7.4	**When you travel or leave home, do you sometimes forget to bring along your TB medicines?**	0 = No 1 = Yes	
7.5	**Did you take your TB medicines yesterday?**	0 = No 1 = Yes	
7.6	**When you feel healthy, do you sometimes stop taking your TB medicines before the end of the 6 months?**	0 = No 1 = Yes	

7.7	**During the last weekend, did you miss taking any of your TB medicines?**	0 = No 1 = Yes	
7.8	**Some people find having to take TB medicines everyday tiresome. Do you ever feel irritated or get cross about taking your TB medicines every day?**	0 = No 1 = Yes	

8. SELF-EFFICACY

Tuberculosis Medicines Taking Self-Efficacy Scale (TMTSES)

I will now ask you a few questions about how confident you feel about certain things that are related to taking TB medicines. This scale will help you answer the questions (holding up scale). This scale is from 1 to 5- choose a number between 1 to 5 with 1 being the lowest level of confidence and 5 being the highest level of confidence. I will show you how to use the scale by asking the interpreter a question and he/she will give an answer using the scale.

Interviewer: You have been told to take your medicine three times a day by the doctor. How confident do you feel that you can take your medicine three times a day? Are you completely certain you can do it, are you slightly certain you can do it or do you feel you are not able to do it?

Interpreter: I usually take my medicines but sometimes at lunchtime I forget to take it because I am busy with some work. So I think I am slightly certain I can take my medicines three times a day.

Did that demonstration help you understand how to reply using this scale? If yes, continue. If no, explain again.

8.1	**How confident do you feel that you can take your TB medicines every single day?**	1	2	3	4	5	
8.2	**How confident do you feel that you will be able to come to the clinic to collect your TB medicines every month?**	1	2	3	4	5	
8.3	**How confident do you feel that you can avoid alcohol when taking TB treatment?**	1	2	3	4	5	
8.4	**How confident do you feel that you can talk to your doctor/nurse/pharmacist about your TB medicines?**	1	2	3	4	5	
8.5	**How confident do you feel that you can take your TB medicines even if they make you feel a bit sick?**	1	2	3	4	5	
8.6	**How confident do you feel that you can take your TB medicines in front of other people who do not know you have TB?**	1	2	3	4	5	
8.7	**How confident do you feel that you can avoid smoking whilst taking TB treatment?**	1	2	3	4	5	
8.8	**How confident do you feel that you can take your TB medicines even if you feel better and no longer have a cough?**	1	2	3	4	5	

8.9*	**How confident do you feel that taking the TB medicines will make you get better?**	1 2 3 4 5	

***Question relates to patient perception of medicines efficacy**

9. INTERVENTION

I will now give you some information about your medicines using a patient information leaflet I have developed. Please tell me which language you would prefer the leaflet to be in? I will explain the leaflet and give you a copy of the leaflet to take home to read and use when you are at home. After one month I shall meet you again at the clinic. This is a note with the date you must come back to the clinic. I will put it in your health passport. Please do not show this leaflet to other TB patients at the clinic until our next visit. It is very important that you do this so that we can see the difference between using this leaflet and not using it.			***For official use only**
9.1	**Language of PIL that is chosen**	1= English 2= isiXhosa	
9.2	**Time taken to explain the leaflet (minutes)**		

---------- END OF BASELINE INTERVIEW ----------

POST-BASELINE INTERVIEW

Date: _____ **Interviewer: _____**

Since we last saw you…			***For official use only**
9.3	**Have you spoken to any other TB patients from this clinic?** ***If yes what did you discuss?***	0 = No 1 = Yes Response:	
9.4	**EXP: Have you shown anyone the leaflet on TB medicines?** **CTRL: Has anyone shown you a leaflet on TB medicines?**	0 = No 1 = Yes	

10. POST-BASELINE KNOWLEDGE TEST

We shall now ask you a few questions about your TB medicines. Some questions will need a yes or no response and others will require you to give the first answer that comes to your mind. If you are not sure you can say 'I am not sure'. At any point, feel free to ask us to repeat the question or to explain the question if you do not understand it.			***For official use only**
10.1	**Can TB be cured?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***	
10.2	**How can a person with TB get better?**	0 = Incorrect 1 = Correct 2= Unsure ***By taking TB medicines as they are told***	
10.3	**How long does a person with TB have to take medicines for?**	0 = Incorrect 1 = Correct 2= Unsure ***At least 6 months***	

10.4	**What is the cause of TB in the body? Is it a virus, bacteria/germ, a tokoloshe or a punishment from God?**	0 = Incorrect 1 = Correct 2= Unsure ***Germ/Bacteria***	
10.5	**What is the name/s of the medicine you are taking for TB?**	0 = Incorrect 1 = Correct 2= Unsure ****Rifafour®; Rimstar 4-FDC®, Ritib® (intensive)-*** *Rifampicin, Isoniazid, Pyrazinamide and Ethambutol* ****Rifinah® ; Rimactazid®(continuous)-****Rifampicin and Isoniazid*	
10.6	**If someone is starting to take TB medicines for the first time, what should they tell their doctor?**	0 = Incorrect 1 = Correct 2= Unsure ***Mark correct only if 2 of the options below are mentioned*** ***-are HIV positive*** ***-are taking any other medicines*** ***-have any allergies*** ***-are pregnant or trying to fall pregnant*** ***-are breastfeeding*** ***-are on an oral or injectable contraceptive***	
10.7	**If a TB patient is about to start taking TB medicines but is also taking other medicines (for example medicines to treat diabetes) what should they do?** **-Stop taking the diabetes medicines** **-Tell the HCP they are taking other medicines** **-Take the diabetes medicines only when they have finish their TB medicines**	0 = Incorrect 1 = Correct 2= Unsure ***Inform their healthcare provider***	
10.8	**What serious problem (other than feeling very sick and possible death) can happen if someone does not take their TB medicine as they are supposed to?**	0 = Incorrect 1 = Correct 2= Unsure ***Development of drug resistant TB***	
10.9	**Can you take your TB medicines on an empty stomach/without food?**	0 = Incorrect 1 = Correct 2= Unsure	

		Yes ***If no why? Answer:***			
10.10	**When you are taking TB medicines, what things should you avoid doing?**	0 = Incorrect 1 = Correct (excessive alcohol and smoking) 2= Unsure ***Excessive alcohol and smoking***			
10.11	**TB medicines are quite big and can be difficult to swallow. If someone has difficulty swallowing their TB medicines what can they do?**	0 = Incorrect 1 = Correct 2= Unsure ***Crush them and take them with small amount of water or food***			
10.12	**Medicines help you get better. Can they sometimes have some unusual effects when you take them?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***			
	If yes: Have you had any unusual effects from taking your TB medicine?	0= No 1= Yes 2= Unsure	***If yes, what unusual effects? (Enter number allocation for question 4.14)**		
10.13	**Some people can have strange effects from taking medicines and these are called side-effects or adverse (bad) effects. Can you tell me which side-effects of TB medicines you know about?** ****Mark the mentioned options***	1= Skin rash		1= Yes	0= No
		2= Nausea		1= Yes	0= No
		3= Vomiting		1= Yes	0= No
		4= Yellow eyes or skin		1= Yes	0= No
		5= Muscle weakness		1= Yes	0= No
		6= Blurry vision		1= Yes	0= No
		7= Dizziness		1= Yes	0= No
		8= Joint pain		1= Yes	0= No
		9=Tingling, burning, numbness or pain in the hands and feet (pins and needles)		1= Yes	0= No
		10= Stomach pain		1= Yes	0= No
		11=Severe rash on body		1= Yes	0= No
		12=Fever		1= Yes	0= No
		13= Orange urine, sweat and tears		1= Yes	0= No
		14= Fatigue/ tiredness		1= Yes	0= No
		Note: Mark correct only if 4 or more side effects are identified 0 = Incorrect 1 = Correct 2= Unsure			
10.14	**What should you do if you experience one or more side-effects?**	0 = Incorrect 1 = Correct 2= Unsure ***Go to the clinic and ask a health professional***			

10.15	**When should you stop taking your TB medicines?**	0 = Incorrect 1 = Correct 2= Unsure ***When you have completed your medicines and are told to stop by doctor, nurse or pharmacist at the clinic***	
10.16	**If your neighbour runs out of TB medicines, can you give him or her some of yours?**	0 = Incorrect 1 = Correct 2= Unsure ***No***	
10.17	**What should you do if you forget to take your TB medicines?**	0 = Incorrect 1 = Correct 2= Unsure ***Take it as soon as you remember***	
10.18	**Have you heard of MDR and XDR TB? What do you think MDR or XDR TB is?**	0 = Incorrect 1 = Correct 2= Unsure ***Must mention its stronger type of TB that is harder to treat***	
10.19	**Is it true that if you do not take your TB medicine correctly, you can get a stronger type of TB?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***	
10.20	**Can this stronger type of TB (MDR or XDR) be cured?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***	
10.21	**Can you use the same medicines you are taking for TB to treat this stronger type of TB (MDR and XDR TB)?**	0 = Incorrect 1 = Correct 2= Unsure ***No***	
10.22	**Do you know how long it takes to cure the stronger TB?**	0 = Incorrect 1 = Correct 2= Unsure ***18 months / 1½ years/ more than a year***	
10.23	**Does everyone who has TB also have HIV?**	0 = Incorrect 1 = Correct 2= Unsure ***No***	

10.24	**Can TB be cured if you have HIV?**	0 = Incorrect 1 = Correct 2= Unsure ***Yes***	
Total Score (out of 24)			%

11. MODIFIED VERSION OF THE 8-ITEM MORISKY SELF-REPORTED ADHERENCE SCALE

We would like to ask you some questions about the TB medicine(s) you are taking			***For official use only**
11.1	**Do you sometimes forget to take your TB medicines?**	0 = No 1 = Yes	
11.2	**Sometimes people may not forget to take their medicines but miss taking it for other reasons. Over the past month (since your last clinic visit) were there any days when you did not take your TB medicines?**	0 = No 1 = Yes	
11.3	**Have you ever reduced or stopped taking your TB medication without telling your doctor, because you felt worse when you took it?**	0 = No 1 = Yes	
11.4	**When you travel or leave home, do you sometimes forget to bring along your TB medicines?**	0 = No 1 = Yes	
11.5	**Did you take your TB medicines yesterday?**	0 = No 1 = Yes	
11.6	**When you feel healthy, do you sometimes stop taking your TB medicines before the end of the 6 months?**	0 = No 1 = Yes	
11.7	**During last weekend, did you miss taking any of your TB medicines?**	0 = No 1 = Yes	
11.8	**Some people find having to take TB medicines everyday tiresome. Do you ever feel irritated or get cross about taking your TB medicines every day?**	0 = No 1 = Yes	

12. SELF-EFFICACY

Tuberculosis Medicines Taking Self-Efficacy Scale (TMTSES)

I will now ask you a few questions about how confident you feel about certain things that are related to taking TB medicines. This scale will help you answer the questions (holding up scale). This scale is from 1 to 5- choose a number between 1 to 5 with 1 being the lowest level of confidence and 5 being the highest level of confidence. I will show you how to use the scale by asking the interpreter a question and he/she will give an answer using the scale.

Interviewer: You have been told to take your medicine three times a day by the doctor. How confident do you feel that you can take your medicine three times a day? Are you completely certain you can do it, are you slightly certain you can do it or do you feel you are not able to do it?

Interpreter: I usually take my medicines but sometimes at lunchtime I forget to take it because I am busy with some work. So I think I am slightly certain I can take my medicines three times a day. Did that demonstration help you understand how to reply using this scale? If yes, continue. If no, explain again.							
12.1	**How confident do you feel that you can take your TB medicines every single day?**	1	2	3	4	5	
12.2	**How confident do you feel that you will be able to come to the clinic to collect your TB medicines every month?**	1	2	3	4	5	
12.3	**How confident do you feel that you can avoid alcohol when taking TB treatment?**	1	2	3	4	5	
12.4	**How confident do you feel that you can talk to your doctor/nurse/pharmacist about your TB medicines?**	1	2	3	4	5	
12.5	**How confident do you feel that you can take your TB medicines even if they make you feel a bit sick?**	1	2	3	4	5	
12.6	**How confident do you feel that you can take your TB medicines in front of other people who do not know you have TB?**	1	2	3	4	5	
12.7	**How confident do you feel that you can avoid smoking whilst taking TB treatment?**	1	2	3	4	5	
12.8	**How confident do you feel that you can take your TB medicines even if you feel better and no longer have a cough?**	1	2	3	4	5	
12.9	**How confident do you feel that taking the TB medicines will make you get better?**	1	2	3	4	5	

13. ACCEPTABILITY AND USEFULNESS OF PIL

ONLY EXP GROUP: We want to find out from you what you think of the PIL we gave you to use a month ago. Don't feel that you have say nice things about it. We need you and what you say to help us make the PIL better for you and other people.			
13.1	**Did you use the PIL in the last month?** **If yes, how often did you use it?**	0= No 1= Yes	
13.2	**What information did you find useful?** **If ALL INFO is the response, then ask: what was the MOST useful?**		
13.3	**What did you find least useful?**		

13.4	**Is there any other information you would like to see in the leaflet?** **If yes, what information?**	0= No 1= Yes	
13.5	**Did the PIL help you to know more about your TB medicines?**	0= No 1= Yes	
13.6	**Did any of your family members or friends read the PIL?**	1= Yes 0= No	
13.7	**Did any family member or friend want a copy of the PIL for themselves?**	1= Yes 0= No	
Reported understanding of text			
13.8	**Are there any words in the PIL that you did not understand?**	Number of words	
	Which words did you not understand?		
13.9	**Was there any information that was confusing or hard to understand?**		
Evaluation of pictograms			
13.10	**Do you like having pictures on the leaflet?**	1= Yes 0= No	
13.11	**Do you think the pictures help you understand and remember the information about your medicines?**	1= Yes 0= No	
13.12	**Were there any pictures that were confusing?**	Number of pictures	
BOTH THE CONTROL AND EXPERIMENTAL GROUPS: TESTING THE PICTOGRAMS			
13.13	Can you explain what each picture means:		
	Pictogram:	1= Correct	

		0=Incorrect	
	Pictogram:	1= Correct 0=Incorrect	
	Pictogram:	1= Correct 0=Incorrect	
	Pictogram:	1= Correct 0=Incorrect	
	Pictogram:	1= Correct 0=Incorrect	
	Pictogram:	1= Correct 0=Incorrect	
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	Pictogram:	1= Correct 0=Incorrect	
	Pictogram:	1= Correct 0=Incorrect	
	Pictogram:	1= Correct 0=Incorrect	
Show the CTRL Group the PIL and explain; EXP group continue with questions below			

13.14	**This is an example of a package insert (PI). You may have seen it in the box with your TB medicines?** **If you had to choose between the PIL and the PI, which would you prefer?**	1= PIL 0 =PI			
	Why do you prefer this one?				
13.15	**Do you think it would be useful to give a new TB patient this PIL?**	1=Yes 0= No			
13.16	**I have two PILs- one with pictures of the side-effects to look out for and one without pictures of the side-effects. Which PIL would you prefer?**	1= PIL with side-effect pictograms 0= PIL without side-effect pictograms			
13.17	**Do you think patients will see the side-effect pictograms and get scared to take the treatment?**	1= Yes 2= No			
13.18	**What do you think is a good way to learn more about TB medicines?**	1 = Posters in the clinics	1= Yes	0= No	
		2 = Leaflets from the clinic to take home	1= Yes	0= No	
		3 = Group education at the clinic	1= Yes	0= No	
		4 = Radio programmes	1= Yes	0= No	

This is the end of the interview. Thank you for your time!

RHODES UNIVERSITY

DEVELOPMENT OF MEDICINES INFORMATION FOR TB PATIENTS

My name is **Sonal Patel** and I am a postgraduate student from the Faculty of Pharmacy, Rhodes University, Grahamstown, South Africa. I would like to invite you to take part in a research study which involves the development of medicines information to help patients take their TB medicines. This consent form gives detailed information about the research study. Once you have read and understood the information in this form, you may ask me any questions. I will then ask you to sign this form if you wish to take part.

WHY ARE WE DOING THIS RESEARCH?

The purpose of my research is to develop simple, easily understood, attractive and user- friendly medicines information for TB patients. My aim is to find out if the information I have designed will help patients understand their TB medicines. I would like to know how good the patient information leaflet is at improving your knowledge about your condition and its treatment and whether you like it or think it is a good idea to have in clinics and hospitals.

I am looking for patients aged 18 years or above who speak either isiXhosa, have a maximum of 10 years of formal schooling, and are taking first-line TB medicines (Rifampicin, Isoniazid, Pyrazinamide and Ethambutol) for between one and three months. You should be able to read at least some English, isiXhosa. If you have received any additional formal TB education besides the standard TB care provided at the clinic, for example workshops or group education on TB, unfortunately, you will not be able to take part in the study.

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. You will first see the doctor/nurse and pharmacist, and then you will see me, Sonal Patel.

The interviews will take about 45 minutes. In the interview I will firstly ask you some questions about yourself and your thoughts about general TB. Thereafter I will ask you questions about your TB medicines. Some of you will receive a patient information leaflet on TB medicines and others will receive standard care as provided at the clinic. If you do not receive a patient information leaflet in the first interview, it will be made available to you in the second interview. You will be given a date to

come back after a month for a second interview. I will again ask you questions about your TB medicines.

HOW WILL THIS STUDY HELP TB PATIENTS?

You will not receive any remuneration, however, your responses will help me improve the medicines information I have developed for TB patients. We would like to have this patient information leaflet given out at other clinics and hospitals so that TB patients like you can learn and understand more about your medicines.

All your details will be kept confidential – this means that I will not tell anyone your name or personal details, and none of this information will appear in the published results from this study.

We would also require your health passport to obtain some information about your health and medicines namely height, weight, bad reactions to medicines, changes in treatment, laboratory results and pharmacy refill dates. This information will also be kept confidential.

*Ethical approval has been obtained from the Rhodes University Ethics Standards Committee and the National Department of Health.

DO YOU HAVE THE RIGHT TO REFUSE OR LEAVE THE DISCUSSION?

If you do not wish to take part in the interview you have the right to refuse. If you take part in the interview, you have the right to leave the interview at any time.

FINAL STEP

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

CONTACT DETAILS:

Researcher: Ms Sonal Patel Cellphone: 072 696 1612
Supervisor: Prof Ros Dowse Cellphone: 083 556 9796

RHODES UNIVERSITY

DEVELOPMENT OF MEDICINES INFORMATION FOR TB PATIENTS

CONSENT

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

Signature: ……(researcher)

Signature: ……(interpreter)

PARTICIPANT TO BE INTERVIEWED:

I, …… would like to take part in this research study.

I give permission to **Sonal Patel** (the researcher) and..... (the interpreter) to ask the necessary questions.

I understand that I am able to withdraw from this research study at any stage.

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

Signature: …….

Witness: …….

Date: …….