

**ILLUSTRATED MEDICINES INFORMATION FOR HIV/AIDS  
PATIENTS: INFLUENCE ON ADHERENCE, SELF-  
EFFICACY AND HEALTH OUTCOMES**

A Thesis Submitted to Rhodes University of the Requirements for the Degree of

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by

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## ABSTRACT

South Africa has an estimated 920 000 patients on antiretrovirals (ARVs), the largest number of patients in any country. ARV therapy demands adherence levels in excess of 95% to avoid development of drug resistance, but adherence to ARV therapy is estimated to be only between 50% and 70%. Poor medication adherence is acknowledged as a major public health problem, reducing the effectiveness of therapy and promoting resistance to ARVs. More than two thirds of the South African population have marginal reading skills and this significantly influences a patient's ability to read and understand health-related information. Patient education materials tailored for the South African population could be a useful aid in facilitating communication with patients and perhaps impact positively on their medicine-taking behaviour. This behaviour is influenced by patient knowledge, beliefs, attitudes and expectations and includes self-management, self-efficacy and adherence. Self-efficacy, which refers to patient confidence in the ability to self-manage medicine taking, is a key factor influencing adherence.

This study aimed to develop illustrated patient information leaflets (PILs) and medicine labels for all first-line ARV regimens used in the public health sector in South Africa and, using a randomised control study design, to investigate the impact of these illustrated information materials on knowledge, medication-taking behaviours and health outcomes in HIV/AIDS patients taking ARVs. To achieve this aim, the objectives were to assess HIV/AIDS and ARV-related knowledge, as well as self-efficacy and adherence to ARV therapy; to assess the influence of demographic variables on knowledge, adherence and self-efficacy; to assess the influence of the information materials on knowledge, self-efficacy and adherence and to assess the association of knowledge with health outcomes.

Medicine labels and PILs, both English and isiXhosa, were developed for ARV regimens 1a, 1b, 1c and 1d. The 8-item Morisky Medication Adherence Scale (MMAS-8) and HIV Treatment Adherence Self Efficacy Scale (HIV-ASES) instruments for measuring respectively adherence and self-efficacy, were modified to optimize clarity, simplicity and cultural acceptability and were translated into isiXhosa using a multi-stage translation-back translation. The questions and the rating scales, for both the MMAS and HIV-ASES, underwent preliminary qualitative evaluation in focus group discussions. Patients were recruited from local Grahamstown clinics. A pilot study to evaluate applicability of the

instruments was conducted in 16 isiXhosa AIDS patients on ARVs and the results from this study informed further modifications to the instruments.

One hundred and seventeen patients were recruited for the randomised control trial and were randomly allocated to either control group (who received standard care) or experimental group (who received standard care as well as pictogram medicine labels and the illustrated PIL). Interviews were conducted at baseline and at one, three and six months. Data were analysed statistically using the t-test, chi-squared test and ANOVA (Analysis of Variance) at a 5% level of significance. Correlations were determined using Pearson and Spearman rho correlations. Approval was obtained from Rhodes University Ethical Standards Committee, Settlers Hospital Ethics committee and the Eastern Cape Department of Health.

The results of this research showed that illustrated PILs and medicine labels enhanced understanding of HIV/AIDS and ARV information, resulting in a mean overall knowledge score in the experimental group of 96%, which was significantly higher than the 75% measured in the control group. Variable knowledge scores were measured in three areas: baseline knowledge of general HIV/AIDS-related information was good at 87%, whereas knowledge scores relating to ARV-related information (60%) and side-effects (52%) were lower. These scores improved significantly in the experimental group over the 4 interviews during the 6 month trial duration, whereas in the control group, they fluctuated only slightly around the original baseline score.

There was no significant influence of gender on knowledge score, whereas health literacy, education level and age tested (at one and three months) had a significant influence on knowledge. Self-efficacy and adherence results were high, indicating that the patients have confidence in their ability to adhere to the ARV therapy and to practice optimal self-care. Age, gender and education, in most cases, significantly influenced self-efficacy, but were found to have no effect on adherence. The CD4 count improved over the trial duration which may have been influenced by a number of factors, including better knowledge of ARVs and improved adherence. No significant parametric correlation was found between knowledge score and change in CD4 count, however, Spearman's rho showed significance ( $r_s=0.498$ ;  $p=0.022$ ).

Both patients and healthcare providers were highly enthusiastic about the illustrated labels and PILs, and indicated their desire for such materials to be routinely available to public sector HIV/AIDS patients. The isiXhosa version of the PIL was preferred by all the patients. These simple, easy-to-read leaflets and illustrated medication labels were shown to increase understanding and knowledge of ARVs and HIV/AIDS in low-literate patients, and their availability in the first-language of the patients was central to making them a highly useful information source.



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## LIST OF ACRONYMS

|          |  |
|----------|--|
| AIDS:    | Acquired Immunodeficiency Syndrome                                   |
| ANOVA:   | Analysis of Variance   |
| ART:     | Antiretroviral Therapy   |
| ARVs:    | Antiretroviral drugs   |
| AZT:     | Zidovudine   |
| BCC:     | Behavioural Change Communication                                     |
| d4T:     | Stavudine  |
| EFV:     | Efavirenz  |
| FGD:     | Focus Group Discussion   |
| HAART:   | Highly Active Antiretroviral Therapy                                 |
| HBM:     | Health Belief Model  |
| HCP:     | Health Care Professional   |
| HIV:     | Human Immunodeficiency Virus   |
| HIV-ASES | Human Immunodeficiency Virus Treatment Adherence Self Efficacy Scale |
| MCC:     | Medicines Control Council (South Africa)                             |
| MEMS     | Medication Electronic Monitoring Systems                             |
| MMAS-8   | 8-item Morisky Medication Adherence Scale                            |
| NLHS:    | National Laboratory Health Services                                  |
| NNRTIs:  | Non-nucleoside Reverse Transcriptase Inhibitors                      |
| NRTIs:   | Nucleoside Reverse Transcriptase Inhibitors                          |
| NVP:     | Nevirapine   |
| OTC :    | Over the counter   |
| OIs :    | Opportunistic Infections   |
| PIs :    | Package Inserts  |
| PIL :    | Patient Information Leaflet  |
| REALM :  | Rapid Estimate of Adult Literacy in Medicine                         |
| TOFHLA:  | Test of Functional Health Literacy in Adults                         |
| UNAIDS:  | Joint United Nations Programme on HIV/AIDS                           |
| UNESCO:  | United Nations Educational, Scientific and Cultural Organisation     |
| WHO:     | World Health Organisation  |
| 3TC:     | Lamivudine   |

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## **CHAPTER ONE**

### **INTRODUCTION**

#### **1.1. Background to research**

According to the *2008 Report on the Global AIDS Epidemic*, issued by the Joint United Nations programme on HIV/AIDS (UNAIDS), an estimated 33.4 million people are living with HIV/AIDS [1]. HIV/AIDS constitutes an epidemic and is one of the most serious health problems that faces South Africa, a country in which 5.21 million people are HIV-positive [2]. South Africa has the highest number of patients (920 000) on ARV therapy, which is the highest figure recorded globally [3]. ARV therapy consists of a highly complex regimen and demands a minimum of 95% adherence for success [4-6]. Adherence is estimated to range between 50% and 70% [7] and although others have suggested much higher levels [8], local doctors and pharmacists have indicated adherence as a significant problem in the study patient population.

Nonadherence may be attributed to a number of factors including poor understanding of the medical instructions, complexity of the dosage regimen and inadequate health literacy [9-13]. As for many chronic illnesses, self-efficacy is being increasingly acknowledged as a key factor in influencing adherence. Self-efficacy refers to patient confidence in his/her own ability to self-manage medicine-taking and to successfully conduct a variety of medicine-related tasks [14,15]. In South Africa, 25% of the Black population are functionally illiterate and a third of the population has received less than seven years of schooling [2]. This places a huge strain on health care providers as more time and explanation is necessary to deliver satisfactory care, including adherence counselling, as well as educating and informing patients to promote optimal medication-taking behaviour.

In South Africa, before initiation of ARV therapy, patients are required to undergo intensive counselling to ensure they understand the complexity of ARV therapy and fully appreciate the importance of adherence to ARVs for their survival. This is a time-consuming and resource-intensive process which is proving difficult for a country that is under-resourced, lacking in HCPs, access to drugs and the clinic facilities necessary to function efficiently. The only form of HIV/AIDS information currently available to patients at local clinics and

hospitals is verbal. The patient therefore receives a huge amount of information containing new, complex concepts and facts which is difficult to fully comprehend, all in a verbal form that is often easily forgotten. A permanent, written source of information may be more useful as it can be taken home and used as a reference once the patients have left the clinic. Although Regulation 10 of the Medicines and Related Substances Control Act, Act 101, has been amended [16], making the provision of patient information leaflets (PILs) mandatory for all dispensed medicines, written medicines information is still not widely available in South Africa. PILs designed and distributed by pharmaceutical manufacturers often fail to consider education, literacy skills, cultural characteristics or needs of the general South African population and are considered to be difficult to read and comprehend [17,18]. One approach to make information materials more readable and user-friendly is to include visuals, an approach that has been found to be particularly successful in low-literate users [17-20].

South Africa has a dearth of research in the field of written ARV-related information and that which is available is too complicated for low-literate patients. A need has been identified for simple illustrated ARV-related information materials to be provided to low-literate patients in South Africa and other developing countries. This study aims to address this gap by designing simple illustrated PILs and medicine labels incorporating information about the three ARVs constituting the most commonly used regimen in South Africa.

## **1.2 Study aim and objectives**

The aim of this study is to develop simple, illustrated, reader-friendly medicine labels and PILs, both in English and isiXhosa, for ARV regimens 1A, 1B, 1C and 1D, and to determine the impact of these illustrated information materials on knowledge, medication-taking behaviours and health outcomes in HIV/AIDS patient taking ARVs.

The objectives are:

- to modify tools used to measure patient behaviours, namely self-efficacy and adherence, to improve their applicability in a low literate population
- to evaluate knowledge of HIV/AIDS and ARV-related information
- to assess the influence of the illustrated information materials on knowledge, self-efficacy and adherence

- to assess the influence of demographic variables on knowledge, adherence and self-efficacy
- to assess the association of knowledge with health outcomes
- to investigate any correlations between knowledge, self-efficacy, adherence and clinical health outcomes.

### **1.3 Significance of research**

It is anticipated that this thesis will contribute to the limited body of literature describing the development and evaluation of medicines information intended for low-literate patients, as well as highlighting the role that simple, easy to read illustrated PILs and medicine labels can play in promoting optimal medicine-taking practices. It is intended that the patient information materials that are designed and tested in this study will be made available to health care providers in South Africa for dissemination to HIV/AIDS patients in their care, with a particular focus on patients attending public healthcare facilities.

Given the paucity of published literature describing the applicability of currently available instruments for assessing patient medicine-taking behaviours in populations with varying literacy and cultural characteristics, it is hoped that this study will provide insight into good practices to adopt in modifying such instruments to ensure their appropriateness and acceptability.

### **1.4 Overview of chapters**

The chapter following this introduction begins with a review of the literature of HIV/AIDS, its transmission, infection, and its impact on the South African economy. ARV therapy is reviewed and adherence to ARVs discussed. The chapter then reviews medicine-taking behaviours in two parts, focusing on adherence and self-efficacy. In the section dealing with adherence, variables influencing adherence as well as the measurement of and barriers to adherence are discussed. Literacy and health literacy is reviewed with a special focus on low-literate patients in the developing world. The review includes a synopsis of patient health-education materials and the use of visual aids and patient information leaflets.

Chapter 3 describes the modification of the HIV-ASES and the MMAS-8 used to measure medicine-taking behaviour, and presents justification for the modifications made to these tools. The pilot study to evaluate the tools is presented along with modifications based on the feedback obtained.

The focus of Chapter 4 is the randomised control trial in which the illustrated information materials are evaluated for comprehensibility and for their influence on knowledge, adherence, self-efficacy and clinical outcomes over a six-month period.

In Chapter 5, the results from the randomised control study are presented. Findings describing three different knowledge areas are reported at four different interview times. The influence of the PILs and labels on knowledge, self-efficacy, adherence and clinical outcomes is described. The chapter then presents results on the influence of age, gender and education on knowledge, self-efficacy and adherence. The acceptability of the PIL and the illustrated labels is described. Finally, correlations between knowledge, self-efficacy, adherence, and clinical health outcomes are presented.

Chapter 6 presents a general discussion, through critical analysis, of the findings and the study limitations.

Chapter 7 concludes this thesis by focusing on the practical applications and findings of the results, recommendations and suggestions for future research.

## **CHAPTER TWO**

### **LITERATURE REVIEW**

#### **2.1 Introduction**

HIV/AIDS is one of the most serious health problems facing developing countries. In this chapter an overview of the HIV/AIDS epidemic is given, including discussion of global and South African statistics. Given the number of patients estimated to be taking ARVs, ARV therapy is described, along with the commonly experienced side effects. Medicine-taking behaviours need to be strictly adhered to in ARV therapy. This chapter reviews patient behaviour in two parts, focusing on adherence and self-efficacy.

Adherence to therapy can be influenced by patient education, and as such patients need to be effectively educated on HIV/AIDS, taking into account their literacy level when designing educational material. As literacy levels throughout developing countries are poor, many patients are unable to understand much of the educational material currently available to them. In light of this, the chapter discusses literacy, focussing on health literacy as well as patient health-education materials and the use of visuals and patient information leaflets in the developing world.

#### **2.2 HIV/AIDS**

##### **2.2.1 Introduction**

The first case of Acquired Immunodeficiency Syndrome (AIDS) was reported in the United States of America (USA) in 1982 [21]. AIDS was initially reported only in homosexual men who were drug users, and was called Gay Related Immune Disease (GRID) [21]. When AIDS was reported in 1983 in women and children, it became apparent that the disease was infectious [21], was caused by a human retrovirus and could infect any person. As a result, the name was changed to Human Immunodeficiency Virus (HIV).

The first case documented in South Africa was in 1982 [21], and since then the numbers have increased dramatically. South Africa has attracted a lot of attention as not only were HIV infections increasing, but the number of deaths due to AIDS was escalating.

AIDS is a crisis in South Africa with implications not only affecting the health care sector but also having an influence on political, economic and social factors. Antiretroviral (ARV) therapy is used to treat HIV/AIDS. This consists of a complex medicine regimen which needs to be followed with 95% adherence for effective treatment [22]. The polytherapy in ARV therapy is a major contributor to the high levels of non adherence.

### **2.2.2 Estimated HIV/AIDS statistics**

An estimated 33.4 million people are living with HIV/AIDS according to the *2008 Report on Global AIDS Epidemic*, issued by the Joint United Nations programme on HIV/AIDS (UNAIDS) [1]. Of these, 31 million are adults, 15.8 are women and 2.1 million are children under 15 years of age. This figure has decreased from the estimated 36 million adults in 2003 [23]. The total number of new infections of HIV in 2008 was 2.7 million and the number of deaths reported due to AIDS was 2 million [1].

Although sub-Saharan Africa accounts for only 10% of the world's population [24], the region accounts for more than two thirds (68%) of the total number of HIV infected people, estimated at 22 million. This proportion has remained consistent from 2003 estimates [23]. In 2007, 75% of the global HIV/AIDS deaths were seen in sub-Saharan Africa [25].

In South Africa, 5.21 million people are reportedly HIV positive, with 23.6% of this number residing in the Eastern Cape [2]. Globally, South Africa is the country with the highest number of patients (920 000) on antiretroviral (ARV) therapy [2]. The reasons why this epidemic is so severe in Southern Africa are unclear, however an amalgamation of many factors may have resulted in the lack of control of HIV. These factors include [24]:

- poverty
- sexual violence
- social problems resulting from family disruptions
- women having a much lower social status than men



- migratory labour systems (studies have reported a relationship between labour migration and HIV in the Eastern Cape, resulting in an increased mortality rate [24])
- high levels of other sexually transmitted diseases.

### **2.2.3 Transmission**

HIV can be transmitted through sexual contact with an HIV infected person. Transmission also occurs through the sharing of needles and/or syringes. This is a primary risk for those who abuse drugs via methods of injection. It is very rare that HIV is transmitted through blood transfusions due to the rigorous screening of blood for HIV antibodies. HIV can be transmitted to a child born of an HIV positive mother, or after birth during breast-feeding [26].

Health care workers are at risk of acquiring HIV due to frequent exposure to needle stick injuries, which may occur if the infected blood gets into an open cut or mucous membrane [26]. Risk of environmental transmission is remote as the survival of the virus within the environment is unlikely. Transmission between household members is rare, however precautions should be taken to avoid exposure to infected blood. Hairdressers, tattoo artists, cosmetologists and massage therapists need to be aware of precautions that need to be taken in order to avoid exposure [26].

### **2.2.4 HIV infection**

Viral glycoproteins bind to the host cell's CD4 and chemokine receptors. Fusion is then preceded by entry into the host cell. Un-coating of the virus then occurs releasing copies of reverse transcriptase single-stranded HIV RNA genome into double-stranded DNA of the host cell. The viral RNA is then incorporated into the host cell genome. Gene transcription occurs by the host cell enzymes which produce viral messenger RNA. After translation, non-infectious virions bud from the host cell membrane. The virions become infectious after proteolytic cleavage [27].

The progression of HIV infection consists of six stages:

- **Stage one:** The **initial infection** (described above), involving the actual transmission of the HIV virus [28].
- **Stage two:** In the **window period**, the virus is present but is not detected by antibodies. This stage may last from a few weeks to a few months. No signs or symptoms are experienced by the patient at this time [28].
- **Stage three:** The **seroconversion period** is the stage when antibodies are produced. Most patients experience flu-like symptoms, although some may be asymptomatic. The symptoms are fever, headache, sore throat, sweating, loss of appetite and swollen lymph glands [28,29].
- **Stage four:** **Asymptomatic stage** is one in which there are no visible signs or symptoms. Antibodies are detectable, thus the patient will have a positive HIV test result. This stage can last from a few months to many years [28].
- **Stage five:** **AIDS-related complex**. This involves the development of mild opportunistic infections due to the damage already incurred by the immune system. Symptoms include flu-like symptoms, weight loss, diarrhoea, fatigue, memory loss, thrush, shingles, herpes simplex, oral hairy leukoplakia and pneumococcal pneumonia [29].
- **Stage six:** **AIDS**. The immune system has now been severely weakened and the person develops life-threatening illnesses very easily. Illnesses such as Pneumocystis Carinii Pneumonia (PCP), Kaposi's sarcoma, tuberculosis (TB), Mycobacterium Avium complex (MAC), cytomegalovirus (CMV), candidiasis, cardiomyopathy, Hodgkin's disease, varicella and histoplasmosis may be present [29].

The World Health Organisation (WHO) has developed a system of clinical staging of HIV/AIDS for HIV infection [30]. This is a method of describing people with HIV at different stages of HIV infection in accordance with their clinical symptoms. When the CD4 count of the patient drops to  $< 200$  cells/mm<sup>3</sup>, OIs (Opportunistic Infections) and neoplasms of AIDS appear, signifying the clinical AIDS stage. There are four stages of HIV infection [30].

- Clinical Stage 1: asymptomatic, normal activity
- Clinical Stage 2: symptomatic, normal activity
- Clinical Stage 3: bedridden less than 50% of the day during the last month

- Clinical stage 4: bedridden more than 50% of the day during the last month.

## 2.2.5 ARV therapy

There is no cure for HIV/AIDS, however, with the introduction of new classes of ARV drugs and their use in combination therapy, patients' lives may be extended by between 25-35 years. In 1987, zidovudine (AZT) was the first drug used to treat HIV/AIDS, and although it was found to be ineffective, it was useful in preventing mother-to-child transmission [21]. In 1996 combinations of ARVs were observed to be more effective in lowering HIV [21]. Currently the most effective treatment in HIV is the use of highly active antiretroviral therapy (HAART) [13,14]. HAART combines three or more ARVs and has been shown to decrease mortality and morbidity as well as the incidence of opportunistic infections. Guidelines suggest the use of two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) and one Protease Inhibitor or a Non-Nucleoside Reverse transcriptase Inhibitor (NNRTI). The use of two NRTIs has been clinically shown in randomised trials to improve the virologic and immunologic profile of the patient [31].

Table 2.1: Drugs used for antiretroviral therapy (ART)

| Class of drug   |  |  |  | Examples   |
|---|--|--|--|--|
| <b>Nucleoside Reverse Transcriptase Inhibitors (NRTIs)</b>      |  |  |  | Zidovudine (AZT)<br>Didanosine (ddI)<br>Stavudine (d4T)<br>Lamivudine (3TC)<br>Emtricitabine (FTC) |
| <b>Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)</b> |  |  |  | Nevirapine (NVP)<br>Efavirenz (EFV)  |
| <b>Nucleotide Reverse Transcriptase Inhibitors (NtRTIs)</b>     |  |  |  | Tenofovir (TDF)  |
| <b>Protease Inhibitors</b>                                      |  |  |  | Saquinavir<br>Ritonavir<br>Indinavir<br>Nelfinavir<br>Amprenavir                                   |
| <b>Fusion Inhibitors</b>  |  |  |  | Enfuvirtide  |
| <b>Chemokine co-receptor antagonists</b>                        |  |  |  | Maraviroc  |
| <b>Integrase Inhibitors</b>                                     |  |  |  | Raltegravir  |

According to the WHO the goals of HAART need to include the following [30]:

- **Clinical goals:** prolongation of life and the improvement of the patients' health-related quality of life.
- **Virologic goals:** stop the progression of HIV and prevent or reduce the development of any resistant strains of HIV.
- **Immunologic goals:** immune reconstitution both quantitatively and qualitatively.
- **Therapeutic goals:** using drugs with the lowest side effect profile, the rational use of ARVs and realistic adherence goals.
- **Epidemiologic goals:** a reduction of HIV transmission is the main objective.

The Director General of the WHO stated that “*Lack of access to antiretroviral therapy (ART) is a global health emergency. To deliver ART to the millions who need it we must change the way we act*” [33]. As South Africa is a developing country with constrained resources, providing large-scale ART rollout initially seemed to be almost impossible. However, in 2001 the pricing of ART decreased by 75%. Recently a court settlement between pharmaceutical industries and the South African government has further reduced the costs of ART. This reduction in cost will expand access to ART by patients in the public health sector [34].

In industrialised countries ARV management is administered by specialist physicians [32]. The care ranges from initiation onto the ARVs to clinical monitoring and resistance testing. The full range of ARVs is available to the physician, and should be used at his or her discretion. Studies have shown that patients under specialist physician care have better health outcomes than those without specialist care [32]. However, for resource-poor developing countries such as South Africa, this is an unrealistic goal. Nurse-led ARV treatment programs have been widely implemented in Africa and other poorly resourced settings. A recent comparative study between nurse- and practitioner-managed ARV delivery and care showed similar health outcomes, indicating that nurse-provided care was not inferior to that of the practitioner [32].

Globally there is an estimated shortage of 4.3 million health care professionals (HCPs) [32]. In South Africa there is one doctor to 100 000 people [32], compared with a typical developed nation such as Sweden, which has one doctor to 330 patients. This advanced level

of individualised care is therefore not attainable due to the sheer epidemic of HIV/AIDS in the country and the large number of patients requiring care.

In order to cater for the lack of HCPs and the large number of patients requiring care, the WHO proposed an approach for developing countries to follow specific protocols and regimens for all HIV/AIDS patients [30]. The regimens are simplified and there is decentralised service delivery to enable nurses to provide care to patients. The WHO suggests that developing countries select a single first-line and a limited second-line regimen for large-scale use. Only patients that do not tolerate or fail the first-line and second-line regimens should be referred for individualised care by a physician. The first-line regimens used in South Africa are listed in Table 2.2.

Table 2.2: First-line regimens used in South Africa

| Regimen   | Drugs   |
|-----------|---|
| <b>1A</b> | Stavudine (d4T) 40 mg every 12 hours<br>Lamivudine (3TC) 150 mg every 12 hours<br>Efavirenz (EFV) 600 mg at night         |
| <b>1B</b> | Stavudine (d4T) 40 mg every 12 hours<br>Lamivudine (3TC) 150 mg every 12 hours<br>Nevirapine (NVP) 200 mg every 12 hours  |
| <b>1C</b> | Zidovudine (AZT) 300mg every 12 hours<br>Lamivudine (3TC) 150 mg every 12 hours<br>Efavirenz (EFV) 600 mg at night        |
| <b>1D</b> | Zidovudine (AZT) 300mg every 12 hours<br>Lamivudine (3TC) 150 mg every 12 hours<br>Nevirapine (NVP) 200 mg every 12 hours |

In April 2010, Regimen 1a was changed to include the phasing out d4T and replacement with TDF. The regimen was amended to reduce side effects experienced with d4T, which would in turn reduce the need for treatment switches. Increased adherence is also expected given the negative perception of the side effects associated with d4T [35].

In 2009 an estimated 25 million HIV-positive people had access to ART in low- and middle-income countries [33]. In sub-Saharan Africa, the number of people taking ARVs in 2009 was estimated at 3.9 million, resulting in 37% coverage of people needing ARV treatment

[33]. In South Africa it was reported that 349 967 male patients and 649 939 female patients were taking ARVs; almost two-thirds (65%) of those taking ARVs are female [33].

### 2.2.5.1 ARV therapy in South Africa

In South Africa, ARV therapy is initiated in patients with a CD4 count  $< 200$  cells/mm<sup>3</sup> (Table 2.3), or in patients who are WHO Stage IV of the disease irrespective of CD4 count [30,35]. Before treatment can be initiated, psychosocial considerations also need to be considered. The patient must attend regular clinic visits and have continuous access to the clinic. There must be no alcohol or drug abuse. Depression should be treated. It is advised that the patient has disclosed their status, as a support group is important to the success of therapy. The patient must also demonstrate insight into the disease, have accepted it and want to take ARVs [36].

Table 2.3: Guidelines for initiation of ARV therapy [30]

| Staging  | Recommendations  |
|--|--|
| <b>WHO stage 1, 2 or 3</b>                     |  |
| CD4 count $< 200$ cells/mm <sup>3</sup>        | Treatment recommended  |
| CD4 count 200-350 cells/mm <sup>3</sup>        | Consider treatment if resources permit   |
| CD4 count $> 350$ cells/mm <sup>3</sup>        | Defer treatment  |
| <b>Severely symptomatic patient</b>            |  |
| WHO stage 4 disease excluding tuberculosis(TB) | Treatment recommended  |
| <b>Patients with tuberculosis</b>              |  |
| CD4 count $< 200$ cells/mm <sup>3</sup>        | <b>Commence ARV after 2 to 8 weeks of TB treatment</b>   |
| CD4 count $> 200$ cells/mm <sup>3</sup>        | Defer treatment until after 6 months of TB therapy completed and commence ARV according to CD4 count criteria above. |

Unless contra-indicated, all patients start therapy on:

- Stavudine (d4T) 40 mg every 12 hours (or 30 mg every 12 hours if  $< 60$  kg)
- AND**
- Lamivudine (3TC) 150 mg every 12 hours
- AND**
- Efavirenz (EFV) 600 mg at night (or 400 mg if  $< 40$  kg) **OR** Nevirapine (NVP) 200 mg daily for the first 2 weeks, increasing to 200 mg every 12 hours after this, provided the patient is of a child bearing age and not on an injectable contraception.

Patients who have been on ARV treatment and have stopped therapy need to consult an ARV expert before a treatment regimen is commenced. Those who were controlled on their ARV

should continue on the original treatment. If the treatment had failed in the past, therapy should be commenced on the appropriate drugs that they have not been exposed to before. Patients need to regularly attend monthly scheduled visits to collect medication and to be seen by the nurse to monitor drug tolerance, adverse events and adherence. A pill count should be conducted at each scheduled visit by the clinic nurse, doctor, pharmacist or therapeutic counsellor. CD4 count and viral load are done six-monthly, while patients are on Regimen 1. Patients initiated on NVP should be seen by the nurse two weeks after initiation of NVP to check for any adverse events, have alanine transaminase (ALT) tests done and have the dose checked [36].

Adherence to ARV treatment is of vital consequence as nonadherence leads to the attainment of resistant strains of the virus and limits treatment alternatives [37]. Viral mutation becomes possible - these mutations lead to drug resistance [38,39]. The general level of adherence for ARV therapy is estimated to be between 46% and 88% [40,41]. Cross resistance in ARV therapy is possible, and thus mutations that are resistant to the drugs pose a huge potential threat to the individual as well as the general public. This highlights the importance of adherence to therapy, as non adherent individuals place a strain on the pharmaceutical industry as the new drugs are of less clinical benefit [38].

### **2.2.6 Adverse effects of antiretroviral drugs**

ARVs have been associated with many adverse effects, some of which are class specific and may be intolerable to the patient. The most common side effects associated with the drugs used in the first-line regimens are listed in Table 2.4.

#### ***Lactic Acidosis***

Lactic acidosis is thought to be secondary to mitochondrial dysfunction due to NRTI treatment. Lactic acidosis is a frequently-experienced side effect, with 15-35% of the adult population being affected after the first six months of therapy [15,33]. Symptoms of mild lactic acidosis are fatigue, abdominal pain, bloating, jaundice and vomiting. A patient with a lactate level of 2-5 mmol/L should have the ARV regimen that they are currently on changed. Levels above 5 mmol/L is confirmation of lactic acidosis and in cases of levels higher than 10 mmol/L, the ARV therapy must be stopped immediately.

Table 2.4: Side effects associated with Regimen 1 ARVs [43-47]

| Drug | Side effect  | Onset of action                            | Clinical monitoring  | Patient management and counselling  |
|------|--|--|--|---|
| EFV  | <ul style="list-style-type: none"> <li>• CNS disturbances such as dysphoria, hallucinations, abnormal dreams, distractedness, dizziness, insomnia</li> <li>• GIT symptoms.</li> <li>• Skin rash,</li> <li>• Congenital anomalies –during 1st trimester of pregnancy</li> </ul> | First few doses or after two to four weeks | <ul style="list-style-type: none"> <li>• Viral load every 3 - 4 months</li> <li>• CD4 counts every 3 – 6 months</li> </ul>   | <ul style="list-style-type: none"> <li>• Side effects are reduced if the daily dose is taken at night but are exacerbated with concomitant administration of alcohol</li> <li>• High fat meals promote bioavailability</li> <li>• Individuals on EFV need to be made aware of the impairment on their ability to perform activities requiring alertness or physical co-ordination such as operating machinery or driving</li> <li>• Dizziness is more rapidly experienced in African–American people than Caucasians</li> </ul> |
| d4T  | <ul style="list-style-type: none"> <li>• Lipodystrophy,</li> <li>• Peripheral neuropathy</li> <li>• Stomatitis</li> </ul>  | 3-24 months                                | <ul style="list-style-type: none"> <li>• Viral load every 3 - 4 months</li> <li>• CD4 counts every 3 – 6 months</li> </ul>   | <ul style="list-style-type: none"> <li>• Doses above 4 mg/kg/day may lead to peripheral neuropathy. If patients develop peripheral neuropathy, treatment must be stopped immediately. If the symptoms abate, d4T may be reintroduced at 50% of the original dose</li> <li>• As food has no influence on absorption of d4T, it may be taken on an empty stomach or with food</li> <li>• the doses of 20 mg and 40 mg have been found to have similar effects on the CD4 count and viral load</li> </ul>                          |
| 3TC  | <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Headache</li> <li>• Fatigue</li> <li>• Diarrhoea</li> <li>• Pancreatitis</li> <li>• Lactic acidosis</li> </ul>  | 2 weeks                                    | <ul style="list-style-type: none"> <li>• Viral load every 3 - 4 months</li> <li>• CD4 counts every 3 – 6 months</li> </ul>   | <ul style="list-style-type: none"> <li>• Food delays the peak concentration of 3TC but does not affect its bioavailability thus 3TC can be taken with or without food</li> </ul>  |
| NVP  | <ul style="list-style-type: none"> <li>• Skin rash,</li> <li>• Hepatitis</li> <li>• Nausea</li> <li>• Vomiting</li> <li>• Headache</li> <li>• Hepatitis</li> </ul>   | Within first 12 weeks                      | <ul style="list-style-type: none"> <li>• Viral load every 3 - 4 months</li> <li>• CD4 counts every 3 – 6 months</li> </ul>   | <ul style="list-style-type: none"> <li>• NVP therapy is initiated with a daily dosage for 14 days to decreases the incidence of a rash. If therapy is stopped for more than seven days, the therapy should then be reinitiated with this ‘lead in’ dosage</li> </ul>  |
| AZT  | <ul style="list-style-type: none"> <li>• Bone marrow suppression - anaemia, neutropenia</li> <li>• GIT symptoms</li> <li>• Myopathy</li> <li>• Lactic acidosis</li> </ul>  | 3-6 months                                 | <ul style="list-style-type: none"> <li>• Viral load every 3 - 4 months</li> <li>• CD4 counts every 3 – 6 months</li> <li>• Full blood counts after one month of initiation and thereafter every three months.</li> </ul> | <ul style="list-style-type: none"> <li>• If the patient develops anaemia or neutropenia, the dose can be reduced to 200 mg 12 hourly</li> </ul>   |



### ***Peripheral Neuropathy***

Peripheral neuropathy is most frequently seen with d4T. It is thought to be due to interference with oxidative metabolism and inhibition nerve growth factor [31]. The symptoms of peripheral neuropathy are numbness in both legs with episodic shooting pains. These symptoms are described as burning, numbness, pins-and-needles, an aching sensation and cramping in the legs. Risk factors are pre-existing neuropathy and CD4 counts < 200 cells/mm<sup>3</sup> [31]. Treatment of the peripheral neuropathy pain includes non-steroidal anti-inflammatory drugs and amitriptyline for the neuropathic pain, as well as vitamin B-complex [31].

### ***Hepatic Toxicity***

Elevated aspartate aminotransferase (AST) and alanine aminotransferase (ALT) are reported in 14-20% of patients and are associated with NRTIs, NNRTIs, protease inhibitors and fusion inhibitors. Hepatotoxicity is often due to co infections such as Hepatitis B or C, OIs, alcohol use or drug interactions. Symptoms such as skin rash, fever and hypotension may be experienced. The symptoms of hepatic toxicity with NVP are severe, therefore if they develop, therapy should be changed [31].

### ***Fat Maldistribution***

Changes in fat distribution occur with ARV treatment - there is a loss of peripheral fat and deposition of fat subcutaneously in visceral stores. These changes occur very slowly but the full effect is evident after a few months. The deposition of fat, lipohypertrophy results in central obesity, dorso-cervical accumulation, breast engorgement and pseudo cushings syndrome [31].

### ***Dermatologic Effects***

A rash is a commonly-reported side effect of the NNRTI class. It is reported in 17% of patients taking NVP and 10% taking EFV. Severe rashes leading to discontinuation of therapy are experienced in 7% of patients taking NVP and 2% taking EFV [13]. Prevention of the NVP-induced rashes cannot be achieved by using antihistamines and prednisone, however these agents are used to treat the rash [31].

### **2.2.7 The economic impact of HIV/AIDS in South Africa**

The economic effects of HIV/AIDS are wide-ranging and significant and affect the government, individual households and businesses [48]. AIDS predominantly affects young adults between the ages of 25 - 45 years, which places a huge strain on the working-age population to support the young and sick. AIDS progression is slow, with a median life span of 8-10 years. This results in declining labour productivity and increased medical costs over this period [48].

Infection rates differ by skill class, resulting in the AIDS epidemic slowing down the population growth and having a differential impact on growth in labour supply by skill category. The peak infection rate in unskilled workers is three times that of highly skilled workers. In South Africa, it has been predicted that AIDS would be responsible for a 20% reduction in the 2010 gross domestic profit [48].

AIDS demands an increased proportion of government spending on the health care budget, which results in a deficit in other sectors. The presence of AIDS often results in a loss of income and an increased number of orphans in individual households. These vulnerable households now require external (government) funding due to the loss of their income-earners. Employers' medical insurance and related staff costs are increased due to absenteeism and disruption of the overall productivity of the firm. Lastly, the macro economy is affected in that there is effectively lower physical and human investment, which results in a lower growth trajectory. The firms find themselves in the paradoxical position where there is increased short term expenditure i.e. spending more money on continually replacing staff due to absentee/sick/dying workers and less investment on training long term employees. Thus despite increased spending, the effective investment in human capital has decreased. This could lead to automation of operations, which would create further unemployment and have a devastating impact on the economy. A culmination of these factors interacts with the South African economic structure, affecting labour, employment, income distribution, saving rates and other economic variables [48].

### **2.2.8 Adherence in ARV therapy**

In general, patients with chronic illnesses are reported to take only half of their prescribed medicines [40]. HIV/AIDS requires 95% adherence to ARVs even in the absence of signs or symptoms. Many factors impact on patient adherence to ARVs [4]. Disease severity has been identified as a major factor, as patients who have experienced side effects from the disease may believe that they are at greater risk of their disease worsening if they do not adhere to ARVs [4].

Despite the many support groups for HIV/AIDS patients, many patients do not want to disclose their status due to the stigma attached to this disease. Culture, religion, health beliefs, health practice and motivation can have both a negative and a positive impact. Research in Botswana showed that major barriers to ARV adherence were lack of funds for medicines and not refilling medication prescriptions [8].

In a South African study using Medication Electronic Monitoring Systems (MEMS), it was reported that only 36% of the patients achieved adherence above the required 95%, which was not congruent with the self-reported adherence of 91% [49]. Most of the adherence data in HIV/AIDS relies on self report [37]. However, a study from Cape Town, South Africa, showed that good adherence in a resource-poor setting is possible and is comparable to adherence in developed countries, with an adherence rate of above 90% for 80% of young children [50]. There is a link between secondary education, access to water and electricity, and improved adherence rates [50]. Poor palatability was the greatest cause for nonadherence and was most commonly experienced with ritonavir. Higher adherence rates were found for regimens that did not include ritonavir [50]. This problem is not unique and has been experienced internationally [50]. Adherence rates were shown to decrease as the number of doses and side effects increased. Adherence rates also decreased if the regimen interfered with daily life [37].

## 2.3 Medicine-taking behaviours

### 2.3.1 Medication adherence

Adherence to prescribed medication has proven to be a major public health problem. The barrier imposed by nonadherence reduces the effectiveness of pharmacotherapy [51,52]. Adherence has been defined by the WHO as [51] “*the extent to which a person’s behaviour, i.e. taking medicine, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider*”. It has been estimated that on average, only one in three patients correctly adheres to the directions given by the HCP [53]. Reported cases of nonadherence to chronic therapy range between 4 - 92%, with an average estimate of 50% adherence to chronic therapy [54,55]. The highest nonadherence rates have been reported with chronic long-term therapy, where the disease has an asymptomatic stage as is found for HIV/AIDS in the WHO clinical stage 1. In these diseases the consequences of nonadherence are often delayed. Rosen *et al.* [56] found that on average, 40% of patients dropped out of ART after only two years of treatment. Low adherence is the second-strongest determinant of death in HIV/AIDS patients after CD4 count [57].

Adherence to medication is influenced by patient beliefs. One of the earlier models linking health behaviour and beliefs is the Health Belief Model (HBM), which was created by Rosenstock as a predictor of patient behaviour in both acute and chronic diseases (1974). The model has been applied to HIV [58] with a suggestion that it may be useful in predicting adherence to ARVs. The HBM proposes that, amongst other health behaviours, adherence depends on a set of core beliefs: firstly, the perceived severity of and susceptibility to the disease, with better adherence being associated with a greater threat of susceptibility and severity; secondly, confidence that the intervention will contribute to improved health which includes willingness to trust in the ability of the health care providers and have sufficient trust to adhere to the selected drug regimen; thirdly, addressing barriers to adherence including cost, side effects, duration of therapy, complexity of regimen, transportation difficulties and disruption of daily activities; and lastly, the possession by patients of basic health literacy skills [40].

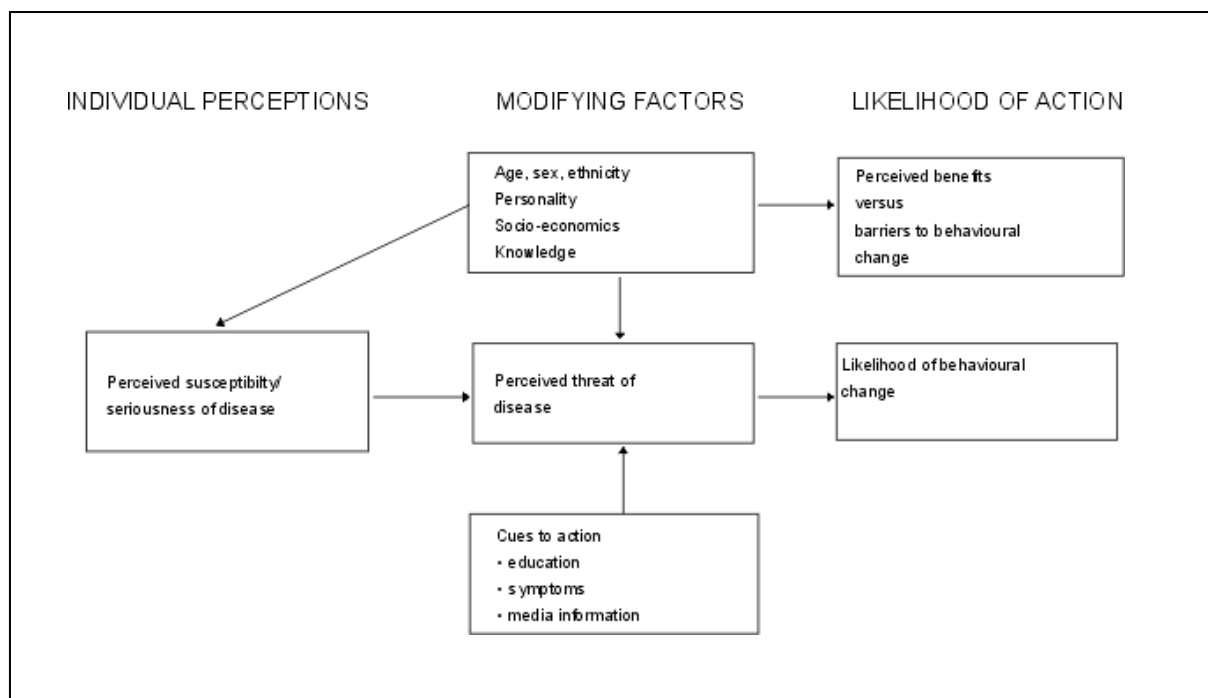


Figure 2.1 Graphic representation of the health belief model [59]

The Theory of Reasoned Action formulated in 1980 by Ajzen and Fishbein [60] states that the intention to adhere is established by behavioural intentions which are a function of attitudes toward the behavior. These attitudes, in turn, are determined both by the beliefs that the behavior will lead to positively or negatively valued outcomes and their subjective norm, which is shaped by the perception of the value that “significant others” place on that behavior along with the motivation to comply with those norms [61].

Negative beliefs about medication are thought to account for an estimated 20% variation in adherence [62]. With inadequate health literacy, patients may have a poorer knowledge, more negative beliefs and negative attitudes towards their therapy which may result in nonadherent behaviour [62]. These medication beliefs are effective predictors of patient adherence, being more accurate and consistent than demographics [62].

### 2.3.1.1 Measurement of adherence in HIV/AIDS patients

Adherence can be measured by two means - a direct measure or an indirect measure. Adherence measured directly involves the chemical detection of the compound in body fluids. This is subject to less bias, but is expensive and difficult. There is also room for error, in that it cannot measure retrospective adherence. It measures the chemical compound at a

particular time, thus the patient may have just taken the medication and adherence over the past month will not be reflected [63,64].

Indirect measures are more commonly used due to the relative ease of administration. Examples of these methods are the physicians' perception, patient interviews, pill counts, prescription refill dates, electronic cap devices and therapeutic outcome [65]. There is no single most effective way to measure adherence in HIV/AIDS patients. However, in literature, self-reports are the most commonly reported means for measuring adherence in HIV/AIDS patients [55].

### ***Self-reported adherence***

Self-reported adherence can be assessed verbally in interviews or via questionnaires and medication diaries. This method relies on honesty and full disclosure and thus may be specific but not accurate [66] if, for example, the patient wishes to please the health care professional (HCP). Patient memory and recall of medicine-taking behaviour is necessary, which can be problematic [67]. Self-reports have been shown to overestimate adherence due to patient bias [7,68]. Miscommunication and a lack of understanding between interviewer and patient may also contribute to incorrect adherence information being collected [67]. Despite weaknesses in self-reports such as social desirability and bias, when used in a controlled design they have been shown to have predictive validity [55].

### ***Pill counts***

These are performed at the patient's home or healthcare facility, and it is assumed the number of pills missing from the container represents the number ingested by the patient [65,66]. Adherence is determined by comparing the amount of medication that should have been taken with the amount missing from the container. Pill counts cannot prove correct time of ingestion or the correct daily dose. However, this method is inexpensive, requires no specialized equipment or tools, and no special skills to conduct the pill counts [65,66].

### ***Electronic devices***

Electronic devices are seen as the 'gold standard' for objective indirect measures of adherence, however they give no indication of how much medicine was ingested. MEMS are computer microchips inserted into the medication package. They record the date and time when the container is opened. This assumes that every time the container is opened,

one dose is removed and ingested [70]. These are expensive devices and may be lost by the patients [65], and random, unnecessary opening of the medicine container results in erroneous data being captured [71].

### ***Prescription refill records***

These data are more accurate as pharmacies routinely record all medication dispensed. Refills are considered to be an effective measure of adherence as they indicate positive behaviour in making the effort to obtain refills, a process which often incurs costs. Grossberg *et al.* [66] compared self-reported adherence to pharmacy refill records and found that pharmacy refill records were sensitive to non-adherence and that self-reported adherence led to discrepancies [66]. Prescription refill records provide information about date of collection of the medicine, however they do not indicate the actual dosing schedule followed [65].

### **2.3.1.2 Barriers to adherence**

Barriers to adherence may be divided into four categories: patient barriers, regimen barriers, social barriers and interactions with HCPs.

#### ***Patient barriers***

Personal factors influencing adherence include psychological issues, belief systems, confusion and forgetfulness and should be considered when the therapy regimen is being tailored. Race, gender, low income, stage of disease or a history of substance abuse have been shown to be poor predictors of adherence [9-11]. However, depression, active drug abuse, low literacy, mental illness, a lack of motivation and social support has been identified as reliable predictors of poor adherence[9-11].

Patients may lose motivation or become complacent with taking their ARVs [72]. Adherence is affected by knowledge in two ways. Increased knowledge leads to a greater understanding of the condition, but it may also increase patient concerns regarding side effects. Anxiety and concerns about one's health seem to improve adherence, although extreme anxiety may lead to abuse of the drug [12,13]. Patients need to see that the benefits of taking the medication outweigh any side effects that may be experienced [12,13]. Inadequate understanding of the disease or failure to understand the importance of adherence can lead to nonadherence.

### ***Regimen/pharmacy related barriers***

The more complex the regimen, the greater the chance of nonadherence due to incorrect recall of medicine-taking behaviour [12,13]. Polytherapy, frequent dosage and the actual timing of dose all contribute to a greater chance of nonadherence. Pill boxes and reminders can help improve adherence, even with complex regimens.

In the South African public health sector, the different ARV regimens are standardized, which restricts the range of ARVs a patient may receive. A lesser focus is placed on the most appropriate therapy for individual patients as it is the best-fit regimen that is considered. The polytherapy and twice-daily dosage associated with HAART may result in confusion and create barriers to adherence. Although the development of fixed dose combinations of the ARVs should help to contribute to adherence, reducing the complexity of the regimens, these combinations still need to be approved by the National Drug Regulatory Authority of the relevant country [24]. Additional data are needed to prove that a once daily dosage is more effective in ARV therapy [24].

### ***Social/environmental barriers***

Significant stigma is attached to HIV/AIDS. Disclosure of an HIV-positive status may result in exclusion from the family, which threatens patients and fuels the reluctance to disclose a positive status [72]. Recently it has been shown that patients who were open about their status and received support had improved adherence [24]. Patients benefit from having the support of family and friends to encourage and remind them of the need to adhere to medication.

### ***Health care system and provider-related barriers***

HIV/AIDS affects people from a diverse range of cultures and health beliefs and it is this diversity that introduces complex challenges in the treatment of the disease. HCPs should provide care in a culturally sensitive manner, approaching prevention, care and treatment in a manner that respects the individual's culture and beliefs. Distrust in the conventional medical system has been reported in some cultures, resulting in patients seeking traditional means of treatment [72]. A positive relationship between a supportive HCP and the patient is crucial as a poor relationship is a good indicator of poor adherence [12,13].

In Khayelitsha, South Africa, continuity of care and seeing the same health care team at each visit were seen to promote adherence [73]. Implications for the health care system are that



large-scale roll-out of antiretroviral agents in South Africa may be more effective if implemented in a greater number small centres rather than in fewer major centres [73]. The location of the clinics and health care facilities may prove to be problematic as many patients need to travel long distances from their home to reach the clinics in urban areas. This often results in patients not returning to the clinic on the appropriate days.

### **2.3.1.3 Interventions for improving adherence**

Most interventions for improving adherence focus on changing adherence patterns. Research has shown that single interventions targeting patient behaviour tend to be ineffective and a multifaceted approach is necessary [74]. Intervention programs should include clear descriptions of the therapy that the patient is required to follow, as well as information on the disease state. It may be useful to analyse and problem solve where nonadherent behaviour was observed or predicted. These programs may incorporate the following elements: modification of schedule, simplification of regimen, referral when professional care is required, intervention devices and means to help recall medicine-taking times, such as alarms, sms reminders and pill boxes [55].

HCPs may need to consider the way that adherence problems are addressed. Patient engagement ought to be in an open respectful style, and patients should be supported in a non-judgemental, non-critical manner [74]. Suggestions for improvement may be given, as well as means to manage any adverse effects [75]. Motivation and support of patients by the HCP, family and friends, may encourage the patient to be adherent. In a study by Knobel *et al.* it was observed that patients with a range of ailments receiving individual advice from the pharmacist, had improved adherence and improved disease outcome [55].

Suitable simple regimens with a once-daily or twice-daily dosing should be considered as these decrease the complexity of the therapy regimen. Pharmaceutical manufacturers are now producing combination medications to lower the pill burden. Extended half-life medications facilitate once-daily dosing, which may be beneficial in improving adherence [74]. Medication combinations with an improved side effect profile would be more beneficial to the patient as patients are more likely to adhere to medication if less side effects are present. An example of this is the combination of tenofovir, 3TC and EFV,

which has a lower incidence of lipodystrophy than the currently used d4T, 3TC and EFV [74].

### **2.3.2 Self-efficacy**

#### **2.3.2.1 Introduction**

Self-efficacy is defined as the personal belief that one can successfully perform a specific action under specified conditions (Bandura 1997). An individual's beliefs in his/her own capabilities are influenced by a combination of self-motivating and self-debilitating thought patterns [14]. These, combined with environmental factors such as social support systems and affective states, result in the outcome of an event [14,76]. If a patient feels that he/she does not possess the abilities to perform a certain task, he/she will avoid the situation.

Self-efficacy is shown to be influenced by four elements. First and most important, are the individual experiences which take into account performance accomplishments. Second, observation of the successes and failures of other individuals during their various experiences influences self-efficacy. Third are the verbal influences, including a social influence. Last, physiological and affective states such as anxiety and stress influence self-efficacy [77,78]. A low self-efficacy results in an inability to effectively resolve and manage situations even though the patients may have the skills to do so [14].

Medication self-efficacy is a concept centered on patients' beliefs of whether they can adhere to the medication indicated and establish control over their self-motivation, behavior and social environment [14]. A link has been shown between self-efficacy and treatment adherence in HIV as well as other disease states [15, 79-81]. Disease states such as asthma, chronic obstructive pulmonary disease, hypertension, osteoporosis and arthritis have instruments that are used to measure the patient's self-efficacy [81].

The lack of self empowerment which is often experienced by patients with low literacy may lead to a poor self efficacy and lack of assertiveness necessary for the management of many chronic illnesses such as HIV/AIDS [72]. Self-efficacy includes patient beliefs, knowledge, performance accomplishments and affective states [81]. These aspects can be analysed while developing the patient-practitioner relationship. Questions designed to measure self-efficacy

may act as a predictor of adherence [81]. As HCPs are currently unable to correctly predict the likelihood of nonadherence, determination of self-efficacy may provide a predictive tool. Research by Reynolds *et al* [80] has shown that an increased ARV adherence has been associated with a higher ARV self-efficacy. This could result in more successful ARV therapy as additional time can be spent on adherence counseling with those patients identified as having a low self-efficacy [80]. If a defaulter could be identified earlier, more counseling and vigorous intervention could be offered.

Education level has been shown to influence self-efficacy [80]. A higher educational level and higher quality of life has been associated with a higher adherence and self-efficacy [80]. Gender was not seen to have any influence on self-efficacy [80]. In a study by Bandura [14] it was shown that patients who had a lower perceived self-efficacy had an increased involvement in unsafe sexual practices, even though they were aware of the high HIV infection risk. This led to a shift in the tactics to educate the patients. Scaring patients into appropriate behavior has been replaced with methods to empower them, allowing them to acquire control over their health matters [14]. Studies have shown that increased social support systems have lead to greater self-efficacy and improved adherence and are able to buffer the effects of non-clinically depressed patients [76]. A greater and positive change in self-efficacy is seen in studies that include performance accomplishments as a means to model desired patient behaviour [77].

#### **2.3.2.2 Measurement of self-efficacy**

The HIV Medication Taking Self-Efficacy Scale was developed by Erlen *et al.* [76] to measure beliefs related to taking ARV therapy. This uses an 11 point Likert scale to rate the patient's perceived confidence in his/her medicine-taking ability. The HIV Treatment Adherence Self Efficacy Scale (HIV-ASES) was developed by Johnson *et al.* [15] to predict patient confidence in being able to adhere to the ARV treatment plan [15]. The HIV-ASES consists of 12 questions [15] relating to the treatment plan, the medication regimen, adherence, nutrition, and exercise, factors all of which could influence adherence [15].

Kalichman *et al.* [82] devised a pictographic and colour visual analog scale to measure self-efficacy in HIV/AIDS patients. A visual analog scale is most often used to indicate the frequency or intensity of symptoms such as pain [83], because it is more sensitive to slight

variations than is a verbal description [83]. The scale was shown to be effective and was considered useful in a low-literate population.

## **2.4 Literacy and health literacy**

### **2.4.1 Literacy**

Literacy is defined by the United States congress in the National Literacy Act of 1991 as “*an individual’s ability to read, write, speak, compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one’s goals, and to develop one’s knowledge and potential*” [84]. The United Nations Educational Scientific and Cultural Organization (UNESCO) has classified literacy into three broad categories, namely [42,86]:

- Illiterates: people who cannot read or write in any language.
- Functionally literate people: those who can read and write but also understand and act on their understanding of the subject matter.
- Literates: people who can read and write.

Illiteracy is, to an extent, wrongly interpreted to mean only the inability to read. However, literacy includes the way an individual organises, interprets and analyses information [85]. This requires certain cognitive ability, without which barriers become apparent in effective communication.

Despite many multifaceted efforts, the literacy rate across the world remains low. According to UN analysis, 776 million people worldwide lack the minimum literacy skills required to function in society. Literacy levels range from 99.2% in Europe to a low level of 63.3% in Africa [86,87]. The three continents with the lowest illiteracy rates below 10% are North America, Australia and Asia [86]. Approximately 23% of the overall adult population is unable to read or write, this figure being even higher in developing countries [87]. Africa has the highest rates of illiteracy, with more than three quarters of the adult population having an illiteracy rate higher than 50% [87,88].

The level of literacy in South Africa has been reported by UNESCO to be 82.4%. However, this high reported level is unlikely given the general lack of formal schooling and the absence of reliable literacy statistics [86]. Educational level as reported in the 2001 consensus [2]

reported under a quarter (22.8 %) of the population to have received no education, half to have the equivalent of 7 years schooling or less and only 20.4% to have completed Grade 12 [2]. It is estimated that three in ten people have started school but have not completed their secondary education [15]. These figures imply a widespread incidence of functional illiteracy. However number of years of formal education is often a poor indicator of reading ability, as it overestimates reading ability by four to five grades [85].

Literacy is a skill that creates a learning platform which empowers individuals in the attainment of skills and promotes personal development, social advancement and economic progress. Assumptions about level of literacy are commonly made. Illiteracy cannot be identified by direct questioning [85]. Studies from developed countries have found that functionally illiterate adults tend to cluster in minority groups, live in poverty, have less education, and tend to be elderly. These are the same population groups that carry the greatest burden of disease and increased health problems [88].

Increased literacy has been associated with improved health status, decreased hospitalizations and higher levels of participation in preventative health behaviors [89]. Literacy has been shown to have a positive effect on patient well-being even when confounding variables such as income, education, employment and nutritional status are taken into account [89].

#### **2.4.2 Health literacy**

Health literacy can be defined as “*the degree to which individuals have the capacity to obtain process and understand basic health information and services needed to make appropriate health decisions*” [90]. Health literacy is a measure of the ability to perform basic reading and numeric tasks associated with medicine-taking behaviour as well as act on health care information [84]. Health literacy is not only important for self-management but also for a range of other health matters including prevention, screening, patient history taking and explanation of the diagnosis [45]. Over the past two decades, a dramatic increase in the literature addressing health literacy reflects the focus on this issue due to the increased drive for social, economic and health development [91]. The central goal of health literacy is the improvement of patient health [92].

Although literacy may be used as an indicator for health literacy, the actual health literacy may be significantly worse than general literacy as it is more context specific. Individuals may be able to read and understand general materials reflecting a familiar context, but in many cases health information contains medical terminology and vocabulary that is unfamiliar [45].

Low health literacy has been associated with poor health care status, problems communicating with HCPs, increased hospitalisations and poorer adherence. Some of the reasons for this association may include an inadequate understanding of the chronic condition that they are experiencing; ineffective care due to misunderstanding of the instructions for therapy from the HCP, unintentional non adherence and lastly a lack of education, awareness and preventative measures [20, 93-95].

Functional illiteracy has been associated with the term 'quiet disability'. For this reason people do not acknowledge or recognize that a problem exists or may attempt to hide the problem even if they do acknowledge it [20,94,95]. Patients with functional illiteracy have been shown to have a lower recall of health information given by the HCP regarding aspects such as the adverse effects and directions for medicine-taking behaviour [45]. Fewer questions are asked by functionally illiterate patients and they may assume a less active role in the education and self-management of their therapy [96,97,99]. Functional illiteracy is often not detected in patients as feelings of humiliation, low self-worth, fear and embarrassment prevent disclosure of the problem [95,99]. These emotional costs are significant, with one study showing that 67.2% of the functionally illiterate patients had not told their spouses of their reading problem and 19% had never told anyone [98]. This presents a significant often undetected barrier in effective communication between HCP and patients with low health literacy.

#### **2.4.2.1 Health literacy and the health care system**

The general health care system requires a certain degree of reading ability from the patient [100]. This includes the ability to read and understand appointment slips and other health-related materials important for successful therapy [45]. Misunderstandings can have severe health consequences for the patient and result in increased expenditure within the health care system. Illiterate adults place strain on the health system in that they are less likely to use

screening procedures, follow up and keep appointments or get medical help sufficiently early [101]. Chronic diseases tend to be more poorly managed and controlled resulting in poorer health status in these patients, they receive less satisfactory health care and have greater need of health services [88,102]. It has been shown that functionally illiterate patients may not understand their disease, implement preventative measures, recognize complications that may arise or be able to identify early symptoms, thus not seeking timely treatment.

#### **2.4.2.2 Health literacy and medication use**

Appropriate medicine-taking behavior requires stringent adherence to prescribed instructions. A minimum requirement to achieve this is the ability to read, understand and follow the label instructions: i.e. functional health literacy is required [84]. Written information is used for dosing instructions on the medication bottles, discharge instructions, consent forms, poison warnings and directions on domestic use products, thus the importance of comprehension is abundantly evident [96]. A lack of understanding of the medicine-taking behavior that needs to be followed may lead to sub-therapeutic blood levels, worsening of symptoms and an increase in hospital admissions [103].

#### **2.4.2.3 Health literacy and HIV/AIDS**

Patients with low literacy levels have little knowledge of HIV/AIDS and its treatment [104]. Low health literacy in HIV-infected patients has been associated with decreased HIV-related mortality and morbidity, reduced CD4 counts and increased viral load [104], as well as lower adherence to ART and increased hospitalisations. This emphasizes the point that health literacy is an important determinant of predicting patient adherence in chronic disease [104]. Adequate health literacy is important for adherence to HAART in HIV/AIDS patients, as therapy consists of complex regimens that require strict adherence [55,56]. Findings such as these have identified the need for interventions in HIV/AIDS to increase adherence and treatment interventions for low-literate patients [104]. Apart from many of the other factors influencing nonadherence in HIV/AIDS, poor health literacy may be directly addressed by increased patient education and behavioural interventions aimed at educating low-literate HIV/AIDS patients.

### **2.4.3 Low-literate patients and written information**

Written patient education materials can be a quick and cost-effective method of providing health care information to patients [87]. The impact of this form of education is heavily dependent on the reading ability of the patient who must comprehend the information in order to apply it [87]. The Joint Commission on Accreditation of Health Organizations (JCAHO) in the United States of America has mandated that patients are to receive medical instructions at a level that they can understand [105], but this often does not occur.

The recommended grade level of written information materials for the general public is 8<sup>th</sup> grade, but for lower literate patients, a grade level between the 3<sup>rd</sup> and 5<sup>th</sup> grade should be maintained [103]. The content of many of the educational materials is not suitable for developing countries where health care is delivered within an under-resourced system, in which patients are not exposed to sophisticated and technologically advanced health equipment and procedures and where many have access only to primary care clinics [106]. HCPs need to play an active role in identifying patients with inadequate health literacy as early as possible without embarrassing them [103]. Patients frequently attempt to hide their illiteracy as they may not be able to read the educational materials given to them and in fact may believe that they are not disadvantaged in being unable to read the materials [94,101].

Patients often offer excuses for not reading a written leaflet, such as “no reading glasses” and “lack of time” [103]. HCPs can circumvent this avoidance behaviour and gauge understanding by asking the patient to demonstrate or reiterate the prescribed medicine-taking behavior [94]. Involvement of the family members of the patient in health education may improve adherence, and this should be considered when the patient is found to be low-literate or at other risk of non adherence [96].

#### **2.4.3.1 Measurement of health literacy**

The most widely used tools for measuring health literacy are the Rapid Estimate of Adult Literacy in Medicine (REALM) [106,109] and the Test of Functional Health Literacy in Adults (TOFHLA) [108,109].



The REALM is a simple test to administer and involves the participant reading aloud a series of health-related words [107,111]. These words are arranged in three columns in order of increasing difficulty. This classifies skills into low, medium and high levels [92,107]. The raw score is the total number of words pronounced correctly and this score is then converted into reading grade range. The REALM tests only for pronunciation and no understanding of the words is tested. It is administered in under two minutes [107,111,112]. The REALM test was specifically designed to be nonthreatening to patients with low literacy [107]. It can be used in primary care settings to identify patients with a low literacy.

The TOFHLA uses the Cloze test, in which every fifth to seventh word of the passage is deleted and the participant required to fill in the missing word by choosing from a number of appropriate words [20,109,111]. This test assesses understanding of the passage but is time-consuming and requires intensive administrator training [20]. The shortened form, which is called the S-TOFHLA has been found to be as effective as the original TOFHLA [109]. Both the TOFHLA and S-TOFHLA are unsuitable for individuals with reading skills below 6<sup>th</sup> grade [20], thus limiting their use in low-literate settings.

A limitation in all health literacy tests is the inability to evaluate illustrations and the design of written material, which may positively impact on understanding [109,111].

## **2.5 Patient information**

### **2.5.1 Introduction**

The World Health Organisation (WHO) has stated that “*patients have the right to be given factual, supportable, understandable and appropriate information, to be provided in such a way as to allow them to decide whether they wish to receive therapy*” [113]. Providing patient information for health promotion purposes and informing patients on appropriate medicine-taking behavior regarding the safe and effective use of medicines is an integral role of HCPs and may result in improved patient wellness [114,115].

Patient education requires the provision of health-related information using a means that best conveys the message to the target population. Forms of such education generally fall into one

of three categories: audio, audio-visual or written, with the materials ranging from dramatisations, traditional media, video, dvd, printed materials and educational visual aids [116-118].

Effective communication with the patient is necessary for the patient to gain insight into their disease state and for the correct medicine-taking behaviours to be implemented and adhered to. Many patients are distracted, forget or do not understand what the HCP has told them, thus making communication between patient and HCP an ongoing challenge [119]. In most cases, verbal information will be the only form of information offered by the HCP to the patient. However, patients tend to retain and recall an average of 20% of any information communicated verbally. One study found that patients forgot half the information given to them by the practitioner within only 5 minutes of leaving the consultation rooms [116]. These limitations make exclusive verbal communication with a patient inadvisable. With the addition of a written form of education, the amount retained increases to 50% [120].

### **2.5.2 Health promotion and HIV/AIDS programs in South Africa**

Behavioural change communication (BCC) is a process which describes the resulting change in health behaviour, in both individuals and the community, through the development of suitably tailored health education [121]. Before individuals and communities can change their health behaviours, the basic facts of the disease need to be understood and the individuals' attitudes of the need to change. A more favourable attitude towards the disease state and medicine-taking behaviour needs to be adopted. This attitude should include a positive standpoint on taking the medication, prevention, and obtaining care from appropriate services. This is not always easy. A change in attitude and belief is sometimes difficult to adopt and to maintain without support [121].

Effective BCC can result in the population having an increased knowledge of the particular area focused on. Dialogue in the greater community may be stimulated, leading to discussions on health issues and further education of the community, thus spreading the impact of the educational intervention from the individual to the community. BCC can help reduce stigma and discrimination against certain diseases by helping to promote essential behavioural changes. Services are promoted to help care, support and prevent certain diseases. BCC can also help provide individuals with skills and the self efficacy to take

charge of their treatment [121].

HIV/AIDS communication programs in South Africa have been successful in reaching a large proportion of the general population [122]. However, there are still some categories where the reach of these programs is poor. The main programs are Khomanani, Soul City, Soul Buddyz, and the loveLife campaigns. The Khomanani program, meaning ‘caring together’, is the national Department of Health’s HIV/AIDS awareness campaign. It has been running since 2001 and is intended for all population groups and ages. The program is communicated through media, including radio announcements and the use of advertisements on television. Soul City and Soul Buddyz are both multimedia HIV/AIDS awareness programs targeting adults and children respectively. Their annual budget is R100 million, and is used to broadcast and promote good sexual health and well being [122]. The loveLife program has run since 1999 and uses a wide range of media sources, with its target audience being teenagers. It also runs youth centres around the country, which provide sexual health information, clinical services and skills development [122].

### **2.5.3 Written health information**

Kitching [116] has stated that a “ *lack of information has been identified as a major factor among 250 reasons why patients do not take their medicines as the prescriber intends*”. Lack of knowledge has been associated with incorrect medicine-taking behaviours and poor adherence [123]. Health and disease exist together in a cultural matrix, and, accordingly, health promotion and education interventions should be culturally sensitive as well as being appropriate for the literacy level of the local populations [123]. More than two-thirds of the South African population have marginal reading skills. This significantly influences the ability to read and understand health-related information.

Patients want to know more about their medications, with their most common expectation being that the HCP will provide them with information regarding the safe and effective use of medicines [78]. Written information should not be the sole means of education. Ideally HCPs should use a combination of both verbal and written information, with the written information acting as a complement to the verbal education provided [87, 124-126]. In many cases HCPs overestimate the health literacy of their patients and provide health information that is not adequately understood [127]. In some cases, this may negatively affect health outcomes

[128]. Written information may also act as a reminder for the health care professional of all the important details to convey. Another advantage to written educational materials is that they are easy to use without the need for any special equipment or training [129].

#### **2.5.4 Theories of learning**

##### ***Information processing theory***

In 1968 a model was proposed by Atkinson and Shiffrin [60,61], based on two types of memory: namely short term and long term. Short term memory contains working and sensory memory. Working memory has limited capacity, which causes people to chunk information to help with memory recall. For information to be remembered, it needs to be moved from short term memory to long term memory. To help with the information shift, knowledge acquisition strategies are used: firstly, the most important information is selected; secondly, the information is repeated to keep it in the working memory; and lastly, the new information is coded to make it meaningful [130].

##### ***Dual coding theory***

Paivio, in his 1990 theory [131], proposed that images and words have different cognitive representations and therefore have different memory storages: verbal memory and sensory memory.

##### ***Multimedia theory***

Active learning can take place when a learner engages in three cognitive processes: selection, organization and integration. There are several principles of Multimedia Theory that need to be understood in relation to written forms of patient education [130].

1. **Multimedia Principle:** People learn better from the use of text and visuals in conjunction rather than text alone. The learner constructs verbal and pictorial mental models and builds connections between them.
2. **Spatial Contiguity Principle:** People learn better when the text and visuals are located near to one another. When the visuals and text are in close proximity the learner is not required to use cognitive resources to visually scan the document and is more likely to hold both in working memory.

3. Temporal Contiguity Principle: Simultaneous presentation of text and visuals results in better learning than successive presentation. Connections can be more easily built and stored in working memory with simultaneous presentation of text and visuals.

### **2.5.5 Format and design of patient information leaflets**

Pharmaceutical companies provide HCPs with medicine information to inform their prescribing [132]. This is usually available as package inserts (PIs) enclosed within medicine containers. These PIs are legal documents which are detailed, technical, scientific and precise, and they comply with legal requirements. In the 1970s PIs were included in medicine packaging to help improve patient knowledge of their prescription medication [132,133]. These PIs were inserted in the medication packaging for patient use and were distributed to HCPs. They contained medical jargon presented in a manner that proved too complex for the general public to understand. The inserts lacked aesthetic appeal and the font size used was small [132,133]. Problems with this information resulted in PIs being improved and this led to the development of patient-specific medicine information.

PILs (Patient Information Leaflets) evolved in the 1980s [133,134]. They contained less medical jargon and were presented in a more aesthetically appealing and user-friendly format. Despite this, studies from the 1990s found that PILs generally did not elicit positive comments from patients due to the poor quality of design and content, indicating the need to make PILs more informative, attractive, understandable and user-friendly [135,136].

The effectiveness of PILs in successfully communicating health information is closely related to design features, which in turn should be considered during the design process [137,138]. Presentation factors to consider include text size, spacing, headings, use of capital letters, size of paper and the quality of paper used [137]. PIL content should be relevant, accurate, applicable, easy to read and understandable [138-140]. PILs could also incorporate a combination of graphics, pictograms and words enhancing its appeal to a wider target audience [96]. The readability of the PIL should match the average reading ability of the target population. A misconception is that patients of higher socioeconomic status with more advanced education levels do not like simplified educational material. Studies have shown

that patients of all reading levels prefer simplified written material and do not tend to find the simpler presentation insulting [96,141-143].

Other characteristics of the target population should be considered. The information and illustrations need to be culturally acceptable, which has been shown to improve patient perception and acceptability of PILs [144]. Comprehension and acceptability is also enhanced if PILS are available in the home language of the target population [16,145]. Written information, if acceptable to the target population, has the potential to reach beyond the initial recipient and to spread through a community as pamphlets and leaflets are often shared and passed around families, friends and neighbours, thus extending the reach of the information to a broader target base. It can also act as a motivator for those individuals who wish to increase their literacy skills [87].

PILs should be easily and readily available to patients [115,145]. PILs are often ignored and should therefore be given to the patient with a brief verbal description to avoid possible preconceived negative opinions of the user-unfriendly nature of the PILs [115].

The following are some specific guidelines that should inform the design of a PIL [116,146,147]:

- the PIL should have a clear and concise title to focus the reader
- text should not be in capital letters as this reduces readability
- adjunct questions should be used as this design encourages patients to examine what they are reading
- the active voice should be used
- information that is generally familiar to people with no pharmaceutical knowledge should be placed first in the PIL
- any negative diction should only be used for emphasis
- sentences should be short and include no more than two ideas
- clauses such as 'unless' and 'except' should be avoided
- text in, the PIL must be clear and large enough to read
- column width should be between 50-89 mm long
- lines of text should be separated by 2.5 mm
- full justification of text should be avoided

- no Roman numerals should be used
- numbers should be written as digits.

Correct medicine-taking behaviour can be taught through the PILs if they are informative and are designed correctly. They may also encourage patients to take a more active role in their therapy, and decisions that need to be made regarding their health [116].

### **2.5.6 South Africa and PILS**

In South Africa the distribution of a PIL with any prescribed medication became mandatory from May 2003, as stated in Regulation 10 of the Medicines and Related Substances Act, Act 101 of 1965, as amended. The Regulation states that [16]: *“each package of a medicine shall have a PIL that must contain the following information(as described) with regard to the medicine in at least English and one other language”*. The Regulation also encompasses warning phrases that must be included in the PIL and guidelines that need to be adhered to.

Despite this legal requirement, PILs for prescription medicines are not widely available in South Africa and are associated with many problems [148]. Their formatting is considered to be user-unfriendly, the readability poor and they are written at a reading level which is higher than that of the target population. The print size is too small and the presentation of information is poorly designed. They include incomprehensible technical language and medical jargon, and in general there is an overall information overload [132,149].

### **2.5.7 Evaluation of readability of PILs**

Readability can be defined as [150] *“all the elements of written material that affect the extent to which readers understand it, read it at an optimum speed, and find it interesting”*. Many different readability formulae have been used to assess readability in PILs [151]. These tests measure the difficulty of materials and produce a grade-level rating [92].

Elements such as vocabulary, sentence length, grammatical complexity and design aspects interact to affect the overall readability of material [150,151]. The concept of these formulae is that the greater the number of multi-syllable words and the longer the sentences, the greater

the reading difficulty [92]. The PILs should be written in accordance with reading level [151], and it is important for HCPs to consider trying to match the patient's reading ability with the skills required to read the material and possibly avoid handing a PIL to a patient who does not possess these skills [152].

The three most commonly used readability tests include the Simple Measure of Gobbledegook (SMOG), the Fry formula and the Flesch-Kincaid formula.

#### **2.5.7.1 Simple Measure of Gobbledegook formula (SMOG)**

A SMOG reading grade is the estimated grade that the patient will be able to read independent of a health care worker [151]. McLaughlin [151] developed this accurate, user-friendly method which estimates the number of years of education needed to read and understand the sample text [151,152]. It is estimated by counting ten consecutive sentences from the beginning, middle and end of the text. All the words with three or more syllables are counted in the sample text. The square root is then taken of this number and three is added to it [151,152]. A reading level of grade 5 according to the SMOG tool means that all readers at this level will understand the sample text [151].

#### **2.5.7.2 Fry Formula**

The Fry formula was developed in 1968 [152-155]. Three 100-word passages in the text are randomly selected, the syllables are counted and the average number of sentences is calculated [152-155]. The grade level rating is obtained by plotting the data on the Fry graph [152]. The Fry formula is suitable for use with PILs intended for low-literate patients as the appropriate grade levels range between grade 1 through to tertiary education [152-155].

#### **2.5.7.3 Flesch-Kincaid readability test**

The Flesch-Kincaid readability test was modified and used by the US Navy [110,152]. Its application follows a similar process to the Fry test. Three 100-word passages are selected, from the beginning, the middle and the end, and the average words per sentence, or average sentence length, and the average syllables per word are determined. The reading



ease is calculated and is then related to a grade level [152]. This method evaluates the readability grade level between grade 5 up to a maximum of grade 12 [152].

#### **2.5.7.4 Limitations of readability tests**

Readability tests may help predict the reading ability needed to understand written information materials, but these are based on the surface characteristics of the sample text. These tests are dependent on the construction of words and sentence factors and do not incorporate the reader's psychological motivation to read the text and their background knowledge of the subject matter [109]. They may predict and measure the primary elements needed for the processing of the text, but they do not adequately measure the cohesion of the text, its comprehension and any learning that takes place [109].

The formulae may underestimate the difficulty of medical information, as these do not account for scientific or medical terms and jargon which are monosyllabic [109]. Readability tests also do not measure the effects of visual illustrations and pictograms on the readability of the materials. Tests to measure health literacy should be conducted in the patient's home language. The readability tests were all designed in English, prejudicing patients where English is not the home language. Translation and administration of these tests in other languages has proved problematic [109].

#### **2.5.8 Pictograms as a communication aid**

Visual aids have been used in health education for a number of decades, a practice that has been particularly prevalent in Africa and in other developing countries. Humans have a cognitive preference for picture-based rather than text-based information, a notion termed the "picture superiority effect" [19]. This, together with the ability of visuals to convey health information to patients irrespective of language or literacy, highlights their usefulness as a communication aid.

Research has proved the value of visuals in enhancing understanding and recall of medicines information, and this positive effect is particularly notable in patients with limited literacy [17,19,20]. Visuals used for this purpose will be referred to as pharmaceutical pictograms, with the term pictograms being defined as "*images created by people for the purpose of quick*

*and clear communication without language or words, in order to draw attention to something” [157].*

Pictograms can convey a single concept in a way that is understandable to the reader, for example, directions or restrictions [157]. Pictograms stimulate interest and convey the relevant medicine information in a user-friendly, attractive and easily accessible way [18]. The attention attracted by pictograms helps to reinforce information pertaining to medication-taking instructions, and to act as an aid to memorising the drug therapeutic plan. Studies in Nepal have shown that visual literacy can be learnt at any age, and in a relatively short time [87]. Pictograms, however, should not be used in isolation and need to be supplemented by written information.

To many viewers, pictograms may seem simple to interpret and the message they communicate easy to understand. However, pictures place a huge cognitive load on patients with low visual literacy skills, as all the individual elements must first be interpreted, after which these elements must be integrated and combined to obtain an overall idea of the intended message [158]. Many unskilled readers may focus on the peripheral details in the picture and miss the core meaning of the pictogram. This emphasizes the importance of the design process in creating new pictograms [158].

#### **2.5.8.1 Designing pictograms**

The ability of an individual to interpret a visual image is influenced by the individual's environment, economic background and culture, as well as their values and their exposure to media and pictorial material [18]. This highlights the importance of involving the target population in all stages of the development process. Research by Dowse [18] suggests that pictograms should ideally be locally developed to achieve optimal efficacy. The target population should be involved in all stages of pictogram development and should ultimately be tested in that population prior to their routine use. Research conducted into the acceptance of the ‘universal language of pictures’ has shown that cultural differences have a large impact as revealed by cross-cultural testing [18]. A well designed pictogram it enhances the recall and comprehension of medicine-related information. The patient may also understand the instructions more quickly and recall them for longer [18].

## **CHAPTER THREE**

### **DEVELOPMENT OF PATIENT INFORMATION MATERIALS AND MODIFICATION OF SELF-EFFICACY AND ADHERENCE INSTRUMENTS**

#### **3.1 Introduction**

This chapter describes the development of PILs and labels as well as the modification of the instruments used to evaluate self-efficacy and adherence. A previously designed template [158] was modified to create PILs for each of the four first-line treatments in ARV therapy. Medicine labels incorporating illustrations were modified. The instruments used to measure self-efficacy and self-reported adherence were designed and validated in developed countries and required modification and testing in the target study population prior to their use in the clinical trial. Modifications to these instruments are described in this chapter.

#### **3.2 Objectives**

The objectives of this phase of the study were:

- To design and develop illustrated, easy to read, simple, informative and understandable PILS for the four first-line regimens of ARV treatment (1A, 1B, 1C and 1D) (Appendix B 1-4 English Versions; Appendix B5-8 isiXhosa Versions).
- To design and develop illustration-based medicine labels for the four first-line regimens of ARV treatment (1A, 1B, 1C and 1D).
- To conduct a preliminary evaluation of these PILs and to make the relevant modifications according to the results.
- To modify and evaluate the existing HIV-ASES and the MMAS-8 for use in a Xhosa low-literate population, ensuring cultural acceptability and understanding of questions.

### 3.3 Design and modification of educational materials

#### 3.3.1 Design of the patient information leaflets (PILs)

A PIL for Regimen 1A had been previously designed by Ramela [158] who had tested it in participants who were not HIV/AIDS patients and who were all ARV-naïve (Table 3.1). This original PIL was used as a template to develop the ARV PIL for the current study [158]. The modification process was informed by guidelines sourced from review articles and primary research papers. The following guidelines were applied:

- medical jargon, complex words and phrases were avoided
- simple words were used at all times
- medical jargon was replaced with commonly used terms
- short sentences were used
- the active voice was used

The PILs (1A, 1B, 1C and 1D) were tailor-designed to incorporate the relevant side effects associated with each regimen. Each modified PIL was formatted as a double-sided A4 sheet consisting of the following sections:

- **Title:** This section names the ARV regimen and includes a statement referring to the use of this PIL in helping maintain health while taking ARVs.
- **Introductory section:** Informs the patient on how ARVs help maintain health.
- **Before using ARVs:** Includes any information that the patient should tell the HCP prior to taking ARVs.
- **How to use this medicine:** Educates the patient on how to take their ARVs and the importance of continuing with all three of their medications.
- **While taking your ARVs:** Includes information on the need to consult an HCP before taking any medication that has not been prescribed, actions to take after forgetting to take medication, and importance of not sharing medicine.
- **Side effects:** Included here are side effects that may be experienced at initiation of treatment, 3 to 6 weeks into treatment and after 3 to 6 months of treatment.
- **Storage of medication:** Appropriate and inappropriate storage is described.
- **Important! section:** Specialised information about pregnancy and ARVs, and the onset of extreme fever and chills is presented.

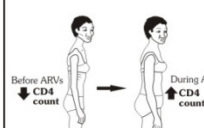







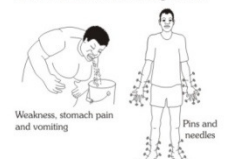


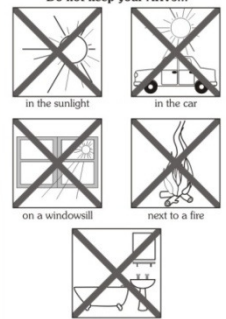

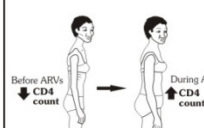







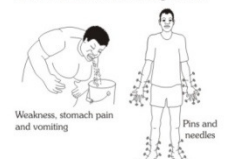


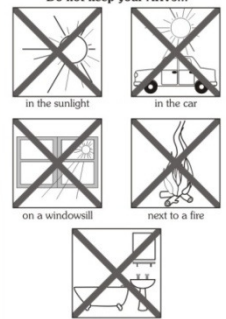
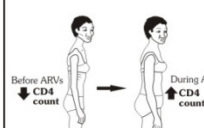







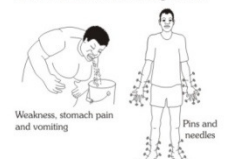


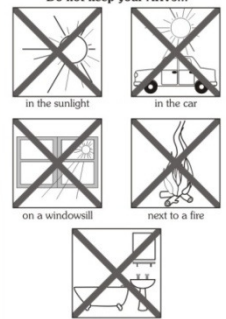
- **Use a condom:** Emphasizes the importance of condom use.
- **Footer section:** Highlights the need to continue taking ARVs for life.

Opinions of the original PIL were sought from both local and international HCPs involved in the management of HIV/AIDS patients. Two informal discussions of approximately 20 minutes each were held with the local doctors, pharmacists and nurses from the Masonwabe Clinic Settlers Hospital, Grahamstown. They were asked for their opinion of the original version of the PIL and encouraged to comment on both the text and pictorial content. Physicians from the Owen Clinic, San Diego, USA, who were familiar with this project and the project setting, were contacted via e-mail and were asked similar questions. There was ongoing feedback and communication with this group of physicians over a period of approximately three months during which time various modifications and versions of the PIL were produced.

### **3.3.2 Modifications made to the original PIL**

Modifications made to the PIL after discussions with HCP are described in Table 3.1. The final version is shown in Figure 3.1.

Table 3.1 Original PIL and modifications made

| Section changes  | Original version of the PIL  |  |                       |                        |  |  |  |              |                        |   |  |
|--|--|--|-----------------------|------------------------|--|--|--|--------------|------------------------|---|--|
| <p><b>Title:</b></p> <ul style="list-style-type: none"><li>No changes were made to this section.</li></ul> <p><b>Introductory section:</b></p> <ul style="list-style-type: none"><li>Each regimen (1A, 1B, 1C, 1D) was named in this section.</li></ul> <p><b>Before taking your ARVs:</b></p> <ul style="list-style-type: none"><li>No changes were made to this section.</li></ul> <p><b>How to take your ARVs:</b></p> <ul style="list-style-type: none"><li>The statement ‘take your medicines after food...’ was changed to “Take your ARVs with or without food.”</li><li>The statement “You must not stop taking any of your medicines. Carry on taking all 3 of your ARVs” was added.</li></ul> <p><b>While taking your ARVs:</b></p> <ul style="list-style-type: none"><li>No changes were made to this section</li></ul> <p><b>Side effects:</b></p> <ul style="list-style-type: none"><li>The side effects “in the first 2 weeks” was changed to the side effects experienced “in the first 6 weeks”.</li><li>Pictograms were included only for the side effects that occur after 3-6 months of taking ARVs.</li><li>Vomiting and stomach pain were removed from the side effects experienced in the first 6 weeks of starting therapy section.</li><li>The statement “if you feel strange in any way while taking ARVS...” was removed.</li><li>Rash pictogram added.</li></ul> <p><b>Storage of medication:</b></p> <ul style="list-style-type: none"><li>The do not store your medicine in the bathroom pictogram was removed and the spacing changed.</li></ul> <p><b>Addition of Important! section:</b></p> <ul style="list-style-type: none"><li>Specialised information about pregnancy and ARVs, and the onset of extreme fever and chills was presented.</li><li>Fever with or without chills pictogram added.</li></ul> <p><b>Use a condom:</b></p> <ul style="list-style-type: none"><li>Emphasizes the importance of condom use. An additional AIDS ribbon was used and the section was enlarged.</li></ul> <p><b>Footer section:</b></p> <ul style="list-style-type: none"><li>The statement “You must take ARVs for the rest of your life” was enlarged and moved to the bottom of the PIL so as to be very clear to the reader.</li></ul> | <div><p><b>ANTIRETROVIRAL THERAPY (ARV)</b><br/><b>Patient information leaflet for Regimen 1a</b></p><p>The information in this leaflet will help you take your ARVs properly and stay as healthy as possible.</p><table><tr><th>WHAT YOUR ARVs DO</th><th>HOW TO TAKE YOUR ARVs</th><th>WHILE TAKING YOUR ARVs</th></tr><tr><td><p><b>ARVs fight HIV/AIDS :</b></p><ul style="list-style-type: none"><li>they stop the growth of HIV virus (but they cannot kill it)</li><li>they help you become stronger</li><li>they increase the CD4 count (good cells)</li><li>they lower the amount of HIV virus in the blood</li></ul></td><td><p><b>Stavudine (d4T)</b></p><p>Take 1 tablet in the morning and 1 tablet at night.</p><p><b>Lamivudine (3TC)</b></p><p>Take 1 tablet in the morning and 1 tablet at night.</p><p><b>Elavirenz (EFV)</b></p><p>Take 1 tablet at night</p><p><b>If possible...</b></p><ul style="list-style-type: none"><li>take your medicines after food and with a full glass of clean water.</li><li>You must continue taking all 3 of your medicines.</li></ul></td><td><p><b>Are you taking other medicines?</b><br/>You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or traditional remedies from the:</p><p><b>If you forget to take your medicine...</b></p><ul style="list-style-type: none"><li>take it as soon as you remember.</li></ul><p><b>Do not share your medicines...</b></p><ul style="list-style-type: none"><li>with friends or family.</li></ul></td></tr></table><br/><table><tr><th>SIDE EFFECTS</th><th>HOW TO STORE YOUR ARVs</th></tr><tr><td><ul style="list-style-type: none"><li>Side effects are unpleasant effects that may appear when taking your medicines, but they can be well managed and treated.</li><li>You may not get these side effects or you may have other side effects that are not listed here.</li><li>If you feel strange or different <b>in any way</b> while taking your ARVs, or if you experience any of the following you must tell the clinic sister as soon as possible.</li></ul><p><b>In the first 2 weeks after starting ARVs:</b></p><p><b>After 3-6 months of taking ARVs:</b></p><p><b>YOU MUST TAKE ARVs FOR THE REST OF YOUR LIFE</b></p><p><b>You can still spread HIV/AIDS by having unprotected sex.</b></p><p>You must use a condom every time you have sex to protect yourself and others.</p><p><b>HOW TO STORE YOUR ARVs</b></p><p><b>Keep all medicines...</b></p><p>where children cannot reach them.</p><p><b>Do not keep your ARVs...</b></p></td><td></td></tr></table><p style="text-align: center;"><small> <b>BHASKERS UNIVERSITY</b><br/>Faculty of Health Sciences<br/>Department of Health, Behaviour and Society<br/>1st Floor, 100-101, August 2008</small></p></div> | WHAT YOUR ARVs DO  | HOW TO TAKE YOUR ARVs | WHILE TAKING YOUR ARVs | <p><b>ARVs fight HIV/AIDS :</b></p> <ul style="list-style-type: none"><li>they stop the growth of HIV virus (but they cannot kill it)</li><li>they help you become stronger</li><li>they increase the CD4 count (good cells)</li><li>they lower the amount of HIV virus in the blood</li></ul>  | <p><b>Stavudine (d4T)</b></p>  <p>Take 1 tablet in the morning and 1 tablet at night.</p> <p><b>Lamivudine (3TC)</b></p>  <p>Take 1 tablet in the morning and 1 tablet at night.</p> <p><b>Elavirenz (EFV)</b></p>  <p>Take 1 tablet at night</p> <p><b>If possible...</b></p>  <ul style="list-style-type: none"><li>take your medicines after food and with a full glass of clean water.</li><li>You must continue taking all 3 of your medicines.</li></ul> | <p><b>Are you taking other medicines?</b><br/>You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or 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unprotected sex.</b></p>  <p>You must use a condom every time you have sex to protect yourself and others.</p> <p><b>HOW TO STORE YOUR ARVs</b></p> <p><b>Keep all medicines...</b></p>  <p>where children cannot reach them.</p> <p><b>Do not keep your ARVs...</b></p>  |  |
| WHAT YOUR ARVs DO  | HOW TO TAKE YOUR ARVs  | WHILE TAKING YOUR ARVs   |                       |                        |  |  |  |              |                        |   |  |
| <p><b>ARVs fight HIV/AIDS :</b></p> <ul style="list-style-type: none"><li>they stop the growth of HIV virus (but they cannot kill it)</li><li>they help you become stronger</li><li>they increase the CD4 count (good cells)</li><li>they lower the amount of HIV virus in the blood</li></ul>    | <p><b>Stavudine (d4T)</b></p>  <p>Take 1 tablet in the morning and 1 tablet at night.</p> <p><b>Lamivudine (3TC)</b></p>  <p>Take 1 tablet in the morning and 1 tablet at night.</p> <p><b>Elavirenz (EFV)</b></p>  <p>Take 1 tablet at night</p> <p><b>If possible...</b></p>  <ul style="list-style-type: none"><li>take your medicines after food and with a full glass of clean water.</li><li>You must continue taking all 3 of your medicines.</li></ul>   | <p><b>Are you taking other medicines?</b><br/>You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or traditional remedies from the:</p>  <p><b>If you forget to take your medicine...</b></p> <ul style="list-style-type: none"><li>take it as soon as you remember.</li></ul> <p><b>Do not share your medicines...</b></p> <ul style="list-style-type: none"><li>with friends or family.</li></ul>  |                       |                        |  |  |  |              |                        |   |  |
| SIDE EFFECTS   | HOW TO STORE YOUR ARVs   |  |                       |                        |  |  |  |              |                        |   |  |
| <ul style="list-style-type: none"><li>Side effects are unpleasant effects that may appear when taking your medicines, but they can be well managed and treated.</li><li>You may not get these side effects or you may have other side effects that are not listed here.</li><li>If you feel strange or different <b>in any way</b> while taking your ARVs, or if you experience any of the following you must tell the clinic sister as soon as possible.</li></ul> <p><b>In the first 2 weeks after starting ARVs:</b></p>  <p><b>After 3-6 months of taking ARVs:</b></p>  <p><b>YOU MUST TAKE ARVs FOR THE REST OF YOUR LIFE</b></p> <p><b>You can still spread HIV/AIDS by having unprotected sex.</b></p>  <p>You must use a condom every time you have sex to protect yourself and others.</p> <p><b>HOW TO STORE YOUR ARVs</b></p> <p><b>Keep all medicines...</b></p>  <p>where children cannot reach them.</p> <p><b>Do not keep your ARVs...</b></p>   |  |  |                       |                        |  |  |  |              |                        |   |  |

# ANTIRETROVIRAL THERAPY (ARV)

## Patient information leaflet for Regimen 1a

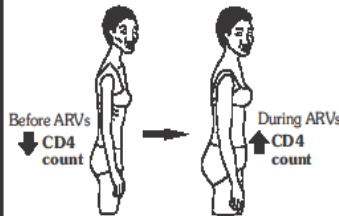
The information in this leaflet will help you take your ARVs properly and stay as healthy as possible.

### WHAT YOUR ARVs DO

#### ARVs fight HIV/AIDS :

- they stop the growth of HIV virus
- they help you become stronger
- they increase the CD4 count (good cells)
- they lower the amount of HIV virus in the blood

#### ARVs do not cure AIDS



### BEFORE TAKING YOUR ARVs

#### Tell your doctor, nurse or pharmacist if you...

- are taking any other medicines
- have any allergies
- are pregnant or trying to fall pregnant
- are breast-feeding
- are on oral or injectable contraceptive
- have anything else wrong with you.

### HOW TO TAKE YOUR ARVs

#### Stavudine (d4T)



Take 1 tablet in the morning and 1 tablet at night

#### Lamivudine (3TC)



Take 1 tablet in the morning and 1 tablet at night

#### Efavirenz (EFV)



Take 1 tablet at night

Take your ARVs with or without food

**You must not stop taking any of your medicines. Carry on taking all 3 of your ARVs.**

### WHILE TAKING YOUR ARVs

#### Are you taking other medicines?

You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or traditional remedies from the:



#### If you forget to take your medicine...

- take it as soon as you remember.

**Do not share your medicines...**  
• with friends or family.



### SIDE EFFECTS

- Side effects are unpleasant effects that occasionally appear when taking ARVs, but they can be well managed and treated.
- You may not get any side effects. However if you experience any of the following tell the doctor or sister at the clinic.

#### In the first 6 weeks after starting ARVs:

- abnormal dreams
- nausea
- dizziness
- diarrhoea
- headache
- skin rash

#### After 3 - 6 months of taking ARVs:

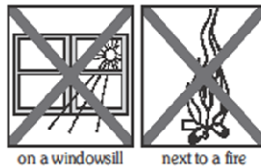
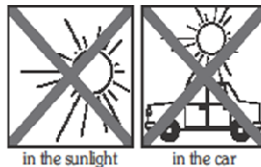
- tingling, burning, numbness or pain in the hands or feet (pins and needles)

#### Go to the clinic AS SOON AS YOU CAN if you experience:

- stomach pain, nausea and vomiting
- severe rash on the body or in the mouth and a fever (hot)

### HOW TO STORE YOUR ARVs

#### Do not keep your ARVs...



#### Keep all medicines...



### IMPORTANT !

#### Go to the clinic AS SOON AS YOU CAN:

- if you are pregnant when taking Efavirenz
- if you experience fever (hot) with or without chills (cold)

### USE A CONDOM

You can still spread HIV/AIDS by having unprotected sex, even if you are taking ARVs.



You must use a condom every time you have sex to protect yourself and others.



July 2009

**YOU MUST TAKE ARVs FOR THE REST OF YOUR LIFE**

Figure 3.1 Final version of PIL for regimen 1A

### **3.3.3 Reasons for modification of PIL**

The importance of adhering to the ARV regimen was considered more important to emphasize than the requirement of taking certain ARVs with or without food. This is a factor known to contribute to non-adherence in this population as many of the patients are unable to afford three meals a day. This makes the requirement to take ARVs with food impossible to adhere to. Changes needed to be made to the PIL to make patients aware of the importance of adherence regardless of having food or not. EFV is the only ARV which should be taken with food for optimal therapy. Food increases the bioavailability of EFV by 50% [44], however EFV may also be taken on an empty stomach.

Local doctors expressed concern with regard to correct medicine-taking behaviour. Doctors suspected some patients of taking one of their three ARVs alone e.g. NVP only, until finished, and then starting with the next ARV such as 3TC. Doctors were concerned that the patients should understand the need to take all three ARVs together. Patients were reminded that they could not stop any of their ARVs.

The HCPs felt that most patients are aware that medication should not be stored in a damp place, making the bathroom storage pictogram redundant. Pictograms illustrating side effects experienced in the first two weeks were not included as the local doctors did not want the pictograms to result in complaints about minor side effects. Pictograms were only included for side effects experienced after 3-6 months. This spacing increased the readability of the PIL by increasing the white space and making the format easier to read.

The largest percentage of HIV/AIDS-infected people in the population are women of child-bearing age, highlighting the importance of providing information on pregnancy and ARVs. Information regarding the risks of taking EFV when pregnant was included.

The importance of preventing the spread of HIV/AIDS by using condoms is a universal message that the HCPs felt very strongly should be included and emphasised. This was accomplished by having this message appear as the last section of the PIL, headed by the words 'use a condom' to emphasize the importance of condom use.



### 3.3.4 Modification of pictograms to be used in the PILs

Communication with the local doctors, pharmacist and nurses was by informal discussions at Masonwabe Clinic, Settlers Hospital. This resulted in identifying a need for two additional pictograms for the PILs that illustrated different side-effects. The original design process was described in detail by Dowse *et al.* [157]. The new pictograms were generated in two ways: either they were drawn from pictures in books/copied from previously designed pictograms, or they were drawn from posed photographs of people from the target population. The design team consisted of the researcher, the supervisor of this project (who has many years of experience in developing pictograms for this target population), the graphic artist, the interpreter and two groups of HCPs, one local group from Masonwabe Clinic and the other an American group of HIV physicians from the Owen Clinic, University of California, San Diego, USA. After the design team analysed and critiqued the pictogram, successive versions were created in an iterative process.

#### ***‘Fever and rash’ pictogram:***

The original pictogram, which was designed to represent just ‘skin rash’ [158], was then modified to incorporate ‘fever and rash’ (Figure 3.2). Problems associated with the ‘fever and rash’ pictogram (Figure 3.2, Version 1) included the following: the rash was not represented severely enough on the body of the pictogram figure; the rash distribution looked like chicken pox or measles; and the rash needed to have a higher concentration of dots to be more representative of Stevens-Johnson Syndrome. The HCPs felt that this would cause the patients to unnecessarily consult the doctor with the onset of any minor rash.

In Version 2 (Figure 3.2) the rash was represented as a more obvious, consistently distributed rash by using shading. HCPs then felt that the rash looked like lesions, scars, infected tissue and/or leprosy. Markings around the mouth made the mouth look disproportionate. Version 3 represented a severe rash as well as Stevens-Johnson Syndrome represented by the darker shaded patches. This version was used in the randomised control trial

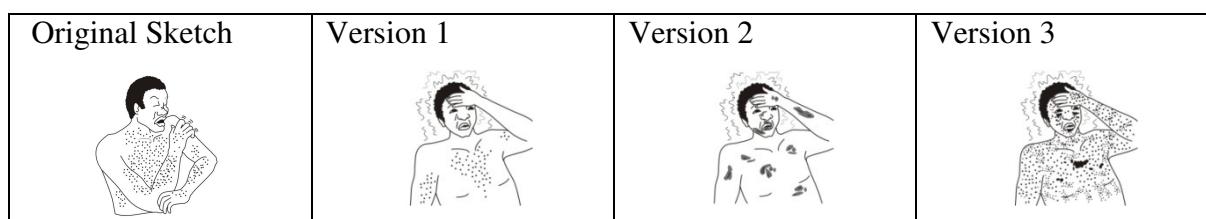


Figure 3.2 Sequential development of ‘fever and rash’ pictogram

### ***‘Fever with or without chills’ pictogram***

The original sketch (Figure 3.3) was drawn by the interpreter who is also a part-time artist. This was then modified by the graphic artist to create the pictogram to be used on the PIL (Figure 3.3).

Problems associated with the ‘fever with or without chills’ pictogram (Figure 3.3, Version 1) were identified by the HCPs and the pictogram was modified appropriately. The lines protruding perpendicularly were taken to represent hair rather than heat. It was felt that all the wavy lines should be more or less parallel. The pictogram was modified to produce Version 2 which was used in the main study.

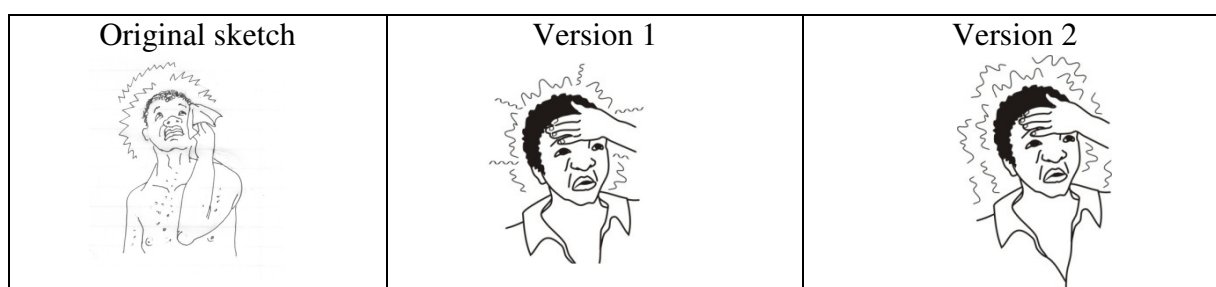


Figure 3.3 Modification steps for ‘fever with or without chills’ pictogram

### **3.3.5 Design of the medicine labels**

Based on a template designed by Ramela [158], labels were modified for all the drugs used in the first line ARV treatments, namely lamivudine (3TC), stavudine (d4T), efavirenz (EFV), nevirapine (NVP) and zidovudine (AZT). The labels are shown in Figure 3.4.

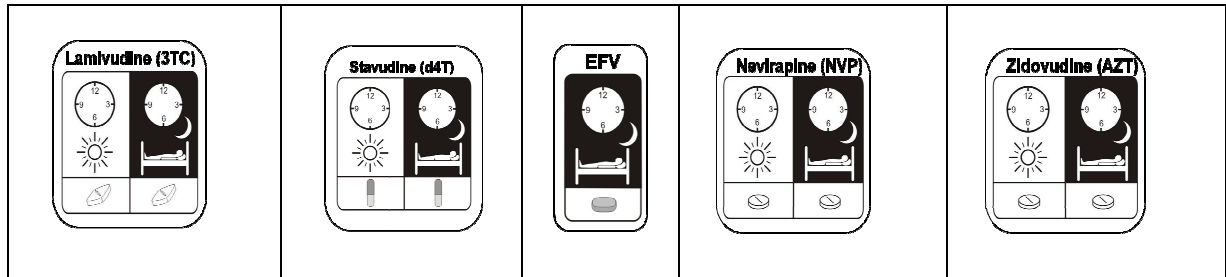


Figure 3.4 Medicine labels used in the study

Pharmacists and doctors from the local hospital were consulted on the dosing regimens and available dosage form for each of the ARVs. The dosage form was subject to specific tender at the time of study. In South Africa, ARVs are provided to the public sector clinics on a tender basis and therefore may change if a different company acquires the tender. Photographs of each dosage form were taken for the graphic artist to draw an exact graphic replica to be used in the PIL and on the labels.

Information on instructions and the physical characteristics of the dosage forms are stated below:

- Lamivudine (3TC) - Take one tablet twice daily with or without food. Diamond-shaped small white tablets.
- Stavudine (d4T) - Take one tablet twice daily with or without food. Capsules with a brown cap and orange body.
- Efavirenz (EFV) - Take one tablet in the morning with or without food. Large oval yellow tablets, with concave edges.
- Nevirapine (NVP) - Take one tablet twice daily with or without food. White round tablets.
- Zidovudine (AZT) - Take one tablet twice daily with or without food. White round tablets.

The pictograms used to represent night and day were previously tested in a similar target population by Dowse *et al.* [18] and were shown to be well understood.

Consultation with local doctors and pharmacists revealed that, in their opinion and from their experience in managing patients from this population, adherence to the regimen was more important than possibly compromising adherence by requiring the ARVs to be taken at specific times in relation to eating, as lack of food due to lack of money was reported to be a

fairly common situation. This made the addition of the original pictogram representing food (Figure 3.5), redundant in all the labels.

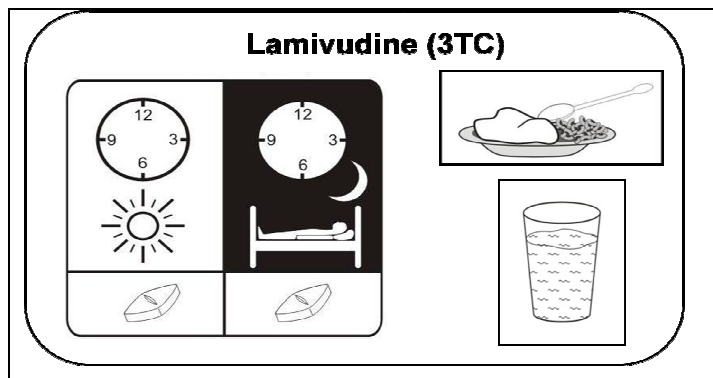


Figure 3.5 Example of original version of the medicine label

The labels, in a matte finish that would not fade or smudge, were printed on paper with a removable backing to enable the labels to be stuck onto the medication boxes. Three hundred 3TC and d4T labels, 200 EFV labels, and 150 AZT and NVP labels were printed for use in the study.

### 3.4 Modification of patient behavioural tools

Two patient behaviours were measured in this study: adherence and self-efficacy. Adherence is an extremely complex basis for medicine-taking behaviour, and nonadherence may be due to many factors. Included in these are lack of understanding of the medical instructions, complexity of the therapy and inadequate health literacy. Among the range of factors identified as being associated with adherence to antiretrovirals (ARVs) is confidence in one's ability to adhere to a treatment plan, also termed "self-efficacy" [159,160].

Most published instruments for measuring self-efficacy and self-reported adherence were designed in developed countries where patient characteristics tend to be significantly different from those in developing countries, where there are less advanced cultures and often much lower literacy levels. Modifications to both the 8-item Morisky Medication Adherence Scale (MMAS-8) to measure self-reported adherence and the HIV-ASES for self-efficacy are described below.

### 3.4.1 MMAS-8 for measuring self-reported adherence

The original MMAS-8 (Table 3.2), originally designed for hypertensive patients, was modified to suit the target lower-literate Xhosa-speaking population currently on ARV therapy. This original scale consists of an eight-item questionnaire. The first seven questions, apart from question 5, are yes/no answers, with 'yes' scoring 1 and 'no' scoring 0. Question 5 is also a yes/no answer but the scores for the answers are reversed i.e. yes (0) and no (1). The last question is answered using a 5-part scale: the options '*usually*', '*sometimes*', '*once in a while*' and '*all the time*' each resulted in a score of 1; the options of '*rarely*' and '*never*' resulted in a score of 0. The individual question scores are added up to attain a final score of between 0 and 8. A score of 8 is an indicator of high adherence and scores between 6 and 7 indicate medium adherence, whereas a score < 6 denotes low adherence [161-163]. The original MMAS-8 has been validated and was found to have a Cronbach alpha of 0.83 [161-163].

Adjustments to each question are described below, and the final questions are given in Table 3.2:

#### Question 1:

- As the scale was to be used in HIV/AIDS patients currently on ARV therapy, the term '*high blood pressure pills*' was replaced with the term '*ARVs*' throughout the scale.

#### Question 2:

- Two weeks may be a difficult time frame for recalling information. Patients visit the clinic every month and thus the time frame was changed to align with monthly clinic visits.

#### Question 3:

- The colloquial term '*cut back*' is not used in the isiXhosa language and was replaced with '*reduced*'

**Questions 4 and 5:** no changes

#### Question 6:

- The concept of having a condition '*under control*' e.g. in this context blood pressure, is not a commonly used term in the isiXhosa language. This question was adjusted to '*when you feel healthy*' to increase acceptability in the target population.

**Question 7:**

- The term '*hassled*' is not used in the isiXhosa language. This question was changed to '*During last weekend, did you miss taking any of your ARVs?*' This was done in order to incorporate a shorter time frame of adherence into the scale. Weekends are a break in the monotony of the routine of everyday life. Thus if the patients were taking their ARVs as part of a daily lifestyle pattern, they would be most at risk of nonadherence over the weekend. Therefore the question was modified to include taking ARVs over weekends.

**Question 8:**

- Words like '*never, almost never, sometimes, quite often and always*' in the form of a rating scale are also not used by the isiXhosa population, thus the final question was adjusted to allow for a dichotomous yes/no answer.
- The words '*hassled*' and '*treatment plan*' were avoided.

Table 3.2 Original and modified versions of the MMAS-8

| Question number | 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 ARVs?   |
| 2               | Over the past two weeks, were there any days that you forgot to take your high blood pressure medicine?                       | Sometimes people miss taking medication for reasons other than forgetting. Over the past month (since your last clinic visit) were there any days when you did not take your ARVs? |
| 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 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 take your medication with you?                                       | When you travel or leave home, do you sometimes forget to bring along your ARVs?   |
| 5               | Did you take your high blood pressure medicine yesterday?   | Did you take your ARVs 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 ARVs?   |
| 7               | Do you ever feel hassled about sticking to your blood pressure treatment plan?  | During last weekend, did you miss taking any of your ARVs?   |
| 8               | How often do you have difficulty remembering to take all your blood pressure medication?                                      | Some people find having to take ARVs everyday tiresome. Do you ever feel irritated about taking your ARVs every day?   |

### 3.4.2 HIV-ASES for measuring self-efficacy

The original HIV-ASES (see Figure 3.6) was modified to make it more appropriate for use in the study population. The HIV-ASES was developed to predict a patient's confidence in being able to take the medication as prescribed consists of two parts: a 12-item scale of treatment-related questions, and a scale consisting of a numerical rating scale which uses a 11-point Likert scale to rate the patient's perceived confidence [15]. The questions relate to the treatment plan, the medication regimen, adherence, nutrition and exercise are all barriers which could lead to non adherence [15].

#### 3.4.2.1 Modifications to the HIV-ASES

##### Introductory section:

- The introductory paragraph was altered to avoid using unfamiliar words:
  - the term '*treatment for HIV*' was replaced with '*medicine*'
  - the sentence '*treatment can involve different things for different people*' was removed as it was felt to add no value to the introduction and was redundant
  - the word '*refer*' was replaced with '*mean*'
  - the word '*diet*' was excluded from the list of activities for keeping healthy as adherence to the ARVs is more important than sticking to a diet plan
  - the term '*treatment plan*' is an unfamiliar one that was excluded as it is not used by HCPs for this population
  - the concept of '*self care*' was replaced with the term '*what you do to keep yourself healthy*'.

##### Question 1:

- In all questions used to rate self-efficacy, the term '*stick to your treatment plan*' was replaced with '*Take your ARVs.*' This was done in order to avoid confusing the patients if they were taking any other medication.

##### Question 2:

- No changes.

##### Question 3:

- The language in this question was simplified to enhance understanding.
- The term '*HIV-infected*' is not used and is simply stated as '*HIV*'.

- The term ‘*or doing other things*’ was removed.

**Question 4:**

- The word ‘*disrupted*’ was difficult to translate into isiXhosa while retaining the meaning, so this question was reworded to: ‘*Take your ARVs even if your daily plans change e.g. if you have to go out of town?*’.

**Question 5:**

- No changes.

**Question 6:**

- The question ‘*Stick to your treatment schedule when it means changing your eating habits?*’ was removed. The importance of adhering to ARVs was more important than risking reduced adherence due to missing ARVs because no food was available.

**Question 7 (original) / Question 6 (modified):**

- This question was used to incorporate activities in addition to eating habits. Local doctors emphasized the importance of a focus on adherence regardless of when food was eaten in relation to timing of the dose.

**Question 8 (original) / Question 7 (modified):**

- As South African HIV/AIDS patients are familiar with CD4 counts, the term “T-lymphocytes” was replaced with the more familiar term.

**Question 9 (original) / Question 8 (modified):**

- No changes.

**Question 10 (original) / Question 9 (modified):**

- The phrase ‘*when getting to clinic appointments is a major hassle*’ was changed to ‘*if there is a problem getting to the clinic*’ to simplify the language used.

**Question 11 (original) / Question 10 (modified):**

- The concept of ‘*people close to you*’ was changed to ‘*friends and family*’, a more direct, familiar way of describing such people.

**Question 12 (original) / Question 11 (modified):**

- The word ‘*positive*’ was simplified to ‘*good*’.
- The term ‘*improve your health*’ was simplified to ‘*making you feel better*’.



### HIV-ASES Test Original Version

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?

### Final modified version of the HIV-ASES test

I am going to ask you about things that may happen when you have to take medicines. Sometimes, this could mean what happens when you are taking your medications, and other times it could mean how you deal with things like what you eat or whether you exercise or take vitamins. So, in these questions, when I ask you about your “treatment”, I am talking not only about your medicine but also other things that you do to keep yourself health.

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).

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

1. Take your ARVs correctly even if side effects begin to interfere with daily activities?
2. Integrate your ARVs into your daily routine?
3. Take your ARVs every day even if it means taking them in front of people who do not know you have HIV?
4. Take your ARVs even if your daily plans change e.g. if you have to go out of town?
5. Take your ARVs even if you are not feeling well?
6. Take your ARVs even if they interfere with (make you change?) your daily activities?
7. Take your ARVs even if you are feeling healthy and the test results (CD4 count) are good?
8. Take your ARVs even when you feel discouraged or are unhappy with your health?
9. Take your ARVs even if it is a problem to get to the clinic?
10. Take your ARVs even if your family or friends say the ARVs are not helping you?
11. Get something good out of carrying on taking your ARVs, even if they are not making you feel better?

Figure 3.6 Original and modified HIV-ASES

### 3.4.2.2 Modifications to the HIV-ASES rating scale

The original HIV-ASES (Figure 3.6) incorporated a numerical rating scale deemed inappropriate for this population based on previous research experience in a similar population. Modified versions of the numerical rating scale (0-10) were developed (see Figure 3.7 below) with three of these including visual images such as a happy or a sad face, and the ‘thumbs up’ sign. Modifications to these scales are reported in Table 3.3.

Table 3.3 Modifications to the HIV-ASES rating scale

| Scale                     | Modification   |
|---------------------------|--|
| Self-efficacy Scale 1     | Original scale   |
| Self-efficacy Scale 2     | Removal of the 0 before single digit numbers.<br>Reversal of ordering so that a higher confidence rating appears in a higher position.   |
| Self-efficacy Scale 3     | Inclusion of a graphical representation of a facial expression to help the patient identify positive and negative associations with confidence.  |
| Self-efficacy Scale 4     | Inclusion of a graphical representation of increased levels of confidence represented in the form of increments in the bar chart. Inclusion of facial expression to help the patient identify positive and negative associations with confidence.  |
| Final Self-efficacy Scale | Inclusion of a graphical representation of increased confidence levels represented in the form of increments in the bar chart.<br>Inclusion of facial expression as well as hand signals to help the patient identify positive and negative association with confidence. Inclusion of a frame around the scale for aesthetic appeal. |

### 3.4.3 Translation of instruments into isiXhosa

The modified questions from both the HIV-ASES and the MMAS-8 were translated into isiXhosa using a multi-stage translation and back-translation process. Consultations took place between the researcher, the interpreter and an expert in the isiXhosa language. The translation was done by the language expert who is a faculty member in the African Languages Department at Rhodes University. The back-translation was done by a different expert. A Xhosa-speaking nurse from Masonwabe Clinic also back-translated the instrument to evaluate the understandability of the words used.

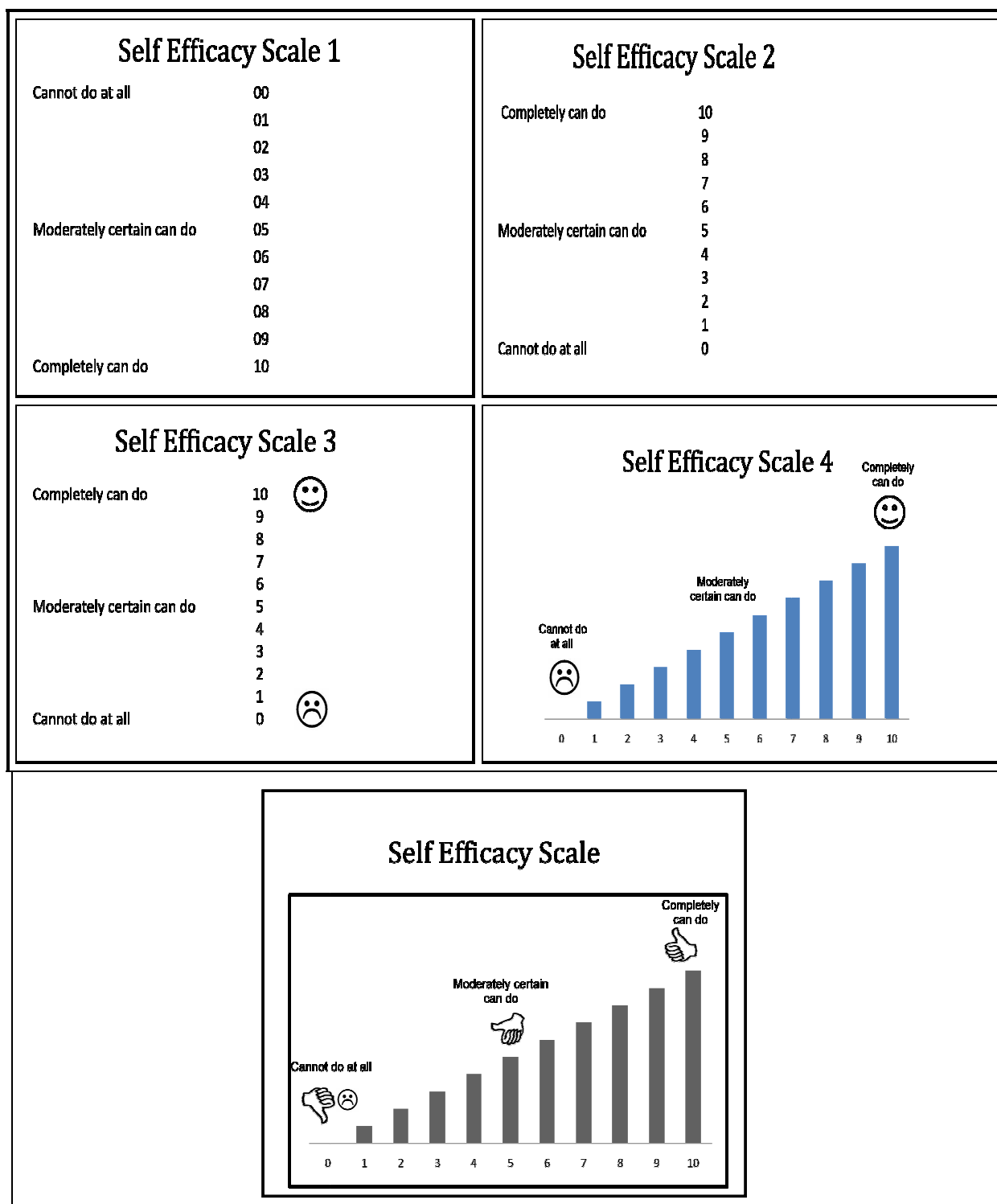


Figure 3.7 HIV-ASES self-efficacy scales

### **3.5 Participant testing of patient information materials**

#### **3.5.1 Study site and study population**

The study site was Grahamstown, a town in the Eastern Cape Province of South Africa. The Eastern Cape is the poorest of the nine provinces [2]. The peri-urban local population, from which the participants were drawn, are of the black Xhosa-speaking population. This is the first language for the majority (86.8%) in the area [2]. The educational level is very low, with under a quarter (22.8%) of the population having no education, half having the equivalent of 7 years schooling or less and 20.4% having completing Grade 12 [2]. It is estimated that 30% had started school but had not completed their secondary education [2]. This low level of education may influence the poor levels of functional literacy, with just 55.9% of the Black African population in the Eastern Cape population being functionally literate [2].

South Africa's health sector is divided into two: the public sector, which serves 85% of the population, and the private sector which serves the remaining 15%. Patients using the public health sector do not pay for services that are provided in hospitals and clinics. The private sector patients pay for services themselves and in many cases are subsidised by medical aid [164,165]. According to the WHO Statistics report during the period 2000 to 2006, for every 10 000 people attending the public health sector in South Africa there were 8 doctors, 41 nurses and midwives, 3 pharmaceutical personnel and 2 community health workers. By comparison, a country such as Sweden has 33 practitioners per 10 000 patients [166]. This highlights the need for more skilled HCPs in the health care sector [168].

The Eastern Cape Province is divided into seven districts, with Grahamstown being in the Cacadu District which is the largest [169]. Grahamstown has seven primary care clinics, one district hospital and one health centre. The Masonwabe HIV/AIDS clinic is in Settlers District Hospital and was established in 2003. Masonwabe is an isiXhosa word meaning 'Let's be happy together'. Masonwabe Clinic reported a total of 1908 patients taking ARVs in the period January to March 2010. The number of ARV-naïve patients starting treatment in 2009 was 156, 13 patients deregistered from ARV treatment and there was

one reported death. In the first three months of 2010, 457 CD4 counts and 467 viral load tests were done. Five hundred and forty eight patients were down-referred to feeder clinics, and of these, 126 patients were down-referred to Raglan Road Clinic [169].

In Grahamstown the initiation of ARVs is done according to a specific protocol consisting of three phases:

- **Phase one** consists of voluntary counselling and testing conducted at a primary care clinic. HIV positive patients proceed to phase two.
- **Phase two** involves referral to Masonwabe Clinic, Settler Hospital from the primary care clinic. The patient is then given short-term prophylactic co-trimoxazole treatment. This enables HCPs to evaluate adherence. Patients who are adherent to the treatment are initiated on ARV treatment and given their ARVs every 2 weeks for a month. Patients are then given ARVs every 28 days for a two-month period.
- **Phase three** consists of down-referral back to the primary care clinic. Down-referral occurs when the patient is stable on ART. The primary care clinics are closer to the patient's residence and thus it is easier for the patient to attend monthly visits to receive their ARVs, every 28 days.

Participants were recruited from Raglan Road Clinic, a primary care clinic serving a socioeconomically poor population of the city. The initial evaluation of the patient information materials was conducted using a focus group discussion (FGD) (Section 3.5.4 below). The inclusion criteria for participants were that they were Xhosa speaking, older than 18 years and had less than seven years of schooling. Exclusion criteria were being HIV positive and taking ARVs. The participants for the FGD were obtained by approaching and gathering participants who were visiting the clinic due to a number of varied ailments.

This was followed by a pilot study to pre-test the materials (Section 3.5.5 below). Inclusion criteria for participants stated that they were over 18 years of age, spoke isiXhosa as their home language, had an education ranging from no formal education to Grade 12 and were prescribed either regimen 1A, 1B, 1C or 1D. These patients were recruited on a Tuesday and Thursday, as these were the days that ARV patients visited Raglan Road Clinic. The patients were approached after they had received standard care from the nursing sisters.

Ethical approval was obtained from Rhodes University Ethical Standards Committee, Settlers Hospital Ethics committee and the Eastern Cape Department of Health.

### **3.5.2 Use of interpreters**

South Africa has eleven official languages. This creates a number of communication problems as HCPs are often unable to communicate in the patients' first language and this creates the need for medical interpreters. Interpreting has been described by many researchers as a complex task that requires mediation between different cultures, language and context [170]. The South African constitution requires that services should be offered to people in their own language, thus clinics and HCPs need to provide service to the population in a language that they can understand [170].

The researcher's first language is English, and as the patients were all isiXhosa-speaking, an interpreter was needed who was trained for this project and who participated in all interviews. The interpreter, EB, was a black Xhosa-speaking male from the same culture as the target population, with an excellent grasp of English. He provided a bridge between the patients and the researcher, facilitating communication.

The interpreter was trained to meet the requirements of the data-collection process. He was instructed to interpret exactly what the interviewer and the participants said and not prompt answers in any way as this would compromise the results. He was encouraged to faithfully report all spoken communication from the participants and to avoid conducting any part of the interview without first being instructed by the researcher. He was requested to make the participants feel as relaxed, comfortable and as stress-free as possible so that they would be more responsive to the questions put to them.

### **3.5.3 Interview process and data collection for FGD and pilot study**

Participants were guaranteed anonymity and after agreeing to participate, had the consent form explained to them, which they then signed. Each participant was reminded that the interview was not a test as it was the material that was actually being tested. They were also

requested to speak openly and honestly about the process as this was essential for the generation of valid, reliable data.

When recruiting participants, a standard approach was used in which the interpreter informed participants about the study. The following approach was adapted from a script used in a previous study [158]:

*“Good morning/ afternoon, my name is Efese and I am an interpreter. This is Kirsty. Kirsty is from the Rhodes University Pharmacy Department. She is doing a project for her studies. We were wondering if you would be interested in participating in a study”.*

If the participant was willing to proceed further, the researcher elaborated on the study by saying:

*“Please sit down and relax, I will not take too much of your time. As mentioned before by my interpreter the project focuses on testing information materials for patients. This is not a test to see how clever you are, it is a test to see if the leaflets we have made are easy to see and understand. I will ask you some questions and I need you to tell me what you think the answer is. Then you can use the leaflet to answer the questions I ask.*

Patients were then screened to ensure they complied with the inclusion criteria. The criteria differed between the FGD and the pilot study as described in Section 3.5.1.

For the FGD, once compliance with criteria was established and individuals agreed to participate, a script was used to guide the discussion and encourage feedback from the participants (Appendix A).

For the pilot study, once compliance with criteria was established and the patients agreed to participate, the patient was asked:

*“Before we start I would like to know if you are taking ARVs and what ARVs you are taking. May I see your health passport please?”*

The patient’s health passport was then checked for the ARV regimen to ensure the participant was taking 1A, 1B, 1C or 1D. This was followed by:

*Thank you very much. Just a few more questions. Have you been to school? If you have, to what standard did you attend and how many years were you at school?"*

If the participant had more than 12 years of formal schooling years, he/she was thanked for volunteering but told that he/she did not qualify for the study.

### **3.5.4 Focus group discussions (FGD)**

FGDs were conducted to determine whether the tools that had been tailored to suit the target population were acceptable and easily understood. The FGD was used to develop the tools, identify any confusion, misconceptions or beliefs about the tools.

Two FGDs were conducted in June 2009 at the Raglan Road Clinic, which was used as it is in a convenient location and has a quiet room within the clinic large enough to accommodate everyone comfortably. The five participants in each FGD were from the same economic, educational and social background as that of the target population (see inclusion criteria in Section 3.5.1).

The FGD facilitator was the researcher, who remained neutral throughout the FGD. It was made clear that there were no right or wrong answers. In the first FGD, the participants had an educational level of Grade 4-7, and in the second FGD all participants had less than a Grade 3 education. A script was followed to ensure that all the relevant questions were addressed and to ensure uniformity between the two FGDs. Participants were made aware that the FGD would be recorded, and responses were also recorded in writing. At the end of the FGD an honorarium of R40 (approximately US\$6) was received by each participant. Modifications were made to the scales prior to use in the pilot study as described in section 3.6.

### **3.5.5. Pilot study**

A pilot study was conducted to ensure that the questions in the questionnaire were understood and acceptable, and to evaluate the need for any further modifications to the MMAS-8 and the HIV-ASES. This was done prior to the application of these instruments in the randomised control trial.



The survey instrument for the pilot study consisted of a questionnaire (Appendix C1). The questionnaires used in this pilot study were adapted from one used in a previous research study [158] and contained four sections:

- Section 1 contained demographic data such as gender, race, age, highest qualification, home language, employment, how ARVs are taken and contact details such as address and cellular phone number.
- Section 2 elicited clinical data from the patient's health passport including CD4 and viral load counts, weight, any side effects experienced, any regimen changes and pharmacy refill dates.
- Section 3 consisted of a series of questions that assessed knowledge of HIV/AIDS, the side effects of the ARVs and knowledge of ARVs.
- Section 4 required the patients to complete a self-efficacy test.
- Section 5 assessed adherence using a modified version of MMAS-8.

The pilot study was conducted in 16 isiXhosa HIV/AIDS patients on ARVs. Individual interviews were conducted in July 2009 at the Raglan Road Clinic. The study population and inclusion criteria for the study are described in Section 3.5.1. Signed consent was obtained after the patient had read and understood the consent form (Appendix C2).

Once the participant had met all the above-mentioned inclusion criteria, demographic information was collected and, after looking at the provided watch face, he/she was asked to state the time.

The patient was then offered both the English and Xhosa versions of the PIL.

*“Now I am going to give you a leaflet to read. Please take your time to read it and then when you are finished I will ask you questions about what you have read. Please tell me when you are finished reading it”.*

When the participant had indicated that he/she had finished reading the leaflet the interviewer continued with:

*“I am now going to ask you questions about the information you have read in the leaflet. Please look at the leaflet and point to where you see the answer first before you give any answers to the question. Do not forget to keep looking on both sides of the leaflet, if you cannot see the answer on one side please turn the leaflet over. Please also remember that*

*all the questions I am going to ask you are about the information you have read in the leaflet, do not give me answers about other medicines or your own medicines if you are taking any”.*

Each question was marked as ‘located’ or ‘not located’ and as ‘correct’ or ‘incorrect’ depending on the answer that the participant gave. All the patients that participated in the study were then counselled on incorrect answers in their medicine taking behaviour, ARV therapy and aspects of HIV/AIDS including side effects and correct storage of ARVs.

The next stage of the interview process was to measure self-efficacy and self-reported adherence using the modified HIV-ASES and modified MMAS-8, respectively. Each question was asked exactly as it appeared in Table 3.2 (HIV-ASES) and Figure 3.6 (MMAS-8). The acceptability of these tools was also assessed. At the end of the interview an honorarium of R40 (US\$6) was received by the patient.

### **3.5.6. Statistical analysis**

Data were analysed using the chi-squared test and ANOVA at a 5% level of significance.

## **3.6 FGD feedback and modifications to patient behavioural tools**

### **3.6.1 Results and modifications to MMAS-8 self-reported adherence scale**

Participants felt that the questions from the modified MMAS-8 were direct and concise and they were able to understand and answer all the questions (Table 3.2). Question 2 was modified to include a time frame of a month rather than that of two weeks. This was done as a month is an easily identifiable time period as monthly clinic visits are made for collection of ARVs. In commenting generally about the medicine-taking process, they unanimously stated that “the doctor knows best”, displaying implicit trust in the doctor and stating that the doctor’s opinion is final and nothing should be changed without the doctor’s approval. One female participant said that she takes her medicine everywhere and that it is, “...like a passport”.

In Question 7, '*During last weekend, did you miss taking any of your ARVs?*', participants felt that the weekend time period was applicable but that the timeframe should also included the weekdays. Thus the question should read, "*During the last week and weekend did you miss taking any of your medicine.*" However, this suggestion was not implemented in order to retain as much of the original MMAS-8 as possible. Patients were able to recall their weekend doses, thus this original wording was retained.

Participants felt that the questions relating to taking medication over different time frames were not applicable as ARVs need to be taken every single day and they emphasised the importance of adherence to ARV therapy. A 78 year old female participant said "[my] medication is like porridge - [I] have to have it."

### **3.6.2 Results and modifications to HIV-ASES**

Acceptability and understanding of scale questions generally was good and questions were considered to be valid and easy to answer. Only Question 2 (Figure 3.6) needed further explanation. This question asked about confidence in being able to '*...integrate your ARVs into your daily routine*' and was not understood by the participants with less than 3 years schooling. Rewording to "*...make a way to take medicine when you are anywhere or doing anything that is part of your daily routine.*" improved its comprehension.

The final self-efficacy scale consisted of the visual analogue scale incorporating the hand signals and facial expressions and was the scale preferred by 60% of the patients. None of the patients (0%) preferred scale one or two (Figure 3.7), where there was no visual representation. The remaining patients had an equal 20% split between scales 3 and 4.

When participants were asked about colour preferences, four preferred red, three chose green, two liked the current scales in black and white and one preferred blue. All the participants, regardless of educational background, thought that a frame should surround the scale. The HIV-ASES was modified according to this feedback and the final version is presented in Figure 3.6.

### 3.7 Results of pilot study

#### 3.7.1 Participant demographics

Over eighty percent (87.5%) of the participants were female (Table 3.4) as more females than males attend the clinic during working hours. This gender spread is consistent with other studies that have been conducted in this population. Only one participant was above 50 years old. There was an equal spread between the other age groups, with just below a third (31.3%) in each category. More than a third of the patients (34.5%) had less than 7 years of formal education.

Table 3.4: Demographics for the pilot study

| Demographic parameter | Participants n (%) |
|-----------------------|--------------------|
| Sex                   |                    |
| Female                | 14 (87.5)          |
| Male                  | 2 (12.5)           |
| Age                   |                    |
| 18-29                 | 5 (31.3)           |
| 30-39                 | 5 (31.3)           |
| 40-50                 | 5 (31.3)           |
| > 50                  | 1 (6.3)            |
| Education             |                    |
| ≤ Grade 3             | 2 (12.5)           |
| Grade 4-7             | 4 (25.0)           |
| Grade 8-10            | 10 (62.5)          |

#### 3.7.2 Self-efficacy as measured by the HIV-ASES

The self-efficacy scale appeared to be well understood. Interestingly, patients reported a high level of confidence in being able to take their medication correctly, which could be a result of the intensive counselling they receive. The results in Table 3.6 show that patients have the lowest self-efficacy when side effects interfere with their daily activities (8.9) even after intensive counselling. The highest level of self-efficacy (9.7) is experienced when the patient is feeling happy about their health and CD4 counts are good.

Table 3.5 Results of average self-efficacy score

| Question<br><i>In the past month, how confident have you been that you can:</i>                           | Average score<br>$\pm$ SD |
|---|---------------------------|
| 1. Take your ARVs correctly even if side effects begin to interfere with daily activities?                | 8.9 $\pm$ 1.97            |
| 2. Integrate your ARVs into your daily routine?   | 9.3 $\pm$ 1.05            |
| 3. Take your ARVs every day even if it means taking them in front of people who do not know you have HIV? | 9.2 $\pm$ 1.97            |
| 4. Take your ARVs even if your daily plans change e.g. if you have to go out of town?                     | 9.6 $\pm$ 1.22            |
| 5. Take your ARVs even if you are not feeling well?   | 9.2 $\pm$ 1.67            |
| 6. Take your ARVs even if they interfere with (make you change?) your daily activities?                   | 9.4 $\pm$ 1.66            |
| 7. Take your ARVs even if you are feeling healthy and the test results (CD4 count) are good?              | 9.7 $\pm$ 1.21            |
| 8. Take your ARVs even when you feel discouraged or are unhappy with your health?                         | 9.2 $\pm$ 1.70            |
| 9. Take your ARVs even if it is a problem to get to the clinic?   | 9.4 $\pm$ 1.66            |
| 10. Take your ARVs even if your family or friends say the ARVs are not helping you?                       | 9.5 $\pm$ 1.33            |
| 11. Get something good out of carrying on taking your ARVs, even if they are not making you feel better?  | 9.4 $\pm$ 1.66            |

There is a significant difference between the self-efficacy of patients with  $\leq$  Grade 3 and those between Grade 3-7 and Grade 8-10, with self-efficacy being significantly lower in patients with  $\leq$  Grade 3 ( $p=0.0000$ ). There is no significant gender influence on self-efficacy. Age is significantly associated with self-efficacy, with patients older than 50 years having a significantly lower self-efficacy ( $p=0.0002$ ).

### 3.7.3 Modified MMAS-8

The average self-reported adherence using the modified MMAS-8 was good. For each individual question, a score of 0 indicates nonadherence and 1 indicates complete adherence, with the exception of Question 5 where the scale is reversed. All the individual scores are then added to get the modified MMAS-8 score. The MMAS-8 total score for the pilot study was 6.2, which falls in the range indicator of medium adherence.

Table 3.6 Results from pilot study of modified MMAS-8

| Question  | Adherence rating $\pm$ SD |
|---|---------------------------|
| 1. Do you sometimes forget to take your ARVs?   | 0.6 $\pm$ 0.5             |
| 2. Sometimes people miss taking medication for reasons other than forgetting. Over the past month (since your last clinic visit) were there any days when you did not take your ARVs? | 0.9 $\pm$ 0.3             |
| 3. Have you ever reduced or stopped taking your medication without telling your doctor, because you felt worse when you took it?  | 0.9 $\pm$ 0.3             |
| 4. When you travel or leave home, do you sometimes forget to bring along your ARVs?   | 1.0 $\pm$ 0.0             |
| 5. Did you take your ARVs yesterday?  | 0.0 $\pm$ 0.0             |
| 6. When you feel healthy, do you sometimes stop taking your ARVs?   | 1.0 $\pm$ 0.0             |
| 7. During last weekend, did you miss taking any of your ARVs?   | 0.9 $\pm$ 0.3             |
| 8. Some people find having to take ARVs every day tiresome. Do you ever feel irritated about taking your ARVs every day?  | 0.9 $\pm$ 0.3             |

Interestingly, complete adherence (0.0) for ARV consumption the previous day was reported. All patients reportedly kept their ARVs with them when travelling. The poorest adherence score (0.6) was obtained for sometimes forgetting to take ARVs. An excellent adherence score (0.9) was obtained for both remembering to take ARVs over the weekend and during the last month.

Interviewer opinion of adherence was also evaluated and was rated on a scale from 0 to 5, with 0 indicating nonadherence and 5 implying complete adherence. In the opinion of the interviewer, the average adherence of the patients was 3.4, and was therefore classified as being in the moderately adherent category (50-79% adherence).

### 3.8 Conclusion

Instruments used to assess aspects of medicine-taking behavior, such as self-efficacy and self-reported adherence, were adapted and evaluated to suit the target population before use in the randomised control trial. Routinely assessing self-efficacy and self-reported adherence may become a valuable tool in predicting those patients who are ready to start ARV treatment as well as identifying those who need additional counseling, thereby optimizing medication management in HIV/AIDS.

## **CHAPTER FOUR**

### **RANDOMISED CONTROL TRIAL FOR THE EVALUATION OF PATIENT INFORMATION MATERIALS**

#### **4.1 Introduction**

The preceding chapter reported the development of patient information materials and the modification of behavioural tools to measure self-efficacy and self-reported adherence. The current chapter evaluates the information materials for comprehensibility as well as their influence on knowledge, adherence, self-efficacy and clinical outcomes over a six-month period.

#### **4.2 Objectives**

The objectives of this stage of the project were to use a randomised control study designed to investigate the influence of simple illustrated PILs and labels for HIV/AIDS patients taking ARVs on:

- knowledge and understanding of information pertaining to HIV/AIDS and ARV-related issues
- self-efficacy using the modified HIV-ASES
- adherence using three methods: the self-report method as measured by the modified MMAS-8, interviewer opinion, and tablet count.

Further objectives were to investigate:

- the association of age, gender, educational level and medication literacy with knowledge, self-efficacy and adherence
- correlations between adherence, knowledge, self-efficacy and clinical health outcomes at one month, and at the end of the randomised control trial
- the acceptability of the PIL and its usefulness to HIV/AIDS patients taking ARVs.

## 4.3 Methodology

### 4.3.1 Study site and study population

The study site, as described in Chapter 3, Section 3.5.1, was extended to include patients from both the primary care clinic (Raglan Road Clinic) and from Masonwabe Clinic at Settlers Hospital.

The study population has been described in Chapter 3, Section 3.5.1. Participants had to be HIV/AIDS patients taking either regimen 1A, 1B, 1C or 1D. Further inclusion factors were age above 18 years, isiXhosa the home language and formal education up to a maximum of Grade 12.

Ethical approval for the study was obtained from Rhodes University Ethical Standards Committee, Settlers Hospital Ethics committee and the Eastern Cape Department of Health.

### 4.3.2 Data collection tool

Modified versions of the questionnaire (Appendix C3-C6) described in Chapter 3, Section 3.5.5 were used for each of the interviews. Interviews were conducted at four different times: baseline (August 2009), one month (September 2009), three months (November 2009) and six months (February 2010). Modified versions of the questionnaire containing pertinent sections were used for data collection at each different interview time. Data collected at the four interview times are presented in Table 4.1.

Table 4.1 Data collected at the four different interviews

| Interview Times | Demographics | Patient records | Knowledge | Acceptability of PIL | Self Efficacy | Adherence | CD4 and VL |
|-----------------|--------------|-----------------|-----------|----------------------|---------------|-----------|------------|
| Baseline        | √            | √               | √         |                      | √             |           | √          |
| 1-Month         | √            | √               | √         |                      | √             | √         |            |
| 3-Month         | √            | √               | √         | √                    | √             | √         |            |
| 6-Month         | √            | √               | √         |                      | √             | √         | √          |



The sections of the questionnaires were described in Chapter 3, Section 3.5.5. An additional section for a medication literacy test was added. This was conducted at the baseline interview and was based on a test that had been previously developed by Ramela [158], who applied it in a similar population. The medicine literacy test consisted of an English paragraph of medicine-related information typically found on a medicine label.

Section 5 was modified to include interviewer opinion of adherence which was rated on a scale of 1 – 5. This scale consisted of different categories each represented by a specific score: nonadherent (1), poorly adherent (2), moderately adherent (3), mostly adherent (4) and completely adherent (5). Adherence data using a tablet count, which was conducted by the primary health care nurses, was also collected at one, three and six month interviews. Section 6, which assessed the acceptability and usefulness of the PIL and the labels to the patient, was used to collect these data only at the three month interview. In addition, pictograms were evaluated for acceptability and understanding.

### **4.3.3 Recruitment and interview process**

The illustrated medicine labels and illustrated PILs were assessed using 116 ARV patients. The same interpreter was used for all stages of this study. Patients were recruited using standardised approach which was previously described in Chapter 3, Section 3.5.3. Patients were guaranteed that their HIV status would remain confidential and were informed that the study would take place over a six month period, during which time they would be required for a total of four interviews. Signed consent was obtained after the patient had read and understood the consent form (Appendix C2).

#### ***Standard care at Masonwabe Clinic***

Standard care at Masonwabe Clinic consists of a consultation of about 10 minutes with the physician to monitor for side effects or other problems with their ARV therapy. Weight and height are recorded in the patients' health passports. The health passport is a book received by each patient attending public health care clinics. It acts as a record for health, clinic visits and medical history. The physician then decides to either maintain current therapy or make regimen changes. The patient waits to see the nurse while the pharmacist prepares the medication. The nurse then conducts a tablet count of the patient's previous month's medicine supply. Medicine for the current month is then given to the patient by the nurse,

who also then counsels the patient. Following the standard care described above, the patients were interviewed for this study in a counselling room in the pharmacy.

### ***Standard care at Raglan Road Clinic***

Raglan Road Clinic is a down-referral primary care clinic where patients are referred once stabilised on ARV therapy. Doctors visit the clinic once a week only, therefore patients normally see a nursing sister. AIDS patients obtain their medication and receive counselling in a separate building. Patients report to the nurses' station and wait in a waiting room with other patients. Health care workers occasionally talk to all the ARV patients while they wait to obtain their medication. The clinic sister weighs the patients, conducts a tablet count and dispenses the medication for the current month. The study interviews were then conducted in a room in the clinic.

The baseline interview process followed that has been described in Chapter 3, Section 3.5.3. Patients were randomly allocated, using stratification based on level of education, into one of two groups by means of a computerised random number generator. Patients in the control group received their medication from the pharmacy and standard care from their respective clinic. After the baseline interview was complete the experimental group received their medication, standard care from the clinic, and the appropriate illustrated medicine labels and illustrated PIL relative to the regimen of ARVs that they were taking.

The patient was asked to show the researcher their health passport. It was explained:

*"I would like you to show me your health passport, I am going to look at it so that I can get information from the doctors and nurses about your health. I will not tell anybody what I see in your health passport, I just need to look at it for the study."*

From the health passport the demographic data, date of next refill, CD4 count data and viral load readings were recorded. The health passport was then also checked for the ARV regimen to ensure the participant was taking 1A, 1B, 1C or 1D. This was followed by:

*"Thank you very much. Just a few more questions. Have you been to school? If you have, to what standard did you attend and how many years were you at school?"*

If the participant had more than 12 years of formal schooling years, he/she was thanked for volunteering but told that he/she did not qualify for the study. Patients were then asked if they had a mobile cellular phone and if they would give the researcher their number. It was explained:

*“The reason that I want to get your cell phone number is so that I can contact you to remind you of your interview if you forget to come. It will be not used for anything else and I will not give it to anyone else.”*

The patient was then asked how they take each of their ARVs. This was recorded as correct or incorrect.

A short medication literacy test with eight questions was then administered to the participants. In isiXhosa the interviewer said:

*“I will now give you a medicine label to read and once you have finished reading it I will ask you questions. All the questions I ask you will be about the medicine label. If you are taking medicines, please do not give answers about your own medicines”.*

The patient was required to read the English text and was asked he questions in English. If the patient did not understand the question it was translated into isiXhosa by the interpreter. The patients were given the option to respond in either English or isiXhosa. A medication literacy score was calculated by summing correct answers. English was used as the language for the medication literacy test as, in South Africa, medicine labels that the patients receive are written in English.

From this point onwards, different formats and scripts were used for the control and the experimental groups as described below.

***Control group:***

*“I am now going to ask you questions about information on HIV/AIDS and your ARVs. Please also remember that all the questions I am going to ask you are about your ARVs, do not give me answers about other medicines or your own medicines if you are taking any”.*

Twenty two questions relating to knowledge were asked and the answers marked as ‘correct’ or ‘incorrect’.

***Experimental group:***

The patient was offered both the English and Xhosa versions of the PIL and asked to choose which version they would like to read.

*“Now I am going to give you a leaflet to read. Please take your time to read it and then when you are done I will ask you questions about what you have read. Please tell me when you are finished reading it”.*

Once reading was complete, the interviewer continued with:

*“I am now going to ask you questions about the information you have read in the leaflet. Please look at the leaflet and point to where you see the answer first before you give any answers to the question. Do not forget to keep looking on both sides of the leaflet, if you cannot see the answer on one side please turn the leaflet over. Please also remember that all the questions I am going to ask you are about the information you have read in the leaflet, do not give me answers about other medicines or your own medicines if you are taking any”.*

Each question was marked as ‘located’ or ‘not located’ and as ‘correct’ or ‘incorrect’.

Patients from both groups were then asked where they learnt about HIV/AIDS and ARVs. A list of sources, from the questionnaire, were read out and the patients were asked to comment on whether or not the source had had an impact on their knowledge.

*“I am now going to ask you where you learnt about HIV/AIDS and ARVs from. I am going to give you examples of different people and things. Please tell me if they/it taught you anything about HIV/AIDS or ARVs.”*

Self-efficacy data were collected using the modified HIV-ASES which was administered to patients in both groups with the words:

*“I am going to ask you about things that may happen when you have to take medicines. Sometimes, this could mean what happens when you are taking your medications, and other times it could mean how you deal with things like what you eat or whether you exercise or take vitamins. So, in these questions, when I ask you about your “treatment”, I am talking not only about your medicine but also other things that you do to keep yourself healthy. .*

*For the following 11 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).*

*In the past month, how confident have you been that you can...”*

The 11 HIV-ASES questions were then asked and answers recorded.

Self-reported adherence data were collected using a modified version of the MMAS-8 in both groups. These adherence data were collected at the one, three and six month interviews.

*“I am now going to ask you some questions about whether you take your medication or not. This is not a test so please know that you can be honest with me.”*

Interviewer opinion of adherence was determined through discussions between the researcher and the interpreter and the decision was recorded. The rating was based on the attitude of the patient and their answers to the MMAS-8 and the tablet count. The patients in both groups were then counselled on any incorrect answers that they offered during the interview.

Patient acceptability of the PIL, in the experimental group, was accessed only at the three month interview.

*“I am now going to ask you some questions about this leaflet and labels. I would like to know what you think about them and what you would like me to change. What you say can help me make them better for other people so please tell me the truth.”*

Answers were recorded. The patient was then asked to explain what each pictogram in the PIL represented. Each pictogram was pointed to and the patient was asked the following:

*“I am pointing at a picture what do you think this picture is telling you? Can you tell me what you think it means?”*

The patients in the experimental group received their medicine with both standard and illustrated medicine labels, whereas those in the control group received standard medicine labels only and no PILs. The patients were encouraged to refer to the PIL before the next interview and if they had any questions regarding HIV/AIDS or their ARV therapy. All patients were given a reminder slip containing the date of their next interview. At the end of the interview the patients were thanked for their time and an honorarium of R40 (approximately US\$6) was offered.

Before the start of the one, three and six month interviews the patients were asked if they still had the PIL and were reoffered a copy of the PIL. The respective interviews then continued in the same manner as described above.

#### **4.4 Data capture**

CD4 count and viral load data for all patients were collected directly from the National Laboratory Health Services (NHLS) in Grahamstown, situated at Settlers Hospital. Permission was obtained from the NHLS to do so as incomplete data were recorded in the outpatient records, with many patients having nothing recorded at all.

A knowledge score for each patient was calculated by summing the correct answers to the 22 questions asked about general HIV/AIDS information and ARV-related information. Self-reported adherence and self-efficacy results were scored as described in Sections 3.4.1 and 3.3.2, respectively. Clinical health outcomes, as reflected in CD4 counts and VL readings, were taken in June/July 2009 and then again at the end of the study, in February/March 2010.

#### **4.5 Data analysis**

Pearson Chi-square tests were used to investigate differences between the control and experimental groups for demographic data, medication literacy score, knowledge, self-efficacy, self-reported adherence and clinical health outcomes. The association of selected variables (gender, age, education, and medication literacy) with knowledge, self-efficacy and self-reported adherence was investigated using one-way ANOVA and t-tests. Any correlations between knowledge, self-efficacy, self-reported adherence and clinical health outcomes was determined using the Pearson and Spearman rho tests. The level of significance was set at 5%.

## **CHAPTER FIVE**

### **INFLUENCE OF PIL ON PATIENT KNOWLEDGE, ADHERENCE, SELF EFFICACY AND CLINICAL OUTCOMES**

#### **5.1. Introduction**

In this chapter, the results from the randomised control study are presented. The influence of simple illustrated PILs and labels on knowledge and understanding of information pertaining to HIV/AIDS and ARV-related issues, self-efficacy, adherence, and clinical outcomes, are described. The chapter then proceeds to present results on the influence of variables such as age, gender and education on knowledge, self-efficacy and adherence. Patient information materials are of little use if they are not regarded favourably by the intended reader [133]. Results are therefore presented that show the acceptability of the PIL and the illustrated labels. In addition the patients' opinion as to the general usefulness of the PIL for other HIV/AIDS patients taking ARVs is also presented. Knowledge alone does not directly predict adherence. The ultimate test of any health intervention intended to impact on patient behaviour is to monitor health outcomes, and this is addressed by showing correlations between knowledge, self-efficacy, adherence, and clinical health outcomes at the one-month interview and at the end of the randomised control trial.

#### **5.2 Quantitative evaluation of the PIL**

##### **5.2.1 Patient demographics**

One hundred and thirty-nine patients were approached to participate in the study. Twenty three patients refused to participate for various reasons but mainly due to a fear of breach of confidentiality. A total of 116 patients were interviewed for the study. Patients were all Black, isiXhosa-speaking and HIV-positive, taking one of the first-line ARV regimens.

The demographic characteristics for the experimental group show that the majority of the patients were female, ranging from 67.0% at baseline to 82.8% at 6 months (Table 5.1). This is not surprising as women account for more HIV infections than men in South Africa [171]. More than half the patients in both groups (53.4% for the experimental group and 51.7% for the control group) had less than seven years of formal schooling. In both groups 17% of the

patients had less than three years of schooling. It was difficult to find patients with less than three years of formal schooling as the study was conducted in an area where access to schooling is available, unlike many rural areas. The distribution of patients with regard to age remained similar in both the control and experimental groups, with the majority of patients being between the ages of 30 and 39. There was no significant difference in any demographic parameter between the control and experimental groups for all interview intervals.

Fifty two patients were lost to follow-up. The attrition for both the experimental and control groups was one in two patients. This high number could be due to several factors including problems getting transport to the hospital or clinic, down referral to another clinic, lack of interest and not feeling that the compensation was proportionate to the amount of time the interview took. Four were lost due to death.

Most of the participants (>85%) were unemployed. All the patients could tell the time from a clock-face. A high percentage of patients (> 70%) had cellular phones.

The mean medication literacy at baseline was 62.3% in the experimental group and 59.1% in the control group. Only a low percentage of patients (28% experimental; 18% control) scored more than 80% in the literacy test. It was observed that the questions producing the lowest scores were those relating to numeracy, implying that difficulty may be encountered in fully understanding comprehensive medicine-taking instructions. The literacy test was conducted in English, which could have influenced the results. This was done as most medicine labels are printed in English. The scores are likely to have been higher if the test had been available in isiXhosa.



Table 5.1 Demographic characteristics, n %

| Demographic parameter*                 | Baseline    |                 | 1-Month     |                 | 3-Month    |                | 6-Month    |                 |
|--|-------------|-----------------|-------------|-----------------|------------|----------------|------------|-----------------|
|  | Exp (n= 58) | Control (n= 58) | Exp (n= 50) | Control (n= 46) | Exp (n=37) | Control (n=46) | Exp (n=29) | Control (n= 35) |
| Gender                                 |             |                 |             |                 |            |                |            |                 |
| Female                                 | 40 (67.0)   | 40 (67.0)       | 40 (80.0)   | 40 (86.9)       | 28 (75.7)  | 35 (76.1)      | 24 (82.8)  | 27 (77.1)       |
| Male                                   | 18 (33.0)   | 18 (33.0)       | 10 (20.0)   | 6 (13.1)        | 9 (24.3)   | 11(23.9)       | 5 (17.2)   | 8 (22.9)        |
| Age (yrs)                              |             |                 |             |                 |            |                |            |                 |
| 18-29                                  | 10 (17.2)   | 8 (13.8)        | 7 (14.0)    | 7 (15.2)        | 5 (13.5)   | 7 (15.2)       | 4 (13.8)   | 6 (17.1)        |
| 30-39                                  | 23 (39.7)   | 26 (44.8)       | 23 (46.0)   | 18 (39.1)       | 17 (45.9)  | 20 (43.5)      | 14 (48.3)  | 15 (42.9)       |
| 40-50                                  | 17 (29.3)   | 15 (25.9)       | 13 (26.0)   | 15 (32.6)       | 10 (27.0)  | 12 (26.1)      | 8 (27.6)   | 8 (22.9)        |
| Above 50                               | 8 (13.8)    | 9 (15.5)        | 7 (14.0)    | 6 (13.1)        | 5 (13.5)   | 7(15.2)        | 3 (10.3)   | 6 (17.1)        |
| Education                              |             |                 |             |                 |            |                |            |                 |
| ≤ Grade 3                              | 10 (17.2)   | 10 (17.2)       | 9 (18.0)    | 8 (17.4)        | 7 (18.9)   | 8 (17.4)       | 5 (17.2)   | 5 (14.3)        |
| Grade 4-7                              | 21 (36.2)   | 20 (34.5)       | 17 (34.0)   | 18 (39.1)       | 12 (32.4)  | 18 (39.1)      | 11 (37.9)  | 14 (40.0)       |
| Grade 8-10                             | 27 (46.6)   | 28 (48.3)       | 24 (48.0)   | 20 (43.5)       | 18 (48.6)  | 20 (43.5)      | 13 (44.8)  | 16 (43.7)       |
| Employed                               | 4 (6.9)     | 8 (13.8)        | 3 (6.0)     | 6 (13.1)        | 3 (8.1)    | 7 (15.2)       | 2 (6.9)    | 5 (14.3)        |
| Ability to tell time from a clock-face | 58 (100.0)  | 58 (100.0)      | 50 (100.0)  | 46 (100.0)      | 37 (100.0) | 46 (100.0)     | 29 (100.0) | 35 (100.0)      |
| Have cellphone                         | 38 (65.5)   | 41 (70.7)       | 33 (66.0)   | 37 (80.4)       | 26 (70.3)  | 36 (78.3)      | 20 (68.9)  | 29 (82.9)       |
| Medication literacy                    |             |                 |             |                 |            |                |            |                 |
| Poor (0-4)                             | 11 (18.9)   | 15 (25.8)       | 9 (18.0)    | 13 (28.3)       | 6 (16.2)   | 11 (23.9)      | 8 (27.6)   | 12 (34.3)       |
| Average (5-7)                          | 31 (53.4)   | 33 (56.8)       | 26 (52.0)   | 25 (54.3)       | 20 (54.1)  | 28 (60.9)      | 12 (41.4)  | 19 (54.3)       |
| Good (8-10)                            | 16 (27.6)   | 10 (17.2)       | 15 (30.0)   | 8 (17.4)        | 11 (29.7)  | 7 (15.2)       | 9 (31.0)   | 4 (11.4)        |

\* No significant difference (p&lt;0.05) between experimental and control group

### **5.2.2 Understanding of PIL**

All the patients chose to read the isiXhosa version of the PIL. In assessing the understanding of the PIL, the European Commission (EC) guideline was used, according to which 16 out of 20 participants (80%) should answer each question correctly [163]. Twenty two questions were asked to assess knowledge of HIV/AIDS, side effects and ARV information. The experimental group patients received the PIL at the baseline interview, but were asked not to refer to it during the subsequent interviews, thereby relying on their knowledge of HIV/AIDS and ARVs acquired from reading and referring to the PIL during the previous month.

The 22 questions were divided into three categories: general HIV/AIDS information, ARV therapy information and side effect information. The results for each category are presented below. The number of patients answering each of the individual questions correctly in the different categories was then calculated and scored.

#### **5.2.2.1 Information pertaining to ARV therapy**

A common trend was identified where ARV-related questions were poorly answered (Table 5.2). Just over half (59%) the patients in the experimental group were able to answer the questions correctly at baseline. A similar score (63%) was seen in the control group. After the introduction of the PIL at one month, the experimental group scores improved to exceed the EC target of 80%. In the control group, however, the mean knowledge score remained consistently low throughout the study.

At baseline, knowledge of the correct use of either EFV or NVP in the experimental group was only 77.6%, which is very poor as 95% adherence is necessary for ARV therapy to be effective. In contrast, both groups met the 80% EC target at baseline for the 3TC usage. Following a twice-daily medicine regimen may be more familiar to this population than taking medicines only at night.

The question concerning consumption of ARVs on an empty stomach was very poorly answered, with results from all four interview times failing to meet the required 80% EC target. This highlights a lack of education regarding the importance of adherence regardless of access to food. It was noted that the community nurses told the patients to take ARVs only

on a full stomach whereas the doctors instructed the patients to take their ARVs regardless of the time since they last ate. The Raglan Road Clinic patients, who had consultations only with nurses, had a lower knowledge score on this question. At the 1-month interview there was significant improvement ( $p=0.018$ ) in patient knowledge in the experimental group in comparison to the control group.

Knowledge of ARV use in conjunction with other over-the-counter medicines not prescribed by a doctor was poorly answered at baseline. Just over one in two patients (55.2%) in the experimental group knew the correct actions to follow. This score was significantly lower in the control group at baseline (34.5%;  $p<0.001$ ). At three months, there was a significantly higher score ( $p<0.001$ ) in the experimental group (94.6%) versus the control group (67.4%) resulting in the experimental group meeting the EC 80% target.

The question pertaining to the use of traditional medicine and ARVs was well answered, with a baseline score of 98.3%. This is not surprising as the information is reinforced regularly during routine counselling.

The question referring to the action needed to be taken if a dose of ARVs is missed was poorly answered at baseline in both the experimental group (8.6%) and control group (22.4%). A low score was consistently obtained for this question throughout the study, thus identifying a lack of education in this area. There was a significant improvement in the experimental group in comparison to the control group ( $p<0.001$ ) at the one month interview.

At baseline, less than half (41.4%) of the experimental group knew about appropriate storage of their medication and just over a third (36.2%) could identify inappropriate places to store medication. Both of these questions were well answered after the introduction of the PIL, with a significant difference between the experimental and control groups at one month ( $p<0.001$ ), three month ( $p<0.001$ ) and six month ( $p<0.001$ ) interviews for both appropriate and inappropriate storage.

The question regarding information to be given to the doctor before taking ARVs was another one that was poorly answered throughout the study. This section of the PIL contained no pictograms, which may have resulted in the poor score. There was a significant difference between the experimental and control groups at the one month interview after the

introduction of the PIL ( $p<0.001$ ). This significance was also apparent at the three month ( $p<0.001$ ) and six month ( $p<0.001$ ) interviews. The highest correct-scoring question investigated knowledge about not sharing medicines. This information is continuously reinforced to the patients during adherence counselling, which may account for the excellent knowledge in this area.

#### **5.2.2.2 Information pertaining to general HIV/AIDS information**

General HIV/AIDS knowledge was good, with an average score of 87% at baseline for both groups (Table 5.3). Interestingly, there was a significant improvement in the experimental group between baseline and one month ( $p<0.001$ ) attributable to the impact of the PIL, with subsequent slight improvements at three and six months, whereas the control group improved slightly at one and three months, and then achieved 100% correct interpretation at six months.

Questions relating to the spread of HIV were well answered, with a baseline knowledge score of 91.4% (experimental) and 86.2% (control), both increasing to 100% at six months. Questions asking about the influence of ARVs on viral load and CD4 count were the least well answered in both groups. The scores improved during subsequent interviews, with the experimental group being consistently higher than the control group. The only significant difference between the groups was at one month for the viral load question ( $p=0.022$ ).

The necessity of taking ARVs for life was well grasped by the vast majority of patients in both groups. Knowledge of ARVs not being a cure but a means to help prevent the spread of HIV was surprisingly low, being answered correctly by 77.6% in the experimental group and 86.2% in the control group at baseline. At baseline, 98.3% (experimental) and 93.1% (control) did not know that they needed to take ARVs for life despite the intensive counselling they receive. Many health promotion and counselling centres focus their education and counselling on the spread of HIV and the importance of taking ARVs for the rest of one's life, therefore it was surprising that at baseline 14% of patients in the control group did not know that they could still spread HIV while taking ARVs.

Table 5.2 Understanding of information: ARV therapy , n%

| Questions on ARVs                    | Baseline           |                    | 1- Month           |                    | 3-Month            |                   | 6-Month          |                    |
|--------------------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|-------------------|------------------|--------------------|
|                                      | Exp<br>(n= 58)     | Control<br>(n= 58) | Exp<br>(n= 50)     | Control<br>(n= 46) | Exp<br>(n=37)      | Control<br>(n=46) | Exp<br>(n=29)    | Control<br>(n= 35) |
| ARV names                            | 45 (77.6)          | 54 (93.1)*         | 46 (92.0)          | 39 (84.8)          | 36 (97.3)          | 44 (95.7)         | 29 (100.0)       | 34 (97.1)          |
| How often and when to take EFV/NVP   | 45 (77.6)          | 53 (91.4)*         | 48 (96.0)          | 42 (91.3)          | 37 (100.0)         | 45 (97.8)         | 29 (100.0)       | 34 (97.1)          |
| Taking ARVs on an empty stomach      | 16 (27.6)*         | 7 (12.1)           | 28 (56.0)*         | 15 (32.6)          | 25 (67.6)*         | 18 (39.1)         | 23 (79.3)*       | 14 (40.0)          |
| Other medicines and ARV use          | 32 (55.2)*         | 20 (34.5)          | 36 (72.0)          | 25 (54.3)          | 35 (94.6)*         | 31 (67.4)         | 26 (89.7)        | 29 (82.9)          |
| Number of 3TC a day                  | 55 (94.8)          | 58 (100.0)         | 50 (100.0)         | 45 (97.8)          | 37 (100.0)         | 46 (100.0)        | 29 (100.0)       | 35 (100.0)         |
| Traditional medicine and ARV use     | 57 (98.3)          | 57 (98.3)          | 48 (96.0)          | 46 (100.0)         | 36 (97.3)          | 46 (100.0)        | 29 (100.0)       | 35 (100.0)         |
| Action if missed dose                | 5 (8.6)            | 13 (22.4)*         | 48 (96.0)*         | 1 (2.2)            | 28 (75.7)*         | 17 (37.0)         | 23 (79.3)*       | 14 (40.0)          |
| Appropriate storage                  | 24 (41.4)          | 27 (46.6)          | 47 (94.0)*         | 21 (45.7)          | 36 (97.3)*         | 21 (45.7)         | 27 (93.1)*       | 12 (34.3)          |
| Inappropriate storage                | 21 (36.2)          | 26 (44.8)          | 47 (94.0)*         | 24 (52.2)          | 34 (91.9)*         | 22 (47.8)         | 28 (96.6)*       | 13 (37.1)          |
| Things to tell Dr before taking ARVs | 22 (37.9)          | 31 (53.4)*         | 42 (84.0)*         | 16 (34.8)          | 28 (75.7)*         | 20 (43.5)         | 25 (86.2)*       | 17 (48.6)          |
| Do not share ARVs                    | 58 (100.0)         | 58 (100.0)         | 49 (98.0)          | 45 (97.8)          | 37 (100.0)         | 46 (100.0)        | 29 (100.0)       | 35 (100.0)         |
| <b>Mean</b>                          | <b>34.5 (59.5)</b> | <b>36.7 (63.0)</b> | <b>44.5 (89.0)</b> | <b>29 (63.0)</b>   | <b>33.5 (90.7)</b> | <b>32 (70.0)</b>  | <b>27 (93.1)</b> | <b>24.7 (70.6)</b> |

\* Significant difference (p&lt;0.05) between experimental and control group

Table 5.3 Understanding of information: HIV/AIDS, n %

| Questions on HIV/AIDS       | Baseline         |                    | 1-Month          |                    | 3-Month          |                   | 6-Month          |                    |
|-----------------------------|------------------|--------------------|------------------|--------------------|------------------|-------------------|------------------|--------------------|
|                             | Exp<br>(n= 58)   | Control<br>(n= 58) | Exp<br>(n= 50)   | Control<br>(n= 46) | Exp<br>(n=37)    | Control<br>(n=46) | Exp<br>(n=29)    | Control<br>(n= 35) |
| Spread of HIV               | 53 (91.4)        | 50 (86.2)          | 47 (94.0)        | 44 (95.7)          | 37 (100.0)       | 41 (89.1)         | 29 (100.0)       | 35 (100.0)         |
| Effect on viral load        | 47 (81.0)        | 45 (77.6)          | 49 (98.0)*       | 39 (84.8)          | 37 (100.0)       | 42 (91.3)         | 29 (100.0)       | 35 (100.0)         |
| Effect on CD4 count         | 44 (75.9)        | 46 (79.3)          | 48 (96.0)        | 40 (87.0)          | 35 (94.6)        | 43 (93.5)         | 29 (100.0)       | 35 (100.0)         |
| Can ARVs cure the HIV virus | 45 (77.6)        | 50 (86.2)          | 45 (90.0)*       | 35 (76.1)          | 36 (97.3)*       | 36 (78.3)         | 26 (89.7)        | 35 (100.0)         |
| Take ARVs for life          | 57 (98.3)        | 54 (93.1)          | 49 (98.0)        | 46 (100.0)         | 37 (100.0)       | 45 (97.8)         | 29 (100.0)       | 35 (100.0)         |
| What to do if pregnant      | 56 (96.6)        | 58 (100.0)         | 49 (98.0)        | 43 (93.5)          | 33 (89.2)        | 45 (97.8)         | 29 (100.0)       | 35 (100.0)         |
| <b>Mean</b>                 | <b>50 (87.0)</b> | <b>51 (87.0)</b>   | <b>40 (96.0)</b> | <b>41 (89.0)</b>   | <b>36 (97.0)</b> | <b>42 (91.0)</b>  | <b>29 (98.3)</b> | <b>35 (100.0)</b>  |

\*Significant difference (p<0.05) between experimental and control group

Table 5.4 Understanding of information: Side effects, n %

| Questions on side effects               | Baseline         |                    | 1-Month          |                    | 3-Month          |                   | 6-Month          |                    |
|---|------------------|--------------------|------------------|--------------------|------------------|-------------------|------------------|--------------------|
|   | Exp<br>(n= 58)   | Control<br>(n= 58) | Exp<br>(n= 50)   | Control<br>(n= 46) | Exp<br>(n=37)    | Control<br>(n=46) | Exp<br>(n=29)    | Control<br>(n= 35) |
| Recognition of general side effects     | 31 (53.4)        | 25 (43.1)          | 45 (90.0)*       | 23 (50.0)          | 35 (94.6)*       | 24 (52.2)         | 26 (89.7)*       | 19 (54.3)          |
| Recognition of late side effects        | 1 (1.7)          | 5 (8.6)            | 43 (86.0)*       | 4 (8.7)            | 34 (91.9)*       | 6 (13.0)          | 24 (82.8)*       | 4 (11.4)           |
| Recognition of early side effects       | 19 (32.8)        | 27 (46.6)          | 45 (90.0)*       | 19 (41.3)          | 35 (94.6)*       | 21 (45.7)         | 27 (93.1)*       | 15 (42.9)          |
| Recognition of fever and chills         | 50 (86.2)        | 45 (77.6)          | 45 (90.0)        | 38 (82.6)          | 36 (97.3)        | 41 (89.1)         | 29 (100.0)       | 33 (94.3)          |
| Recognition of lactic acidosis symptoms | 49 (84.0)        | 43 (74.1)          | 42 (84.0)        | 36 (78.3)          | 37 (100.0)*      | 37 (80.4)         | 28 (96.6)        | 33 (94.3)          |
| <b>Mean</b>                             | <b>30 (51.7)</b> | <b>29 (50.0)</b>   | <b>44 (88.0)</b> | <b>24 (52.0)</b>   | <b>33 (93.6)</b> | <b>26 (56.0)</b>  | <b>27 (92.4)</b> | <b>21 (59.0)</b>   |

\*Significant difference (p<0.05) between experimental and control group

The questions related to ARVs and pregnancy were well answered, with 100% correct in both groups at six months. Many of the patients were aware that a doctor needed to be consulted during their pregnancy and that EFV should be substituted for NVP.

### **5.2.2.3 Information pertaining to side effects**

Side effect information was the most poorly understood of the three information areas. The average score at baseline for both groups hovered around 50% (Table 5.4). After the introduction of the PIL, the experimental group showed improvements in average score, reaching the 80% EC target. The control group did not show any significant improvement and remained at an average score between 50-59%.

The questions regarding recognition of side effects experienced after three to six months of therapy were, at baseline, the most poorly answered in both experimental (1.7%) and control groups (8.6%). These scores did result in a significant improvement in the experimental group in comparison to the control group at the one-, three- and six- month interviews ( $p < 0.001$ ). By the one-month interview, after the addition of the PIL, knowledge of side effects experienced after three to six months, in the experimental group had increased to meet the 80% EC target. Questions concerning general and early side effects also showed significant improvements between the control and experimental groups after the addition of the PIL where  $p < 0.001$  at the one-, three- and six- month interviews. Surprisingly, correct answers decreased between the three- and six-month interviews. Questions on the topic of fever and chills and lactic acidosis showed an increasing knowledge score through the interviews in the experimental group.

### **5.2.3 Knowledge means**

The knowledge mean for the PIL was calculated by summing the correct responses for all 22 questions. In the experimental group the knowledge mean increased at each interview (Table 5.5), with a 36% increase in knowledge score between baseline and six months compared with only a 3% increase in the control group. The mean for the experimental group remained high throughout the one to six month study period, reflecting the positive effect of the PIL on both short- and long- term memory. The most dramatic improvement in overall patient knowledge scores occurred at the 1-month interview in the experimental group after

the addition of the PIL (Table 5.5). There was a significant difference between the control and experimental groups knowledge means at three ( $p=0.001$ ) and six months ( $p=0.011$ ).

Table 5.5 Overall knowledge scores at the four interview times

| Knowledge Score            | Baseline       |                 | 1-Month        |                 | 3-Month        |                | 6-Month        |                 |
|----------------------------|----------------|-----------------|----------------|-----------------|----------------|----------------|----------------|-----------------|
|                            | Exp (n= 58)    | Control (n= 58) | Exp (n= 50)    | Control (n= 46) | Exp (n=37)     | Control (n=46) | Exp (n=29)     | Control (n= 35) |
| Mean $\pm$ SD <sup>a</sup> | 13.4 $\pm$ 2.8 | 15.8 $\pm$ 2.4  | 19.5 $\pm$ 2.5 | 15.8 $\pm$ 2.9  | 21.0 $\pm$ 1.0 | 15.8 $\pm$ 2.9 | 21.0 $\pm$ 1.6 | 16.4 $\pm$ 2.5  |
| %                          | 61.0           | 71.9            | 88.6           | 71.6            | 95.5           | 71.8           | 95.6           | 74.7            |
| p-value                    |                | 0.379           |                | 0.382           |                | 0.001*         |                | 0.011*          |

\* Significant difference ( $p<0.05$ ) between experimental and control group

<sup>a</sup> Mean  $\pm$  SD of the total of 22 questions answered correctly

Table 5.6 presents statistical analysis of the differences in knowledge scores occurring at the different interview times within each group. In the experimental group, there was a significant improvement in the number of questions answered correctly between baseline and one month ( $p<0.001$ ), baseline and three months ( $p<0.001$ ), baseline and six months ( $p<0.001$ ), one month and three months ( $p = 0.004$ ), and one month and six months ( $p = 0.020$ ). In the control group, no significant improvement in knowledge scores occurred between any of the interview times.

Table 5.6 Significance of changes in knowledge scores within each group between the four interviews

| Period   | p-values     |         |         |         |          |         |         |         |
|----------|--------------|---------|---------|---------|----------|---------|---------|---------|
|          | Experimental |         |         |         | Control  |         |         |         |
|          | Baseline     | 1-Month | 3-Month | 6-Month | Baseline | 1-Month | 3-Month | 6-Month |
| Baseline | -            | 0.000*  | 0.000*  | 0.000*  | -        | 0.533   | 0.445   | 0.379   |
| 1-Month  | 0.000*       | -       | 0.004*  | 0.020*  | 0.533    | -       | 0.703   | 0.463   |
| 3-Month  | 0.000*       | 0.004*  | -       | 1.000   | 0.445    | 0.703   | -       | 0.462   |
| 6-Month  | 0.000*       | 0.020*  | 1.000   | -       | 0.374    | 0.463   | 0.462   | -       |

\* Significant difference ( $p<0.05$ )

## 5.2.4 Overall patient knowledge score

Individual knowledge scores were grouped into 4 categories (Table 5.7). At the conclusion of the study, 52% of the experimental group achieved a 100% correct knowledge score compared to no-one in the control group.



A target of 95% was chosen to mark excellent knowledge due to the high adherence necessary for effective ARV therapy. At baseline, not one patient in either group achieved this. However, by the six-month interview, the vast majority (86.2%) of the experimental group had achieved an excellent knowledge score, in contrast to the control group which still had no patients achieving the 95% knowledge score.

A score between 80-94% reflected good knowledge, and in the experimental group at the baseline interview this increased from 22% to 44% at the 1-month interview. Following this increase the score then decreased as more patients moved into the  $\geq 95\%$  category. In the control group the number of patients with good knowledge remained consistently low, in the range 20- 28%.

A score between 50-79% was considered to reflect moderate knowledge. At baseline the majority of the patients in both groups scored in this category, with a similar percentage (71.4%) in the control group not progressing beyond this category at the last 6-month interview. Only control group patients were found in the poor knowledge category ( $< 50\%$ ).

Table 5.7 Categorical knowledge scores at the four interview times, n%

| Knowledge Score       | Baseline    |                 | 1-Month     |                | 3-Month    |                | 6-Month    |                 |
|-----------------------|-------------|-----------------|-------------|----------------|------------|----------------|------------|-----------------|
|                       | Exp (n= 58) | Control (n= 58) | Exp (n= 50) | Control (n=46) | Exp (n=37) | Control (n=46) | Exp (n=29) | Control (n= 35) |
| Excellent $\geq 95\%$ | 0 (0.0)     | 0 (0.0)         | 22 (44.0)   | 0 (0.0)        | 25 (67.6)  | 0 (0.0)        | 25 (86.2)  | 0 (0.0)         |
| Good 80–94%           | 13 (22.0)   | 14 (24.2)       | 22 (44.0)   | 10 (20)        | 10 (27.0)  | 13 (28.3)      | 3 (10.3)   | 7 (20.0)        |
| Moderate 50-79%       | 45 (77.6)   | 42 (72.4)       | 6 (12.0)    | 32 (64.0)      | 2 (5.4)    | 31 (67.4)      | 1 (3.4)    | 25 (71.4)       |
| Poor $< 50\%$         | 0 (0.0)     | 2 (3.4)         | 0 (0.0)     | 2 (4.0)        | 0 (0.0)    | 2 (4.3)        | 0 (0.0)    | 3 (8.6)         |

### 5.2.3 Adherence

Adherence was measured in two ways: the MMAS-8 self-reported adherence score and an interviewer adherence rating. The variability and unreliability of these two methods as measures of adherence will be addressed in the discussion. Although pill counts were planned, they did not result in any constructive data as they were conducted by the clinic sisters, with no opportunity for the researcher to implement quality control procedures. According to these data, the majority of the patients seemed to be 100% adherent, which is

almost certainly an inaccurate reflection of actual adherence. Results from the pill counts have therefore not been presented.

### **MMAS-8**

In the experimental group, the MMAS-8 score decreased from 7.43 at the 1-month interview to 7.39 at the 3-month interview, but then increased to 7.68 at the 6-month interview (Table 5.8). A similar pattern was observed in the control group. This could possibly be explained by the attitude of the patients who became more comfortable with the interview process and with the researcher and her interpreter during each successive interview, therefore offering a more honest assessment of self-reported adherence.

### ***Interviewer rating of adherence***

The average interviewer adherence rating of the experimental group patients ranged between 3.68 and 3.90 (Table 5.8) and was therefore classified as being in the moderately adherent category (50-79% adherence). Both the groups seemed to have improved adherence over the period of the trial although there seemed to be a decreased adherence at the three month interview.

Table 5.8 Adherence scores at the different time intervals

|  | <b>1-Month</b> |                | <b>3-Month</b> |                | <b>6-Month</b> |                |
|--|----------------|----------------|----------------|----------------|----------------|----------------|
|  | <b>Exp</b>     | <b>Control</b> | <b>Exp</b>     | <b>Control</b> | <b>Exp</b>     | <b>Control</b> |
| MMAS-8*                                      | 7.43 ± 0.9     | 7.50 ± 1.0     | 7.39 ± 0.9     | 7.33 ± 1.0     | 7.68 ± 0.7     | 7.74 ± 0.7     |
| Interviewer rating of adherence <sup>a</sup> | 3.68           | 3.18           | 3.90           | 3.70           | 3.80           | 4.30           |

\* MMAS-8 score interpretation: 8 (high adherence), 6 - < 8 (medium adherence), < 6 (low adherence)

<sup>a</sup> Interpretation of interviewer adherence rating; 0 (nonadherence) to 5 (complete adherence)

Table 5.9 shows that there was a significant difference in the experimental group MMAS-8 scores between 1-month and 3-month ( $p < 0.001$ ), 1-month and 6-month ( $p = 0.04$ ) and 3-month and 6-month ( $p < 0.001$ ). In the control group, there was a significant improvement in MMAS-8 scores between 1-month and 3-month ( $p = 0.05$ ) and 1-month and 6-month ( $p < 0.001$ ). Although not significant, there was an improvement between the control group's MMAS-8 score between three and six months.

Table 5.9 Significance of change in MMAS-8 scores at the three interview times, n%

| Period  | p-value      |         |         |         |         |         |
|---------|--------------|---------|---------|---------|---------|---------|
|         | Experimental |         |         | Control |         |         |
|         | 1-Month      | 3-Month | 6-Month | 1-Month | 3-Month | 6-Month |
| 1-Month | -            | 0.00*   | 0.04*   | -       | 0.05*   | 0.00*   |
| 3-Month | 0.00*        | -       | 0.00*   | 0.05*   | -       | 0.12    |
| 6-Month | 0.04*        | 0.00*   | -       | 0.00*   | 0.12    | -       |

\*Significant difference (p<0.05)

Correlation of the MMAS-8 score with knowledge, with self-efficacy and with health outcomes (CD4 count and viral load) was investigated at one month and at six months and these results are presented in Table 5.10. No significant correlations were found at one month. At six months, in the experimental group, a significantly positive correlation was found between the MMAS-8 adherence score and an increased CD4 count. In the control group, increased adherence was associated with an increased self efficacy, but no other parameters.

Table 5.10 Correlations between MMAS-8 score and other parameters

| Parameters    | p-value      |         |         |         |
|---------------|--------------|---------|---------|---------|
|               | Experimental |         | Control |         |
|               | 1-Month      | 6-Month | 1-Month | 6-Month |
| Knowledge     | 0.46         | 0.12    | 0.63    | 0.17    |
| Self-efficacy | 0.08         | 0.15    | 0.17    | 0.04*   |
| CD4           | 0.33         | 0.04*   | 0.20    | 0.21    |
| Viral load    | 0.72         | 0.53    | 0.53    | 0.71    |

\*Significant difference (p<0.05) within the experimental and the control groups

### 5.2.6 Self-efficacy

As for self-reported adherence, the validity of these self-reported self-efficacy data is questionable. Given that the self-efficacy scale ranged from 0 (extremely low self-efficacy) to 10 (excellent self-efficacy), the results found in this study are consistently high in comparison with findings in studies from other countries [15,82]. The challenges and problems associated with using this type of instrument in the study population will be addressed in Section 6.3 of the Discussion.

Table 5.11 Mean HIV-ASES scores at the different time intervals

| HIV-ASES score | Baseline      |               | 1-Month       |               | 3-Month       |               | 6-Month       |               |
|----------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                | Exp           | Control       | Exp           | Control       | Exp           | Control       | Exp           | Control       |
| Mean $\pm$ SD  | 9.1 $\pm$ 1.0 | 9.7 $\pm$ 0.7 | 9.5 $\pm$ 0.8 | 9.8 $\pm$ 0.6 | 9.6 $\pm$ 0.8 | 9.7 $\pm$ 1.0 | 9.7 $\pm$ 0.7 | 9.7 $\pm$ 0.8 |
| p-value        | 0.00*         |               | 0.00*         |               | 0.00*         |               | 0.00*         |               |

\*Significant difference ( $p < 0.05$ ) between experimental and control group

The HIV-ASES scores of the experimental group improved throughout the trial in comparison to the control group which remained at 9.7 (Table 5.11). Improvements within the experimental group between all interviews over the period of the trial were significant ( $p < 0.001$ ).

Self efficacy was found to have a significant influence on knowledge score and CD4 count in the experimental group at both baseline and six months (Table 5.12), and with CD4 count in the control group at baseline only. No significant effect was seen at 6 months for the control group. An increased self-efficacy was associated with a higher knowledge score and a higher CD4 count.

Table 5.12 Correlations between self-efficacy and other parameters

| Parameters | p-values     |         |         |         |
|------------|--------------|---------|---------|---------|
|            | Experimental |         | Control |         |
|            | 1-Month      | 6-Month | 1-Month | 6-Month |
| Knowledge  | 0.000*       | 0.002*  | 0.647   | 0.446   |
| CD4        | 0.05*        | 0.014*  | 0.011*  | 0.484   |

\*Significant difference ( $p < 0.05$ ) within the experimental and the control group

### 5.2.7 Clinical health outcomes

The only CD4 count results considered for analysis were those from participants still enrolled in the trial at 6 months (experimental 20; control 24). The mean CD4 count of the experimental group increased from 367.8 to 434.2, an 18 % increase which tended to significance ( $p = 0.053$ ). In comparison, in the control group only a 5% increase was noted (355.0 to 374.9) ( $p = 0.226$ ), which was also not significant ( $p = 0.226$ ) (Table 5.13). The change in CD4 count (experimental 68.42; control 19.88) was not significantly different between the two groups ( $p = 0.072$ ), possibly due to the low sample size at the six month follow-up as well as the large variance.

Table 5.13 Differences between initial (baseline  $\pm$  1 month) and final (6-month  $\pm$  1 month) mean CD4 count and mean viral load

| Parameters                               | Experimental      |                  |         | Control           |                  |         |
|--|-------------------|------------------|---------|-------------------|------------------|---------|
|  | Initial<br>(n=20) | Final<br>(n=20)  | p-value | Initial<br>(n=24) | Final<br>(n=24)  | p-value |
| CD4 count<br>(cells/mm <sup>3</sup> )    | 367.8             | 434.2            | 0.053   | 355.0             | 374.9            | 0.226   |
| $\Delta$ CD4 count $\pm$ SE <sup>a</sup> | -                 | 68.42 $\pm$ 40.5 | -       | -                 | 19.88 $\pm$ 25.9 | -       |
| Viral load                               | 51339             | 16042            | 0.00*   | 69520             | 16317            | 0.00*   |

\* Significant difference (p<0.05)

<sup>a</sup> Standard error

Patients with a good immune system have CD4 counts between 450 and 1500 cells/mm<sup>3</sup>. Eighteen of the patients (6 experimental; 12 control) had CD4 counts above 450 cells/mm<sup>3</sup> at the start of the trial. This number increased to 27 patients (13 experimental; 14 control) at the end of the six month study period. CD4 counts below 450 cells/mm<sup>3</sup> are usually associated with OIs. The majority of study patients had CD4 counts in this category. Serious OIs occur with a CD4 count below 200 cells/mm<sup>3</sup>. Sixteen of the study patients (experimental 8; control 8) had CD4 counts below 200 cells/mm<sup>3</sup> at the start of the trial. By the end of the trial these numbers had decreased in both the experimental (3) and control (5) groups. The mean viral load in both groups decreased significantly between baseline and 6 months (p <0.001).

The influence of knowledge score on the change in CD4 count was analysed with both parametric and non-parametric tests due to distribution of the results not approximating normal (p<0.001). In the experimental group, using Pearson Correlation, it was observed that although not significant (p=0.051), there was a moderate correlation with a substantial relationship ( $0.4 \leq r \leq 0.7$ ). There was, however, significance between these constructs observed when Spearman's rho was used ( $r_s=0.498$ ; p=0.022) (Table 5.14). In the control group, there was no significant influence of knowledge on the change in CD4 count with almost no relationship between these constructs ( $r < 0.2$ ;  $r_s=0.098$ ).

Table 5.14 Correlations between knowledge score and change in CD4 count

|                     | Exp                   | Control              |
|---------------------|-----------------------|----------------------|
| Pearson Correlation | p=0.051; r=0.432      | p=0.577; r=0.117     |
| Spearman's rho      | p=0.022*; $r_s=0.498$ | p=0.642; $r_s=0.098$ |

\* Significant influence (p<0.05) of knowledge score on change in CD4 count within the experimental and the control group

## 5.2.8 Relationship of variables with knowledge scores

### 5.2.8.1 Effect of education on knowledge score

It was expected that a positive relationship would exist between an increased education level and overall understanding, and this was supported by the results (Table 5.15). The patient group who had less than Grade 3 had the lowest knowledge score, being significantly lower than the other educational groups. Patients in the other two educational categories displayed similar knowledge results.

Education was shown to have a significant effect on knowledge in the experimental group at the baseline ( $p=0.004$ ), one ( $p=0.002$ ), three ( $p=0.004$ ) and six ( $p=0.045$ ) month interviews. The control group also showed a significant influence of education on knowledge at baseline ( $p=0.044$ ), one ( $p=0.012$ ) and three month ( $p=0.004$ ) interviews.

The < Grade 3 group were particularly poor at identifying the need to take ARVs regardless of access to food, and had limited knowledge of the fact that ARVs do not cure HIV. Other questions that resulted in significantly poorer results in this educational group were ‘side effects that may be experienced after three to six months of therapy’, ‘what to tell the doctor before taking ARVs’ and ‘when taking ARVs what should you do before taking any other medication’ ( $p=0.012$ ,  $p=0.035$  and  $p=0.036$  respectively).

Table 5.15 Association of knowledge score with different educational levels

| Education level | Knowledge Score (%) |         |         |         |          |         |         |         |
|-----------------|---------------------|---------|---------|---------|----------|---------|---------|---------|
|                 | Experimental        |         |         |         | Control  |         |         |         |
|                 | Baseline            | 1-Month | 3-Month | 6-Month | Baseline | 1-Month | 3-Month | 6-Month |
| < Grade 3       | 44.5                | 75.2    | 77.4    | 75.2    | 47.8     | 45.8    | 43.7    | 65.7    |
| Grade 4 -7      | 63.4                | 88.8    | 94.2    | 94.5    | 72.8     | 71.9    | 72.1    | 71.8    |
| ≥ Grade 8       | 66.0                | 93.2    | 96.5    | 98.4    | 73.4     | 72.9    | 73.3    | 72.9    |
| p-value         | 0.004*              | 0.002*  | 0.004*  | 0.045*  | 0.044*   | 0.012*  | 0.004*  | 0.279   |

\*Significant influence ( $p<0.05$ ) of education on knowledge score within the experimental and the control groups

### 5.2.6.2 Effect of medication literacy on knowledge score

Health literacy scores were divided into three categories; 0 - 4 (poor), 5 - 7 (average) and 8 - 10 (good). The average knowledge scores in each of these categories are presented in Table 5.16. As expected, the knowledge scores increase with increasing health literacy score. Similar results were noted in knowledge scores of patients in the 'average' (95.8%) and 'good' (96.2%) groups, whereas the 'poor' category displayed significantly ( $p=0.001$ ) lower knowledge scores. Medication literacy and patient knowledge in the experimental group were strongly associated at all time intervals, whereas this was only the case at baseline for the control group.

Table 5.16 Average percentage knowledge score in each medication literacy category

| Medication literacy | Knowledge Score (%) |         |         |         |          |         |         |         |
|---------------------|---------------------|---------|---------|---------|----------|---------|---------|---------|
|                     | Experimental        |         |         |         | Control  |         |         |         |
|                     | Baseline            | 1-Month | 3-Month | 6-Month | Baseline | 1-Month | 3-Month | 6-Month |
| Poor (0-4)          | 52.6                | 74.0    | 84.3    | 82.0    | 45.8     | 53.7    | 65.6    | 60.8    |
| Average (5-7)       | 63.8                | 89.7    | 95.7    | 95.8    | 71.8     | 75.2    | 73.1    | 74.6    |
| Good (8-10)         | 63.9                | 92.3    | 95.8    | 96.2    | 73.2     | 70.8    | 73.7    | 76.9%   |
| p-value             | 0.008*              | 0.025*  | 0.001*  | 0.004*  | 0.001*   | 0.860   | 0.911   | 0.495   |

\*Significant influence ( $p<0.05$ ) of medication literacy on knowledge score within the experimental and the control groups

### 5.2.6.3 Effect of gender and age on knowledge score

Generally, no association of gender with knowledge was found. This reinforces previous findings from a study conducted in a similar population [17].

The age group of over 50 years had the lowest knowledge score, being significantly lower than the other age groups at 1 month ( $p=0.009$ ) and 3 months (0.003) (Table 5.17). Patients in the other three age categories displayed similar knowledge results. The > 50 yr age group were particularly poor at identifying their ARVs ( $p=0.003$ ), and had limited knowledge on CD4 counts ( $p=0.005$ ) and the effect of ARVs on CD4 cells ( $p=0.005$ ). Aberrations in the results are difficult to account for and this apparent random variability can be observed in the association of knowledge with age.

Table 5.17 Average percentage knowledge score in each age category

| Age<br>(Yrs) | Knowledge Score (%) |         |         |         |          |         |         |         |
|--------------|---------------------|---------|---------|---------|----------|---------|---------|---------|
|              | Experimental        |         |         |         | Control  |         |         |         |
|              | Baseline            | 1-Month | 3-Month | 6-Month | Baseline | 1-Month | 3-Month | 6-Month |
| 18-29        | 65.9                | 90.3    | 94.5    | 98.4    | 63.4     | 73.2    | 72.7    | 72.6    |
| 30-39        | 64.0                | 96.6    | 96.8    | 95.5    | 65.3     | 63.2    | 67.9    | 67.0    |
| 40-50        | 60.6                | 89.6    | 90.5    | 90.6    | 70.5     | 74.2    | 72.5    | 72.2    |
| > 50         | 52.8                | 74.0    | 75.6    | 78.5    | 55.6     | 57.3    | 52.6    | 57.8    |
| p-value      | 0.731               | 0.009*  | 0.003*  | 0.481   | 0.920    | 0.043*  | 0.815   | 0.869   |

\*Significant influence ( $p < 0.05$ ) of age on knowledge score within the experimental and the control group

## 5.2.9 Relationship of variables with adherence and self-efficacy

No general consistent associations or trends were noted for the association of education, gender or age with adherence. This may in part be due to the unreliability of the adherence results (Table 5.18).

Table 5.18 Effect of demographic variables on adherence

| Variables | p-value      |         |         |         |         |         |
|-----------|--------------|---------|---------|---------|---------|---------|
|           | Experimental |         |         | Control |         |         |
|           | 1-Month      | 3-Month | 6-Month | 1-Month | 3-Month | 6-Month |
| Education | 0.096        | 0.409   | 0.260   | 0.534   | 0.304   | 0.001*  |
| Gender    | 0.343        | 0.145   | 0.243   | <0.001* | 0.001*  | 0.440   |
| Age       | 0.113        | 0.580   | 0.248   | 0.179   | 0.457   | 0.131   |

\*Significant influence ( $p < 0.05$ ) of variables on adherence within the experimental and the control groups

At baseline, education was positively associated with self-efficacy in both groups (experimental  $p = 0.001$ ; control  $p = 0.047$ ), where an increased self-efficacy was associated with a higher education level (Table 5.19). Thereafter, at one ( $p = 0.005$ ) and three months ( $p = 0.001$ ), only the experimental group showed a significant association with education. In the experimental group, gender had a significant effect on self-efficacy at the three ( $p = 0.031$ ) and six month ( $p = 0.028$ ) interviews. Age had a significant effect on self-efficacy in the experimental group in all but the six month interviews, where the lowest self-efficacy was associated with the age group > 50 years. There was no significant influence of age on self-efficacy in the control group.



Table 5.19 Effect of variables on self-efficacy

| Variables | p-value      |         |         |         |          |         |         |         |
|-----------|--------------|---------|---------|---------|----------|---------|---------|---------|
|           | Experimental |         |         |         | Control  |         |         |         |
|           | Baseline     | 1-Month | 3-Month | 6-Month | Baseline | 1-Month | 3-Month | 6-Month |
| Education | <0.001*      | 0.005*  | 0.001*  | 0.492   | 0.047*   | 0.459   | 0.658   | 0.367   |
| Gender    | 0.923        | 0.894   | 0.031*  | 0.028*  | 0.156    | 0.399   | 0.268   | 0.994   |
| Age       | <0.001*      | 0.006*  | 0.014*  | 0.396   | 0.253    | 0.788   | 0.910   | 0.868   |

\*Significant influence ( $p < 0.05$ ) of variables on self-efficacy within the experimental and control groups

### 5.2.9 Patient acceptability of PIL

Acceptability data were collected at the three-month interview, and the results are presented in Table 5.20. All but one patient liked the way the PIL looked and felt that the PIL was easy to read. Most of the patients (94.3%) felt that the writing was large enough as well as the sentence length being appropriate (94.1%). All the patients felt that not only was the PIL a useful source of information to take home, but if it was all the information that they were given on HIV/AIDS and their ARVs, it would be enough. The patients felt that the information was sufficiently detailed enough without creating misunderstandings.

Most of the patients (97.1%) commented that they had referred to the PIL in the last three months, however fewer (25.7%) had any questions regarding their ART over the same time period. All the patients felt that the PIL helped them understand more about both HIV/AIDS and their ARVs. Interestingly half the patients shared their PIL with the surrounding community, showing it to family members (57.1%) and friends (48.6%). This is a very positive finding as the information in the PIL then has a chance to become disseminated more widely. It also highlights the usefulness of the PIL and the high regard in which the patients held it.

Very few patients (17.1%) claimed not to understand words in the PIL. Words not understood were the drug names lamivudine, stavudine, efavirenz, zidovudine and nevirapine. It was explained to the patient that they are the names of the drug similar to a person having a name. It is impossible to avoid using these words in the PIL. Words that were not understood tended to be medical terms such as ‘allergies’, ‘oral contraceptive’, ‘viral load’, ‘CD4’ and ‘antiretrovirals’ and are difficult to simplify with one substitute word or term. The meaning of these words was explained to the patients.

Miscellaneous aspects of the PIL that elicited positive comments from the patients included its simplicity, the value of the storage and side effect sections, the style of the PIL where pictograms are incorporated in text and the description on how to take the ARVs. Some suggestions for modifying the PIL included incorporating coloured pictograms, having more text and not using as many pictograms in the PIL. The patients were enthusiastic about having this type of information available as it addressed many questions and areas of concern, particularly when commencing ART. The labels were received with enthusiasm by both the participants and the HCPs. All the participants liked the pictures on the labels and felt that the pictures would help them to remember to take their ARVs and to take them at the right time.

Table 5.20 Patient acceptability, n%

| Question  | Participants, n (%) |
|---|---------------------|
| <b>Readability</b>  |                     |
| Do you like the way the leaflet looks?  | 34 (97.1)           |
| Was it easy to read the leaflet?  | 34 (97.1)           |
| Is the writing large enough?  | 33 (94.3)           |
| What do you think of the length of the sentences?   | 32 (94.1)           |
| Is there enough space between the lines?  | 34 (97.1)           |
| <b>Content</b>  |                     |
| If you had just started taking ARVs, do you think a leaflet like this would be useful for you to take home?                                 | 35 (100.0)          |
| If you had just started taking these medicines and this was all the information you were given about them, do you think it would be enough? | 35 (100.0)          |
| Did you use or refer to the PIL in the last 3 months?   | 34 (97.1)           |
| At any stage in the last 3 months, have you had questions about your HIV/AIDS or your ARVs?   | 9 (25.7)            |
| Did the PIL help you understand more about HIV/AIDS?  | 35 (100.0)          |
| Did the PIL help you to understand more about how to take your ARV's?   | 35 (100.0)          |
| Did any of your family members read the PIL?  | 20 (57.1)           |
| Did any friends read the PIL?   | 17 (48.6)           |
| <b>Words in text</b>  |                     |
| Are there any words in the text that you did not understand?  | 6 (17.1)            |
| <b>Labels</b>   |                     |
| Do you like the labels with pictures on them?   | 35 (100.0)          |
| Do you think the pictures helped you take your ARVs correctly?  | 35 (100.0)          |
| Did the labels with pictures help you to remember to take your ARVs at the right time?  | 35 (100.0)          |
| <b>Pictograms</b>   |                     |
| Do you like having pictures in the leaflet?   | 35 (100.0)          |
| Do you think having pictures will help you understand and remember the information better?  | 35 (100.0)          |

## **5.2.10 Pictogram interpretation**

### **5.2.10.1 Interpretation of side effect pictograms**

#### ***Dizziness pictogram***

To score a correct answer, patients needed to describe a dizzy feeling or state that it was dizziness; headache was not accepted as correct. There was 100% correct interpretation with this pictogram (Table 5.21). The patients felt that the idea of dizziness was well represented by the patient leaning against the door, as well as the twirl above the head. However, some patients thought that a headache was also represented by the pictogram as ‘lady is holding her head’.

#### ***Lactic acidosis pictogram***

Patients were expected to mention abdominal pain and vomiting. All the participants correctly interpreted it (Table 5.21), commenting that these were familiar symptoms and experiences and are therefore easily identifiable. Patients tended to create their own meaning for the cause of the vomiting, with one saying a pregnant woman was vomiting and another that there had been overconsumption of alcohol.

#### ***Headache and fever pictogram***

Some patients interpreted the wavy lines around the head to imply dizziness, and others interpreted the pictogram as representing a fever and a cold. Most of the patients (93.4%) interpreted it correctly (Table 5.21). Headache was much more easily identified than fever. No attempt was made to depict ‘with or without chills’. However, as the pictogram was accompanied by text, patients who could read were able to integrate the visual and textual elements.



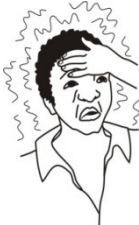
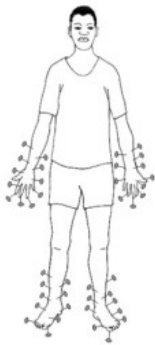

#### ***Peripheral neuropathy pictogram***

The criterion for correct interpretation included mentioning either pins and needles, cramps, burning, tingling, or pain in the arms and legs. This pictogram was well interpreted at 93.3% correct (Table 5.21). Two of the participants felt that the pictogram represented bone and joint pain. One participant felt the pictogram showed an allergic reaction.

### ***Severe rash pictogram***

This was well interpreted (100% correct). Many recognised that it was a ‘bad’ or a severe rash. The darker patches were used to represent a Stevens Johnson-type rash and although the patients did not know what Stevens Johnson syndrome is, they felt that the pictogram was informative but did not scare them unnecessarily.

Table 5.21 Interpretation of side effect pictograms

| Pictogram   | Correct<br>n (%) | Pictogram  | Correct<br>n (%) |
|---|------------------|--|------------------|
| Dizziness<br>            | 24 (100.0)       | Lactic acidosis<br>        | 35 (100.0)       |
| Headache and fever<br> | 33 (94.3)        | Peripheral neuropathy<br> | 28 (93.3)        |
| Rash<br>               | 35 (100.0)       |  |                  |

### **5.2.10.2 Interpretation of storage pictograms**

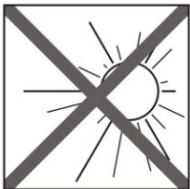


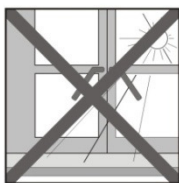


#### ***Storage pictograms***

The vast majority of the participants interpreted these pictograms correctly (Table 5.22). One participant did not understand the meaning of the prohibition cross, another felt that the sun looked like a clock. The ‘do not store medication in the car’ pictogram was interpreted by one

patient as avoiding the security risk of keeping medication in the car as many people can get into the car.

Most patients are aware that medication needs to be stored away from children so the relevant pictogram was easily interpreted correctly by all the participants. The other storage pictograms were generally well interpreted, with results exceeding 90%.

Table 5.22 Interpretation of storage pictograms

| Pictogram  | Correct<br>n (%) | Pictogram   | Correct<br>n (%) |
|--|------------------|---|------------------|
| Do not store medication near the sun<br>    | 34 (97.1)        | Do not store medication in the car<br>            | 34 (97.1)        |
| Do not store medication near the fire<br> | 35 (100.0)       | Do not store medication near a sunny window<br> | 34 (97.1)        |
| Store medication away from children<br>   | 35 (100.0)       | Store medication in a cool dry place<br>         | 32 (91.4)        |






### 5.2.10.3 Interpretation of miscellaneous pictograms

#### *Alternative sources to purchase medicines*

The pictogram showing ‘places that you can buy medicine’ was well interpreted. A ‘spaza’ is a small general trading store commonly seen in the township areas of South Africa and carrying a small range of over-the-counter (OTC) medicines. In South Africa it is

estimated that up to 80% of the population visit a traditional healer or isangoma prior to visiting a primary health care centre [173], so an image was included in this pictogram.

Table 5.23 Interpretation of pictograms showing alternative sources to purchase medicines

| Pictogram  | Correct<br>n (%) | Pictogram   | Correct<br>n (%) |
|--|------------------|---|------------------|
| Spaza<br>       | 34 (97.1)        | Isangoma<br>  | 35 (100.0)       |
| Supermarket<br> | 33 (94.3)        | Pharmacy<br> | 33 (94.3)        |
| Clinic<br>    | 33 (94.3)        |   |                  |

### *Miscellaneous pictograms*


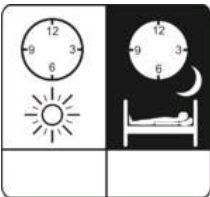

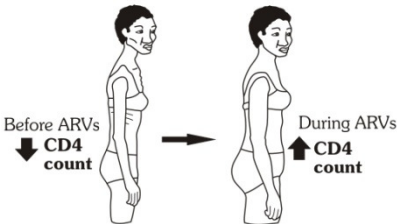

The pictogram representing a pregnant woman was easily interpreted, as was the ‘take medication at night’ and ‘take medication twice a day’ pictogram once in the morning and once at night (Table 5.24).

The CD4 pictogram was the most poorly interpreted pictogram at 88.6% correct interpretation (Table 5.24). Misinterpretations were that the medication should not be taken as ‘if you are thin you will get fat.’ Another patient did not want his wife to take the medication as she would get fat.

Sharing of prescription medicines is common among patients irrespective of illness and economic status. There was a 94.3% correct interpretation of the pictogram (Table 5.24).

One of the difficulties encountered, and which is well documented for potential misinterpretation, is the isolation of a body part such as the hands [20]. A female participant was distracted by the ‘lack of hygiene’ in the pictogram as no gloves were being used.

Table 5.24 Interpretation of miscellaneous pictograms

| Pictogram  | Correct<br>n (%) | Pictogram   | Correct<br>n (%) |
|--|------------------|---|------------------|
| Pregnant woman<br>            | 27 (100.0)       | Take twice a day.<br> | 35 (100.0)       |
| Take at night.<br>          | 35 (100.0)       | CD4 pictogram<br>    | 31 (88.6)        |
| Do not share medication<br> | 33 (94.3)        |   |                  |

## CHAPTER SIX

### GENERAL DISCUSSION

#### 6.1 Patient information leaflets

User-friendly simple PILs and medicine labels were designed with careful consideration of the characteristics and opinions of the target population, and this approach proved successful, resulting in an excellent overall understanding of 89%. The PIL designed by Ramela [158], which was the starting template, resulted in an average of only 60% understanding, although this was tested in an ARV-naive population. This study adapted a rigorous, user-centred design and development process, which focused on including simple text and making the PIL as readable as possible. The majority of studies on medicine-related information materials originate from developed countries with high literacy levels, and even here, a consistent finding is that they are generally written at levels significantly higher than the reading comprehension levels of most patients [133,174]

Krige *et al.* [148] evaluated PILs currently available in South Africa for prescription and OTC medicines and concluded that they “...do not communicate efficiently in the health communication environment” and in fact present many barriers to communication. Participants commented negatively on the excessive amount of information, much of which they considered superfluous, as well as small print size and inadequate white space. They also noted the use of incomprehensible technical language and medical jargon and felt that there were too many difficult words, concluding that the leaflets were boring and user-unfriendly. These PILs had been designed in accordance with Medicine Control Council recommendations with medico-legal issues of design as the focus, with little consideration given to the needs of the patient [175]. Grime *et al.* [176] also noted that, in most medicine leaflets, the patient voice is not considered.

In contrast, my results showed that 97% of patients liked the overall layout and format of the PIL and were highly enthusiastic about it. All patients felt that the study PIL helped them learn more about HIV/AIDS and ARVs. The positive opinions and good understanding of the study PIL support previous research where a similar approach was used [177]. PILs may be used as a supplement to the verbal information given by the HCP and act as a permanent



source of information and to stimulate patient recall [158]. Patients initiated on ARV therapy receive a large amount of information at the initial consultation. This information is given to them at a time when they are both physically and emotionally vulnerable, and they are expected to adhere to a stringent medicine-taking regimen. This highlights the gap that PILs could address, particularly at this crucial time in the medicine-taking continuum.

The study PIL was not designed to comply with South African legal guidelines, as previous studies had clearly identified the problems inherent in this approach [176]. The approach adopted in this study placed the needs of the patients at the core of the design process i.e. adopting a user-centred process. However, this was done in parallel with consultations with HCPs to ensure provider acceptability of the end product. If the providers do not approve of the PIL, it would be unlikely to be used.

In Regulation 10 of the Medicines and Related Substances Control Act, Act 101, as amended, the provision of PILs is mandatory with all prescribed medication [176]. However, this is not occurring in practice. There is minimal written HIV/AIDS-related medicines information available and distributed in sub-Saharan Africa [177,178], and patients in South Africa attending public sector facilities receive no written information. The information, if available at all, is at present usually contained in a complex package insert written at a high readability level and printed on thin, semi-transparent paper in a small font. Each of the three individual ARVs comprising the ART regimen has its own package insert. The amount and complexity of all this information presents a daunting and overwhelming reading challenge for patients with limited literacy skills [179].

Designing the PIL consisted of a multifaceted process where the target population was identified and the complexity of the information was considered before inclusion. The study PIL was brief and informative, and encouraged correct medicine-taking behaviour. It addressed information on the safe and effective use of medicines and side effects, information areas identified as the principle expectation for medicines information [115,180]. Linguistically transparent simple words and commonly used phrases were used in the PIL, with short sentences and words that could be pronounced phonetically. Any extraneous material and unnecessary medical jargon that may divert the reader's attention was eliminated, making the PIL as simple as possible and following the 'Coherence Principle' from Mayer's theory [130], which states that the minimum number of words should be used.

Studies support the intuitive view that, regardless of education level, patients, and others, prefer easy to read simple materials [96,141].

In order to increase patient understanding and recall, the study PILs were designed using a combination of visuals and text. This has been reported as having a positive effect on patient understanding [116,181-183]. Mayer's cognitive theory of learning [130] and Paivio's dual coding theory [131] suggest that visuals and text have different cognitive representations, stimulating dual information processing systems and memory storage pathways. The 'Multimedia Principle' in Mayer's theory [130] suggests that learning is achieved more effectively using a combination of visuals and text, than by text alone. The inclusion of visuals in the PIL also served to interrupt text-dense, user-unfriendly portions of text. The large amount of space around the visuals and text allowed for easy reading, as did the use of short paragraphs. Visuals were located adjacent to associated text, in accordance with the 'Spatial Contiguity Principle' which states that corresponding words and pictures should be positioned near each other [130]. This positioning makes it much easier for patients to locate information in the text, where the visuals can then also stimulate recall of the information.

Even with this intensive development process, not all the patients attained acceptable knowledge scores, reflecting poorly on reading ability and depth of understanding of the population. Many of the patients were educated during the apartheid regime under which the quality and standard of schooling was highly variable. The study participants were drawn from a population group that would have received, in many situations, a poor standard of education. Just under a quarter of the study population had a maximum of three years of schooling, categorising them as functionally illiterate, but despite this the average overall knowledge score after the addition of the PIL in the experimental group was 96%, in comparison to the control group where the knowledge score was 75% . In the South African Demographic and Health Survey (SADHS) report, 2003 [184] it was reported that low-literate individuals had a lower knowledge of AIDS than literate individuals. A similar finding in this study showed that patients with a poor medication literacy score (0-4) had a significantly ( $p=0.025$ ) lower HIV/AIDS and ARV-related knowledge score than those with a higher literacy level.

Certain information in the PIL appeared difficult to understand irrespective of educational level. Participants were all AIDS patients taking ARVs, but still were particularly familiar

with possible side effects of ARVs, with only half the patients at baseline displaying adequate (60-80%) knowledge. By the end of the 6-month trial, patients who had received the PIL had increased their average score to 92%.

The most intensive counselling occurs at initiation of therapy, with the focus being on information about side effects that are likely to appear within the first month of taking ARVs. This means that late side effects may not be as well addressed, resulting in the poor knowledge observed in this area. Confusingly, knowledge of the initial side effects that may be experienced was also very poorly answered. Side effects of ARVs have a significant effect on health-related quality of life [157,185]. Many patients manage the side effects by attempting to reduce them with nonadherence (decreased dose and/or stopping treatment altogether). This intentional nonadherence leads to decreased efficacy of HIV treatment [186]. The patients demonstrating this nonadherent behaviour had a poorer understanding of HIV and felt that ARV treatment intruded into their lives [185]. HCPs are hesitant to provide patients with comprehensive information on side effects as they seem to suspect that patients will be more likely to report side effects, not all of which are causing problems or are, in fact, not actually being experienced. Further research in the form of a well-designed prospective study conducted in HIV/AIDS patients should investigate this issue.

With South Africa's current HIV prevalence estimated to be 5.2 million, much HIV/AIDS-related information appears frequently in all types of local media such as television, radio, newspapers, billboards, posters and pamphlets [3]. It was therefore expected that general information about issues concerning this disease would be well known. The study findings supported this prediction as general HIV/AIDS knowledge was above 98% in both groups at the conclusion of the study. However, a significant lack of knowledge of ARV information was noted within the groups studied and, if extrapolated to the general HIV positive population, indicates that many patients are not aware of correct medicine-taking information.

In South Africa it is estimated that approximately 60-80% of the population visit a traditional healer prior to visiting clinics [173] and consequently much media attention has focused on the dangers of using both traditional medicine and ARVs. A 47 year old study patient commented that even though her husband is a traditional healer she only takes ARVs, and does not take any traditional medicines. At the baseline interview the question on the use of OTC medicines taken concomitantly with ARVs was answered poorly in both experimental

(55%) and control groups (35%) in comparison with the question referring to traditional medicine and ARVs in both groups (98%). The same level of attention has not been focused on OTC medicines and ARVs, and the study patients did not have the same awareness of the possible dangers. This is an area that this study has identified as needing attention and should receive greater emphasis during routine counselling of AIDS patients.

The relationship of ARVs with CD4 counts and viral load appears to be challenging to understand when reading it for the first time. In discussions at Masonwabe Clinic, HCPs concurred that CD4 counts and viral load are difficult concepts to fully comprehend, even for those patients who have been taking ARVs for a few months. After the introduction of the PIL, knowledge in this area increased significantly, showing the value of well-designed written information in helping patients learn and understand a difficult new concept.

Aspects relating to pregnancy are thoroughly dealt with in HIV/AIDS counselling groups and programmes, as the age group most affected by HIV/AIDS is women of child-bearing age [2]. The intensive counselling that these patients receive as regards HIV and pregnancy has had a positive effect, as many of the patients knew that EFV cannot be taken by pregnant women and that, when pregnant, EFV is substituted with NVP.

Patients have the right to receive health-related information in their first language. Regulation 10 of the *Medicines and Related Substances Act, Act 101 of 1965*, as amended, [186] in April 2003, requires that each package of medicine shall be accompanied by a PIL containing the information in at least English and in one other official language. The PILs in this study were first developed in English, and were then translated into isiXhosa, with both language versions being available to all participants. All the patients chose to read the PIL in their first language, in accordance with previous studies conducted in a similar target population [187,188]. This reinforces the necessity of having PILS available in different languages.

Having the PIL available in the patient's first language has been shown to be more effective in both utility and acceptance [20,189,190]. Ideally, the PIL should have been designed in the final language in which it is distributed. However, in South Africa with 11 official languages, it is unlikely that the designer would be fluent in all the languages. This emphasises the importance of the translation stage. Great care needs to be exercised when translating to ensure that the context and inherent meaning of the information remains unchanged. In this

study, a multi-process back-translation was used. The translation was done with an African languages expert and an interpreter from the target population. This rigorous approach is recommended to detect any inconsistencies in the translation.

The majority of the patients found the PIL easy to read, which was heartening as very simple text was used, no phrases were included that were unfamiliar to the population and pictograms were used to help facilitate understanding.

The medicine labels were received with great enthusiasm by both the participants and the HCPs. All the participants liked the pictures on the medicine labels, felt that the pictures would help them to remember to take their ARVs and to take them at the right time. The labels were designed to help patients remember at a glance, as well as being clear enough for patients with minor visual impairment. The labels cannot be used in isolation, as all the instructions cannot adequately be explained on a label. It is essential that the labels are combined with written information and a verbal explanation of the desired medicine-taking behaviour. Many patients commented that they cannot read the clinic labels on their ARVs and that the illustrated medicine labels played a valuable role in guiding them in how to take their ARVs correctly. Patients also requested that, once the study ended, they still be provided with the illustrated medicine labels.

### **6.1.1 The use and acceptability of visuals in PILs**

Visuals in the PIL attract the attention of the reader and may facilitate the speed at which information and message transfer takes place [18,96]. The pictograms used in the PIL were carefully designed in a previous study to incorporate any cultural diversity of the target population [177].

Visuals in the PIL were generally shown to be well interpreted by the patients, although there were some misinterpretations. Misinterpretations occur as pictorial illiteracy is almost as widespread as illiteracy [191], and inevitable in a low-literate population group such as the group used in the study, for example, this was evident in the interpretation of the CD4 pictogram, where 12% of the participants misinterpreted the pictogram. Another misinterpretation was identified in the pictogram for peripheral neuropathy. The colloquial term ‘pins and needles’ is commonly used to describe peripheral neuropathy, however this is

not a phrase that is used in the isiXhosa language. Although many of the participants had heard of the term, they did not use it in their colloquial speech. The Xhosa word “inkantzi” is the closest description which translates to cramps. Although many patients had some idea of the concept of ‘pins and needles’, they stated that they would not use it in their everyday speech.

The Medicines Control Council and the South African Department of Health are not convinced of the benefit of pictograms, given the possibility of their misinterpretation [18]. However, the use of pictograms can be beneficial in practice if they are used in conjunction with verbal counselling although they must be thoroughly explained in order to avoid misinterpretations and to reach their full potential as an information aid.

Findings from the study show that all the participants felt that they would benefit from having pictograms to explain their medication. As such, they would like pictograms to be used by the clinics that they frequent. The benefit of using the pictograms in HIV/AIDS education may far outweigh the initial time needed to be spent by the HCP in explaining the pictogram. The benefit of pictograms has been reported both locally, within South Africa [17,192,193], and internationally [194-197]. However, these studies describe pictogram use in medicine labels with the only other study of pictogram use for low-literate patients in a leaflet [17]. The patients that would receive most benefit from the pictograms are those who have limited reading skills. These patients require significant explanation from the HCPs as they are unable to read and comprehend the labels on the medicine containers. Time could be saved as the pictograms would provide a faster and more effective way of communicating medical information [18].

## **6.2 Patient adherence to therapy**

With approximately 310 000 deaths in 2009, HIV/AIDS consumes much of the media’s attention and dominates health-related discussions [190]. Although it is well established and well known that a high level of adherence (at least 95%) is required, a study conducted by Gallant *et al.* [181] on HIV/AIDS patients reported that only a third of patients felt that nonadherence to ARVs was a serious problem, and 11% surprisingly felt that nonadherence did not present a problem at all. Studies conducted into ARV therapy have reported adherence levels ranging from 50% to 70% [7]. One factor, apparently unique to

South Africa, that impacts on adherence to ARVs in South African public sector HIV/AIDS patients is the disability grant patients receive when their CD4 counts are  $<200$  cells/mm<sup>3</sup> [198]. This aims to provide some income to patients who are unable to work to support themselves due to the disease [198]. The disability grant for one person is often used to support an entire household. An observation in a recent study by Ruud *et al.* [198] was that patients were afraid of losing their disability grant when the CD4 count improved due to ARV therapy, and this created a conflict between maintaining adherence to ARVs or choosing to discontinue therapy in order to continue receiving the disability grant.

This study was designed to measure adherence objectively, using tablet counts conducted by the nursing sisters, and subjectively, using two methods: firstly the modified self-reported MMAS-8, and secondly, recording researcher opinion. Unfortunately MEMS, could not be used as the system is expensive and adequate funding to support this method was not available. All adherence results discussed here were generated using the self-reported MMAS-8 method. Pill count results recorded by the nursing sisters were not used in the analysis as they seemed to be inconsistent and had not been adequately reported in the patient records.

Adherence, as reflected by the MMAS-8 scores, was high, which is common in self-reported studies [62], and the scores significantly improved between the 1-month and the 6-month interview. These high scores may be due to a reluctance to disclose nonadherent behavior because of fear of negative consequences and treatment by the researcher or clinic nurse. A non-judgmental and supportive attitude is paramount in obtaining an honest reflection of adherence by the patient [62]. In my opinion, which is derived from close observation of all patients during the interviews, adherence improved as the study progressed. Adherence in the opinion of the interviewer was determined by a factors such as, patients attendance to follow-up interviews (taking into account the date that they should return to the clinic and the date that they actually returned), the patients attitude towards their therapy and if there was any history or evidence of substance abuse.

Adherence in the experimental group was significantly higher at the 6-month interview than at the baseline interview and this may, in part, be associated with the improvement in knowledge observed in the experimental group. An improvement in adherence was also observed in the control group despite no increase in knowledge, a phenomenon which may be

attributed to the Hawthorne effect [59,199]. Merely participating in the study may have prompted patients to pay more attention to issues related to their ARVs and to HIV/AIDS and have raised their awareness. The Hawthorne effect may lead to inflated estimates in both groups [199].

Chesney has reported that patients taking all their ARVs were twice as likely to achieve optimal viral loads in comparison to those with less than 70% adherence [6]. With 95% adherence, 81% of patients experienced viral suppression. When adherence levels dropped to between 80-95%, viral suppression dropped to 50%, and with adherence below 70%, only 6% showed improvements in viral loads [5]. Surprisingly, no significant association was found in the current study between increased adherence and reduced viral load count at either of the interviews, although this trend was noted in the data, a finding supported by previous studies [5,6,181].

At the 6-month interview, increased adherence was found to have a significant influence on CD4 count, a finding supporting previous studies [39]. The CD4 count reflects disease state, with consistent adherence to ARVs resulting in maintenance of the CD4 count. Only at the end stages of HIV/AIDS does the CD4 count drop regardless of adherence.

Adherence was not significantly influenced by self-efficacy. This is unexpected as self-efficacy has been reported to be positively associated with ARV adherence [200-202]. Although not significant, a trend was observed of an increased self-efficacy score being associated with higher adherence. As argued by Bandura [77], a patient with the confidence, and who has invested the effort to adhere to medication regimens, would display better adherence than someone lacking confidence in their ability to adhere and in the therapy itself.

The knowledge score had no significant effect on adherence, despite a trend showing higher knowledge and better adherence. Prior studies reporting the association of literacy skills and knowledge with adherence are inconsistent [183], with some studies reporting higher literacy being associated with higher adherence [203,204] and others showing no association [182,183]. Kalichman *et al.* [203,205] also reported that patients with limited literacy skills had greater difficulty adhering to their ARV therapy and that these patients tended to be unaware of how their medication works. They were also less likely to employ any behaviour strategies to improve adherence [205]. It might be anticipated, with increased knowledge of



the disease and the benefits of ARVs, that their adherence would improve significantly due to a greater understanding of the disease and the importance of adherence. However, in a study conducted by Wolf *et al.* [206] it was reported that self-efficacy, rather than treatment knowledge, was a more accurate predictor of adherence.

There was no significant association of gender, age or education with adherence. This is consistent with other studies reporting that patient demographics are not accurate predictors of patient adherence [62]. However, patients of advanced age have been reported to display a lower adherence level [182].

With self-reports, patients tend to overestimate their adherence [62], but it was noted in this study that, as they became more comfortable and less threatened by the interview situation, they appeared more comfortable with admitting less-than-perfect behaviour. Later responses are likely to be more honest and thus reflect a more accurate adherence state. MMAS-8 adherence data were collected for the first time at the 1-month interview and did seem to include excessive variability. The patients were aware that they should be following a strict medicine-taking regimen while on ARVs. They were aware of the response that indicated complete adherence. This may have caused variability in the data, where some patients are honest and others are portraying the adherence that they feel is acceptable to an HCP.

### **6.2.1 Measurement of adherence**

Adherence in clinical settings is not routinely monitored using self-reports. The most common ways of assessing adherence are pill counts and a three-day recall [206,207], although only pill count was used in both study sites. Patients are aware of the fact that their pills are counted at each clinic visit. Consequently, there is a possibility that they may have deliberately removed excess pills from the pill container if they had missed any doses, resulting in an inaccurate adherence level being reported. Conducting home pill counts at unexpected time intervals may result in a more accurate reflection of adherence. However, making home visits in a resource-poor setting is an unrealistic expectation to place onto the already overloaded and understaffed clinic HCPs. There is also the stigma associated with HIV/AIDS, where visible visits by an HCP may place confidentiality at risk.

Patients at Masonwabe Clinic are given a tick chart for all their ARVs, and this tick chart is checked at each clinic visit. Problems associated with using these charts to evaluate adherence include forgetting to tick the chart after taking a dose, or deliberately ticking the chart although doses were missed. A possible medication reminder trigger could take the form of sms texting to the patients. Even in the study population, where 85% were unemployed and where almost all patients were from a low socioeconomic sector, over 70% had cell-phones. The study was designed in such a way as to mimic standard practice as far as possible, thereby optimising the translatable nature of this research. The reality of practice in this setting is that this patient population is mobile and, in many cases, is difficult to contact. Future research could investigate the feasibility of such an intervention.

More research clearly needs to be conducted to identify what constitutes an effective adherence measure. Using self-report in tandem with a pill count may be a more accurate predictor of adherence as self-reports are specific but not sensitive, whereas pill-counts are more objective [65]. The modified MMAS-8 proved to be an easy to use scale that was effortlessly understood by the patients and holds potential for routine use in the low-literate South African population.

### **6.3 Patient self-efficacy**

The assessment of self-efficacy used the modified HIV-ASES on a scale ranging from poor (0) to excellent (10). Self-efficacy scores in the experimental group were extremely high (9.1 to 9.7) with a significant improvement between all the time intervals. Self-efficacy of the control group also remained consistently high throughout the six month trial. One reason for this over-estimation may be due to the type of patient who agreed to participate in the study. It is possible that patients who were more confident and who were not intimidated by the requirements of the study agreed to participate [15]. The majority of research conducted into self-efficacy has focused on development and validation of tools, with very few reporting on the relationship between self-efficacy and adherence or health outcomes.

Findings from the study suggested that the influence of a patient's own experiences had the greatest effect on self-efficacy, with negative physiological and affective states resulting in a lower self-efficacy score. However, Johnson *et al.* [15] expressed uncertainty as to whether

an advanced disease state causes lower self-efficacy or whether the low self-efficacy contributes to the worsening of the disease state.

Social influence on self-efficacy was evident in the study. The question relating to taking medication in front of other people who are unaware of the patient's HIV status generally resulted in a lower self-efficacy score. Another trend was observed where the highest self-efficacy scores were experienced in patients happy with their health and CD4 counts, where anxiety about their health was lower.

Results from the study show that education had a significant influence on self-efficacy. A higher education level and more developed health literacy skills may better equip patients in their dealings with the health care system. Studies have shown that better health literacy skills are associated with easier navigation of the healthcare system and improved provider-patient communication [15]. The South African public healthcare system tends to be an autocratic one in which patients often feel disempowered and are usually reluctant to ask questions. Study patients, when asked if they had any questions, invariably declined.

Gender had no significant association with self-efficacy, which is consistent with published results [15]. As expected, a higher self-efficacy was associated with an increased CD4 count, a finding supported by the study conducted by Johnston *et al.* [15]. In a number of previous studies self-efficacy has been shown to be associated with adherence [15,76,80], although a significant association was not established in this study.

The ability to predict self-efficacy may be an important factor in determining whether therapy can be initiated or if more intensive counseling is necessary. This is necessary as solid support exists where negative beliefs about medication have been shown to be significantly associated with low medication adherence [76]. It may be advantageous to routinely measure self-efficacy to distinguish those individuals who are ready to initiate therapy from those where more intensive counseling is necessary. These simple instruments are key components in determining readiness for therapy and tailoring communication about medicines in time constrained settings [76].

## **6.4 Clinical health outcomes**

In both the control and experimental groups the increase in CD4 count reflected improvement in clinical outcomes during the study. The number of patients with CD4 counts < 200 cells/mm<sup>3</sup> decreased, while those with CD4 counts >450 cells/mm<sup>3</sup> increased. Overall, there was a significant correlation between knowledge score and CD4 count, and in the experimental group, there was a moderate correlation with a substantial relationship. This lack in apparent significance is supported by other studies where no linear relationship was present between health outcomes and health knowledge [206,208].

Although adherence to ARV therapy is known to lead to a decrease in the viral load of the patient, this study found no consistent association between self-reported adherence and viral load count, apart from in the experimental group at six months. This lack of significance may be attributed to the fact that self-reported adherence is notorious for inconsistencies, a result observed in this study. The significant influence of adherence on CD4 count at the six month interview in this study was a positive finding, supporting previous studies conducted in this area where adherence had a significant effect on clinical outcomes [22,203,205]. A further significant finding of this study was the positive association of self-efficacy with an increased CD4 count.

## **6.5 Modification of behavioural tools**

Instruments used in this study to assess the medicine-taking behaviours of adherence and self-efficacy are typically designed for use in developed countries, where literacy rates tend to be much higher than those in South Africa and other developing countries. It is essential to evaluate their applicability in a population with different characteristics, such as literacy skills, culture, language, before using them for the routine collection of data. Invariably some changes are required, as was identified in this study. Complex instruments are difficult to apply in this setting, so the focus should be on creating new or modifying existing instruments so that they are simple, short, effective, and easy to administer.

When administering a self-report test to measure a behaviour, it is important that the patient understands that honesty in responding is key to the working of any self-reported scales [161-163]. A problem that was identified in both the modified MMAS-8 and HIV-ASES was that

some of the patients invariably offered a response that reflected ideal medicine-taking behaviour rather than describing their actual behaviour. The MMAS-8 and HIV-ASES were initially identified as possible tools due to their relative simplicity, ease of administration and short length (only 8 and 11 questions respectively). During the translation of individual questions, process factors such as cultural acceptability, complexity and familiarity of individual words were addressed. Phrasing of the questions was carefully considered as it is essential to retain the original meaning to ensure validity of the instrument [146]. The isiXhosa language expert noted that some of the English phrases and colloquial terms used in the scales were not applicable or culturally acceptable to the Xhosa-speaking study population. A word such as 'hassled' is not used in the Xhosa language and cannot be directly translated, so the sentence needed to be rewritten using different words but still retaining the same meaning. Individual words may be too complex or may not lend themselves to translation into a certain language and must therefore be substituted for a more familiar term. The language had to be simplified to be congruent with the limited health literacy skills of the study population e.g. words such as 'treatment plan', 'situations' and 'schedule' were simplified before translation. Colloquial terms such as 'cut back' and 'hassled' are not used in the Xhosa population thus were replaced with more suitable terminology. The generic term 'medication' was replaced with 'ARVs' to make the instrument ARV-specific.

The MMAS questions included a time frame of one month for patients' self report which was increased from the original two weeks due to the clinic schedule in South Africa. Research by Wolf *et al.* [206] with HIV patients with low literacy in the U.S. found that a time frame of more than 3 days was problematic for HIV patients with low literacy. However, in this population a time frame of one month was appropriate due to the presence of the tick charts and the monthly clinic visits of the South African patients.

Further research is needed to develop and validate alternatives to the 11-point rating scale used in the original HIV-ASES scale. Participants found it difficult to comprehend, with their responses being clustered at the beginning (0), middle (5) or end (10) of the scale. This finding, and the general response to the HIV-ASES scale, supports previous findings, where the recommendation was that a three point scale may be more effective for use in a low-literate population [81].

Many of the patients were unable to fully grasp the idea of associating their confidence level with a point or number on the scale. The Multimedia Principle of Mayer's cognitive theory of multimedia learning [130] was applied when modifying the scale, where visuals and text were used in conjunction to promote learning and understanding of the concept of a confidence rating scale. The modified HIV-ASES contained visual representations (bar chart, hand signals and smiley/sad faces) of confidence levels to help patients differentiate between the levels and to make this association. The scale that included the hand signals and smiley/sad faces was preferred by the patients who felt it was more understandable with the visuals. The study findings are aligned with those of Kalichman *et al.* [82] who used a visual analogue scale that included hand signals which received a positive response. However, even with visuals, the scale needed to be explained in detail to ensure correct use and avoid errors in the data.

Study patients appeared comfortable with using the rating scale of both instruments; they all understood the questions with no ambiguities in wording being identified. This high level of understanding may have been due to the intensive translation and adaptation process used in order to make the scales suitable for the target population.

## **6.6 HIV/AIDS programme reach in South Africa**

A South African survey conducted in 2008 reported that 10% of the adult population had not been reached by any of the HIV/AIDS programmes [178]. A gap was identified where there seemed to be a lack of HIV/AIDS education in the older population age group of over 50 years [178]. In this study, the older population (> 50 years) had a significantly lower knowledge score than the other age categories. This gap needs to be breached as there is a fairly high prevalence of HIV/AIDS among older people [2] as well as poorer knowledge. The awareness messages were best received by 15-24 year-olds, with this age group being the target audience of many of the HIV/AIDS campaigns in South Africa, with a 90% coverage [178]. Despite the improved reach of these awareness campaigns, accurate knowledge about HIV/AIDS is poor [178].

## 6.7 Limitations of the study

The PILs were tested only in the isiXhosa population, one of more than 10 ethnic groups within South Africa. The study was based in a semi-rural town in the Eastern Cape and participants were mainly from a low socioeconomic class. This population group is inevitably not representative of all ethnic and economic groups within South Africa. Extrapolating results to people living in other settings (rural; large urban cities) as well as to other ethnic groups located in South Africa should therefore be done with caution.

South Africa is a multiracial country with 11 official languages. The researcher is not fluent in isiXhosa and therefore an interpreter was needed throughout the study. All communication was conducted via the interpreter; therefore, direct communication between the researcher and the patient was minimal. This resulted in the interpreter being the person mainly responsible for direct communication with the patient. Although this may be seen as a limitation of the study, the interpreter had no vested interest in the outcome of the results, and therefore represented a neutral, unbiased intermediary. This also obviated any possible direct influence the researcher may have unknowingly exerted over the patient.

Patient enrolment was a problem encountered early in the study, although once the nurses started to encourage participation and the '*bush telegraph*' started spreading, there seemed to be a more positive response to the study. The '*bush telegraph*' is a term used to describe how many of the study patients had been encouraged by someone else to participate in the study, and therefore they were aware of who we were and why we were there before any formal introductions. The patients who were willing to participate in the study were all good natured and were enthusiastic throughout the interviews. No hostility or resistance was encountered during the study. The enrolment difficulties were more apparent at Masonwabe Clinic than at Raglan Road Clinic. Nurses at Raglan Road Clinic received the study with great enthusiasm and encouraged the patients to participate in the study. Most of the participants from this clinic were referred by the nurses. However, nurses at Masonwabe Clinic did not actively encourage the patients to participate in the study and did not refer patients to the study. They did, however, find the study information materials useful and wanted to incorporate them into their treatment plan.

Attrition was a significant problem encountered in the study, with almost half the patients not returning to follow-up interviews. The patients were reminded via an sms of their follow-up interviews, and despite this, they still did not return. This resulted in home visits to some of the patients to conduct the follow-up interviews. Home visits are time consuming and many of the patients were not at home when the researcher arrived to conduct the interview. In South Africa, ARV patients require a supporter that is involved in sharing the responsibility of adherence to the medication. Attrition may have been reduced if the supporters were also involved in the study



## **CHAPTER SEVEN**

### **CONCLUSION**

This thesis has investigated the influence of illustrated PILs and medicine labels on patient knowledge, adherence, self-efficacy and clinical health outcomes. One component of the research was the modification of tools to measure patient medicine-taking behaviour and the evaluation of these behaviours in a low-literate population. The associations of variables (age, gender, education and medication literacy) with knowledge, self-efficacy and adherence were determined. The investigation of correlations between knowledge, self-efficacy, adherence and clinical outcomes represents a significant contribution to knowledge in this area of research.

There was an excellent understanding of the PIL, a highly positive finding given the poor literacy levels of the study population. It seems safe to conclude that this can be attributed to PIL design, which involved collaboration with end-users of the leaflets as well as with HCPs, a process integral to achieving the successful outcomes reported in this study. The iterative refining and modification process is time-consuming and labour intensive, but does contribute towards a favourable outcome and is an approach that should be considered by all developers of written health materials as it ensures the inclusion of the patient voice. Adopting such a process would help to ensure that any special considerations and needs such as limited reading skills, diverse health beliefs and culture would automatically be considered. This research has indicated a need to include culturally sensitive, simple and understandable text as well as visuals in the design of PILs.

The findings suggest that, in general, knowledge of HIV/AIDS was good. HIV/AIDS programme reach in South Africa seems to be having an impact, with advertisements on TV, radio, magazines, pamphlets, newspapers, posters and billboards communicating HIV/AIDS-related information to the public on almost a daily basis. However, this research identified an aspect of ARVs where inadequate knowledge exists: there is a gap in patient knowledge of side effects. As the side effects from ARVs have been shown to be an important determinant of adherence, a recommendation is made to HCPs to focus more on informing patients about side effects.

The appropriateness of the illustrated PIL and medicine labels is clearly supported by the current findings, where the PIL was positively and enthusiastically received by both study patients and HCPs. All the patients found the PIL and medicine labels understandable, acceptable and useful and were enthusiastic about this inclusion into their therapy plan. In the study it was overwhelmingly evident that patients preferred to receive information in their first language. Medicines information, especially for epidemics such as HIV/AIDS, should be available in all the 11 official languages of South Africa.

In South Africa, there is a paucity of research into the field of HIV/AIDS-related information. There is an urgent need for simple information materials to be provided to low-literate patients in developing countries. The only HIV/AIDS information currently offered to patients at local clinics and hospitals is verbal and often too complex, containing an overload of information making it user-unfriendly.

The most obvious finding to emerge from this study is that the patients considered themselves to have extremely high adherence and self-efficacy, whereas the local doctors and pharmacist had identified adherence as a problem in many of the patients in the target population. These overestimated self-reports may be due to a reluctance of the patients to disclose nonadherent behavior because of fear of negative consequences and inadequate treatment by the researcher or clinic nurse. The high adherence and self-efficacy suggest that, in general, the HIV-ASES and the MMAS-8 were appropriate instruments for data collection in terms of length, simplicity and construction of individual questions, but the validity of the self-reported data from both of these tools appears questionable. Modification of both instruments is recommended to improve their sensitivity. Observations from this study indicate that continued use of a self-reported instrument over a prolonged period may improve its applicability as patients become familiar with its use and are able to use the rating scales more accurately.

The observed relationships between the targeted variables (age, gender and education) and knowledge, self-efficacy, adherence and clinical outcomes yielded variable outcomes. Generally, there were no significant associations between variables such as age, gender and education on the reported adherence. Although knowledge and self-efficacy had no significant influence on adherence, a trend was observed in which better knowledge and higher self-efficacy scores were associated with higher adherence. Older patients (over 50 yrs) had the lowest knowledge score, which was significantly lower than the other age

groups. Self-efficacy was found to be significantly influenced by knowledge as well as by age and education. Medication literacy and education were shown to have a significant effect on knowledge in the experimental group at all interviews.

A dearth of information pertaining to correlations between clinical outcomes, knowledge, adherence and self-efficacy was identified. One of the more significant findings in HIV/AIDS to emerge from this study is that knowledge has moderate correlation and a substantial relationship with clinical outcomes. When analysed using non-parametric tests, this influence was significant in the experimental group. Another important finding that has not been previously reported is the strongly significant correlation between self-efficacy and the clinical outcome of CD4 count. Surprisingly, no correlation was found between adherence and clinical outcomes, this is possibly due to the low sample size at the six month follow-up as well as the large variance.

The study makes a noteworthy contribution to research methodology involving the use of self-report instruments for measuring patient medicine-taking behaviours in low-literate, culturally diverse populations. All questions in these instruments require individual scrutiny for cultural and linguistic relevance and, if translated, should retain the original meaning. Current rating scales demand a certain level of numeracy and require modification where these skills are limited. The rating scale that consisted of 11 points was not fully utilised, with choices tending to cluster around three areas: low, middle and high. Further investigation into modifying the rating scales should focus on avoiding either a dichotomous yes/no response or too wide a scale range, but should still offer some range in response choices. The findings from this study suggest that a 3-point scale might be the most appropriate.

Future research should focus on linking behaviours related to medicine-taking with clinical health outcomes. Another area which merits further investigation is the presentation of side effect information accompanied by pictograms, and whether this contributes to knowledge acquisition and ultimately health outcomes. Finally, a study similar to the one described in this thesis should be conducted in a larger population to build on the foundation of the findings generated from my research. With increased power, the association of knowledge, self-efficacy, adherence and health outcomes can be meaningfully and rigorously investigated.

In closing, the study has enhanced our understanding of the impact that illustrated PILs and medicine labels have on patient knowledge, medication-taking behaviour and health outcomes in a low-literate population. The findings of this study provide valuable insight into the development of tailored medicines information and medicine labels as well as its potential role in optimising safe medicine-taking practices in ARV therapy.

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## **APPENDIX A**

### **Focus Group Discussion script**

## Focus Group Discussion Script

My name is Kirsty-Lee Barford. I am a masters student in the Faculty of Pharmacy at Rhodes University and am doing research which involves the way patients take medicine. This is my interpreter Efese Betela, he will help me so that you can understand what I am saying.

Thank you for attending this meeting. I will be passing an attendance register around. Please fill in all the details. If you need any help filling in the register, please ask Efese or me.

I have designed some questions to ask you to help me find out more about how you take your medicines. I need you to tell me about what you think of them.

I'd first like to explain the two parts.

The first part helps me understand how confident you are that you can take your medication.

I am going to show you five different scales. Each scale is different but is used to answer the questions, the scales go from you cannot do at all to you can completely do. I want you to look at each scale.

- Scale 1: This scale goes from cannot do at all, moderately certain can do and can completely do (*point to each separation*) you can answer between these. When I ask you a question you must answer by pointing to where on the scale your answer is.
- Scale 2: This scale goes from can completely do, moderately certain can do to cannot do at all, and (*point to each separation*) you can answer between these. When I ask you a question you must answer by pointing to where on the scale your answer is.
- Scale 3: This scale goes from can completely do, moderately certain can do to cannot do at all, and (*point to each separation*) you can answer between these. When I ask you a question you must answer by pointing to where on the scale your answer is.
- Scale 4: This scale goes from cannot do at all (no line and sad face), moderately certain can do and can completely do (happy face and large line) (*point to each separation*) you can answer between these. When I ask you a question you must answer by pointing to where on the scale your answer is.
- Scale 5: This scale goes from cannot do at all (no line, hand signal and sad face), moderately certain can do and can completely do (happy face hand signal and large line) (*point to each separation*) you can answer between these. When I ask you a question you must answer by pointing to where on the scale your answer is.

In the second part I am going to ask you questions about how you take your medicines. A scale is also used, I want you to point to where your answer lies.

I am going to ask you questions then I am going to show you the 5 different scales. I would like you to show me which scale you prefer and what you like or dislike about each scale.

I have got permission from the Rhodes University Ethics Committee as well as Cacadu Municipality and the Eastern Cape Department of Health.

The purpose of today's meeting is to get your opinion on the use and design of the questionnaires and the scales. I'd like to thank you for your participation and would encourage you to express all your feelings and opinions as there are no right or wrong answers.

### **Final modified version of the HIV-ASES test**

I am going to ask you about things that may happen when you have to take medicines. Sometimes, this could mean what happens when you are taking your medications, and other times it could mean how you deal with things like what you eat or whether you exercise or take vitamins. So, in these questions, when I ask you about your "treatment", I am talking not only about your medicine but also other things that you do to keep yourself healthy.

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).

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

1. Take your ARVs correctly even if side effects begin to interfere with daily activities?
2. Integrate your ARVs into your daily routine?
3. Take your ARVs every day even if it means taking them in front of people who do not know you have HIV?
4. Take your ARVs even if your daily plans change e.g. if you have to go out of town?
5. Take your ARVs even if you are not feeling well?
6. Take your ARVs even if they interfere with (make you change?) your daily activities?
7. Take your ARVs even if you are feeling healthy and the test results (CD4 count) are good?
8. Take your ARVs even when you feel discouraged or are unhappy with your health?
9. Take your ARVs even if it is a problem to get to the clinic?
10. Take your ARVs even if your family or friends say the ARVs are not helping you?
11. Get something good out of carrying on taking your ARVs, even if they are not making you feel better?

### **Specific Questions on the HIV-ASES scale**

Which scale is easiest to answer from?

Why do you like this scale?

Can you understand the happy/sad faces?

Can you understand the hand signals?

Which do you prefer?

Do you have any ideas to improve the scale?

Which scale is most difficult?

## **MMAS-8**

1. Do you sometimes forget to take your ARVs?
2. Sometimes people miss taking medication for reasons other than forgetting. Over the past month (since your last clinic visit) were there any days when you did not take your ARVs?
3. Have you ever reduced or stopped taking your 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 ARVs?
5. Did you take your ARVs yesterday?
6. When you feel healthy, do you sometimes stop taking your ARVs?
7. During last weekend, did you miss taking any of your ARVs?
8. Some people find having to take ARVs everyday tiresome. Do you ever feel irritated about taking your ARVs every day?

Did you understand these questions?

## **APPENDIX B**

### **PATIENT INFORMATION LEAFLETS (PILs)**

|    |                    |                  |     |
|----|--------------------|------------------|-----|
| B1 | PIL for Regimen 1A | English Version  | 141 |
| B2 | PIL for Regimen 1B | English Version  | 143 |
| B3 | PIL for Regimen 1C | English Version  | 145 |
| B4 | PIL for Regimen 1D | English Version  | 147 |
| B5 | PIL for Regimen 1A | isiXhosa Version | 149 |
| B6 | PIL for Regimen 1B | isiXhosa Version | 151 |
| B7 | PIL for Regimen 1C | isiXhosa Version | 153 |
| B8 | PIL for Regimen 1D | isiXhosa Version | 155 |









































**APPENDIX C**  
**QUESTIONNAIRES AND CONSENT FORM**

|    |                              |     |
|----|------------------------------|-----|
| C1 | Pilot Study Questionnaire    | 159 |
| C2 | Consent Form                 | 168 |
| C3 | Baseline Study Questionnaire | 171 |
| C4 | 1-Month Study Questionnaire  | 180 |
| C5 | 3-Month Study Questionnaire  | 181 |
| C6 | 6-Month Study Questionnaire  | 183 |

# QUESTIONNAIRE: UNDERSTANDING OF ARV PIL

## Pilot Study Interview

Interviewer: \_\_\_\_\_

Date: \_\_\_\_\_

Respondent Name: \_\_\_\_\_

Interview site:

Group Allocation

|                      |                           |
|----------------------|---------------------------|
| Control <sup>1</sup> | Experimental <sup>2</sup> |
|----------------------|---------------------------|

### SECTION 1: DEMOGRAPHICS

1.1 Gender

|                   |                     |
|-------------------|---------------------|
| Male <sup>1</sup> | Female <sup>2</sup> |
|-------------------|---------------------|

1.2 Race

|                    |                    |                       |                     |
|--------------------|--------------------|-----------------------|---------------------|
| Black <sup>1</sup> | White <sup>2</sup> | Coloured <sup>3</sup> | Indian <sup>4</sup> |
|--------------------|--------------------|-----------------------|---------------------|

1.3 Age

|                      |                      |                      |                   |
|----------------------|----------------------|----------------------|-------------------|
| 18 – 29 <sup>1</sup> | 30 – 39 <sup>2</sup> | 40 – 50 <sup>3</sup> | > 50 <sup>4</sup> |
|----------------------|----------------------|----------------------|-------------------|

1.3.1 Age specified

|  |
|--|
|  |
|--|

1.4 Highest qualification

|                        |                          |                           |
|------------------------|--------------------------|---------------------------|
| ≤ Grade 3 <sup>1</sup> | Grade 4 - 7 <sup>2</sup> | Grade 8 - 10 <sup>3</sup> |
|------------------------|--------------------------|---------------------------|

1.4.1 Number of years of formal education

|  |
|--|
|  |
|--|

1.5 Home language

|                       |                        |                      |                    |
|-----------------------|------------------------|----------------------|--------------------|
| isiXhosa <sup>1</sup> | Afrikaans <sup>2</sup> | English <sup>3</sup> | Other <sup>4</sup> |
|-----------------------|------------------------|----------------------|--------------------|

*If other, please specify*

1.6 Are you currently employed?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

1.7 If yes, what work do you do?

|                       |                             |                         |                          |
|-----------------------|-----------------------------|-------------------------|--------------------------|
| Clerical <sup>1</sup> | Farm <sup>2</sup>           | Domestic <sup>3</sup>   | Education <sup>4</sup>   |
| Mechanic <sup>5</sup> | Shop assistant <sup>6</sup> | Hospital <sup>7</sup>   | Self-employ <sup>8</sup> |
|                       |                             | Unemployed <sup>9</sup> | Other <sup>10</sup>      |

*If other, please specify*

1.8 Can you tell the time from a clock face?

|                  |                 |                           |
|------------------|-----------------|---------------------------|
| Yes <sup>1</sup> | No <sup>2</sup> | Digital only <sup>3</sup> |
|------------------|-----------------|---------------------------|

1.9 Do you have a cell phone?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

1.10 How do you take your ARVs?

3TC

|                      |                        |
|----------------------|------------------------|
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |

d4T/ AZT

NVP/ EFV

|                      |                        |
|----------------------|------------------------|
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
|----------------------|------------------------|

## SECTION 2: HEALTH PASSPORT DATA

### 2.1 Body Mass Index

2.1.1 Weight

2.1.2 Height

Body Mass Index

### 2.2 Chronic medication for co-morbidities or opportunistic infections

---

---

### 2.3 Adverse Reactions

---

### 2.4 Regimen changes

---

### 2.5 Clinical Data

#### 2.5.1. CD4 count

---

#### 2.5.2 Viral load

---

### 2.6 Pharmacy refill dates

---

---

## SECTION 3: EVALUATION OF HIV/AIDS KNOWLEDGE AND ARV INFORMATION

|   |                      |                    |    |    |
|---|----------------------|--------------------|----|----|
| 3.1.1. Language of PIL that is chosen for reading | English <sup>2</sup> | Xhosa <sup>1</sup> |    |    |
| 3.1.2 Regimen of ARVs                             | 1a                   | 1b                 | 1c | 1d |
| 3.1.3 Time taken to read the leaflet in minutes   |                      |                    |    |    |

### 3.2 Finding and Understanding of instructions

*EXP and CTRL: Ask patient the question and assess if answer is correct or incorrect.*

*EXP: Ask patient to locate the answer on the PIL. Then ask patient to explain in their own words.*

3.2.1. What are the names of the ARV medicines that you are taking?

Can you tell me the names?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.2. How often and when should efavirenz/ nevirapine be taken?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.3. Can a person spread HIV/AIDS to other people while taking ARVs through unprotected sex?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.4 Can you take your ARVs on an empty stomach?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.5 Like other medicines, ARVs have both good and unpleasant effects.

What are some of these unpleasant or side effects?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.6 What do ARVs do to the amount of HIV virus (viral load) in the body?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.7 Can the ARVs cure the HIV virus?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.8 When you are on ARVs, what must you do before you take other medicines?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.9 What should you do if you have a fever with or without chills (get hot, then cold)?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.10 How long do you have to take ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.11 If you experience stomach pain, nausea and vomiting after you have been on

ARVs, what should you do?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |

Can you tell me in your own words?

|                  |                      |                        |
|------------------|----------------------|------------------------|
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup> |
|------------------|----------------------|------------------------|

---

3.2.12 Where should you keep your ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.13 Can you tell me some of side effects that might happen in the first

6 weeks of starting ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.14 What happens to the good cells (CD4 cells) when you start taking the ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.15 Can you tell me some of the side effects that might happen after 3-6 months

of taking ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.16 What should you do if you forget to take a dose of ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.17. If a friend runs out of his/her ARVs can you share your ARV's with that friend?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.18 Are there any things that you should tell the doctor about before taking ARVs  
for the first time?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.19 Are there any places where you shouldn't keep your ARVs?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.20 How many times a day should you take Lamivudine (3TC)?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.21 If you see the sangoma who gives you medicine, can you take it with your  
ARVs or what must you do?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.22 If you are pregnant or trying to get pregnant , what should you do?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---



### 3.3 No. of questions answered correctly (total questions=22)

3.3.1 CONTROL: Answered questions correctly without PIL

3.3.2 EXPERIM: Located information correctly

3.3.3 EXPERIM: Answered questions correctly with PIL

|  |
|--|
|  |
|  |
|  |

### 3.4 Rating for understanding of the leaflet

Both located and understood (total score =40)

|  |
|--|
|  |
|--|

### 3.5 Sources of information for patients

3.5.1 Where have you learnt about HIV/AIDS from?

|                                      |                  |                 |
|--------------------------------------|------------------|-----------------|
| Doctor <sup>1</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Nurse <sup>2</sup>                   | Yes <sup>1</sup> | No <sup>2</sup> |
| Pharmacist <sup>3</sup>              | Yes <sup>1</sup> | No <sup>2</sup> |
| Community Health worker <sup>4</sup> | Yes <sup>1</sup> | No <sup>2</sup> |
| Religious leader <sup>5</sup>        | Yes <sup>1</sup> | No <sup>2</sup> |
| Isangoma <sup>6</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Family <sup>7</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Friends <sup>8</sup>                 | Yes <sup>1</sup> | No <sup>2</sup> |
| School <sup>9</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Posters <sup>10</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Newspapers <sup>12</sup>             | Yes <sup>1</sup> | No <sup>2</sup> |

3.5.1 Where have you learnt about your ARVs from?

|                                      |                  |                 |
|--------------------------------------|------------------|-----------------|
| Doctor <sup>1</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Nurse <sup>2</sup>                   | Yes <sup>1</sup> | No <sup>2</sup> |
| Pharmacist <sup>3</sup>              | Yes <sup>1</sup> | No <sup>2</sup> |
| Community Health worker <sup>4</sup> | Yes <sup>1</sup> | No <sup>2</sup> |
| Religious leader <sup>5</sup>        | Yes <sup>1</sup> | No <sup>2</sup> |
| Isangoma <sup>6</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Family <sup>7</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Friends <sup>8</sup>                 | Yes <sup>1</sup> | No <sup>2</sup> |
| School <sup>9</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Posters <sup>10</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Newspapers <sup>12</sup>             | Yes <sup>1</sup> | No <sup>2</sup> |

## SECTION 4: SELF EFFICACY

### Modified HIV-ASES test – Barford and Dowse

I am going to ask you about things that may happen when you have to take your ARVs. Sometimes, this could mean what happens when you are taking your medications, and other times it could mean how you deal with things like what you eat or whether you exercise or take vitamins. So, in these questions, when I ask you about your “treatment”, I am talking not only about your ARVs but also other things that you do to keep yourself healthy.

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).

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

1. Take your ARVs correctly even if side effects begin to interfere with daily activities?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

2. Integrate your ARVs into your daily routine?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

3. Take your ARVs every day even if it means taking them in front of people who do not know you have HIV?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

4. Take your ARVs even if your daily plans change e.g. if you have to go out of town?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

5. Take your ARVs even if you are not feeling well?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

6. Take your ARVs even if they interfere with (make you change?) your daily activities?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

7. Take your ARVs even if you are feeling healthy and the test results (CD4 count) are good?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

8. Take your ARVs even when you feel discouraged or are unhappy with your health?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

9. Take your ARVs even if it is a problem to get to the clinic?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

10. Take your ARVs even if your family or friends say the ARVs are not helping you?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

11. Get something good out of carrying on taking your ARVs, even if they are not making you feel better?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

## SECTION 5: SELF REPORTED ADHERENCE

### Modified Version Of The 8-Item Morisky Self-Reported Adherence Scale

1. Do you sometimes forget to take your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

2. Sometimes people miss taking medication for reasons other than forgetting. Over the past month (since your last clinic visit) were there any days when you did not take your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

3. Have you ever reduced or stopped taking your medication without telling your doctor, because you felt worse when you took it?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

4. When you travel or leave home, do you sometimes forget to bring along your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

5. Did you take your ARVs yesterday?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

6. When you feel healthy, do you sometimes stop taking your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

7. During last weekend, did you miss taking any of your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

8. Some people find having to take ARVs everyday tiresome. Do you ever feel irritated about taking your ARVs every day?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

#### 9 Researcher's Calculation of Participant Adherence<sup>2</sup> (Pill count)

- 9.1 Number of days between first and second interview : \_\_\_\_\_
- 9.2 Number of tablets that should have been taken by the participant : \_\_\_\_\_
- 9.3 Number of tablets that should be left in the packet : \_\_\_\_\_
- 9.4 Number of tablets actually remaining in the packet : \_\_\_\_\_
- 9.5 Number of extra tablets (no. of tabs. remaining - no. of tabs. that should be left in the packet) : \_\_\_\_\_

|                      |   |                                     |
|----------------------|---|-------------------------------------|
| <b>Calculation :</b> | <b>No. of tablets taken</b>                       | <b>X 100 = Percentage Adherence</b> |
|                      | <b>No. of tablets that should have been taken</b> |                                     |

#### 9.6 Percentage Adherence<sup>2</sup> (Tablet count)

|  |
|--|
|  |
|--|

- 9.7 In the researcher's opinion, was the participant adherent ?

| Non-adherent <sup>1</sup> | Poorly <sup>2</sup> | Moderately <sup>3</sup> | Mostly <sup>4</sup> | Totally <sup>5</sup> |
|---------------------------|---------------------|-------------------------|---------------------|----------------------|
| 0 - 20%                   | 21 - 49%            | 50 - 79%                | 80 - 99%            | 100%                 |



RHODES UNIVERSITY

FACULTY OF PHARMACY

## MEDICINES INFORMATION FOR HIV/AIDS PATIENTS ON ANTIRETROVIRALS (ARVs)

My name is Kirsty-Lee Barford and I am a post-graduate student from the Faculty of Pharmacy, Rhodes University. I invite you to take part in a research study which involves HIV/AIDS patients who are taking antiretrovirals (ARVs). I have produced new information leaflets and medicine labels which contain information about your ARVs and I would like to test them.

This consent form gives detailed information about the research study. Once you have read and understood the research, you may ask me any questions and then you will be asked to sign this form if you wish to take part. You will receive this copy to take home as a record.

### WHY ARE WE DOING THIS STUDY?

The purpose of this study is to give patients like you information about your ARVs in a format that we hope you will be able to read and understand. We would like to test if the information you are given helps you understand more about your medicine, how to take it and the effect it has on your body. I do not want to test your intelligence, I only want to test how good the leaflets are that I have produced and see if they improve your understanding and knowledge of ARVs.

I am looking for patients who are:

- HIV positive, female or male, who have been taking ARVs for the past 2 months or more
- 18 years and older( if you are under 21 years please talk to your parents about taking part in this research study)
- taking regimen 1a (stavudine, lamivudine and efavirenz) or regimen 1b (stavudine, lamivudine and nevirapine) therapy
- getting their ARVs from Masonwabe clinic at Settlers Hospital in Grahamstown
- able to read some English or isiXhosa

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

I will interview you at Masonwabe clinic, Settlers Hospital, a total of four times. You will first see the doctor and the pharmacist, and then you will see me, Kirsty-Lee Barford

#### Interview 1

- This will be the first time I see you when you come to the clinic for your ARV appointment this will take about 45-60 minutes. In this interview I will ask you questions about yourself and about your ARVs. You will be put into one of two different groups. Once you are in a group you cannot change to another group because that will affect the reliability of the results.

The two groups are:

- Group A who will get standard care with standard medicine labels and any written information you are normally given
- Group B who will get standard medicine labels with some pictures and a simple leaflet with pictures

#### Interview 2

- This will take about 30 minutes and this will be one month later (1 month after interview 1)

#### **Interview 3**

- This will take about 30 minutes and this will be two months later (3 months after interview 1)

#### **Interview 4**

- This will take about 30 minutes and this will be three months later (6 months after interview 1)

### **HOW WILL THIS STUDY HELP PATIENTS LIKE YOU?**

After testing our labels and leaflets, we will know which ones are better in helping you to understand more about your ARVs and we will be able to improve them. The more you understand, the better you will be able to take care of yourself when taking ARVs. We would like to provide the ARV clinics in Grahamstown and the surrounding areas with the best labels and leaflets for them to give to their patients on ARVs.

### **PRIVACY**

I will need to look at your patient file to record information such as your CD4 count, viral load, your body weight and the medicines you are taking. Please would you give me permission to look at your patient file. All your details will be kept confidential – this means that I will not tell anyone your name or any of your personal details, or your HIV status or that you take ARVs, and none of this information will appear in the published results from this study.

### **DO YOU HAVE THE RIGHT TO REFUSE OR LEAVE THE STUDY?**

If you take part in the study, you have the right to leave the study at any time. If you do leave, I would like you to tell me, Kirsty-Lee Barford, why you wanted to leave the study, but you do not have to do this if you do not want to.

### **WHAT DO I DO NOW?**

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.



RHODES UNIVERSITY

FACULTY OF PHARMACY

## CONSENT FORM

### MEDICINE INFORMATION FOR HIV/AIDS PATIENTS ON ANTIRETROVIRALS (ARVs)

I, **Kirsty-Lee Barford** (the researcher) and Efese (interpreter), swear that all the information obtained during this research study will remain strictly confidential.

**Signature:**

\_\_\_\_\_

**Signature:**

\_\_\_\_\_

I, \_\_\_\_\_, would like to take part in this research study. I give permission to the nurses, doctors and pharmacists at the clinic to allow the researcher access to my file and to my personal information. I understand that all information gathered from this research study will be kept private.

**Signature:** \_\_\_\_\_

**Witness:** \_\_\_\_\_

\_\_\_\_\_

**Date:**

# QUESTIONNAIRE: UNDERSTANDING OF ARV PIL

## Baseline Interview

Interviewer: \_\_\_\_\_

Date: \_\_\_\_\_

Respondent Name: \_\_\_\_\_

Interview site:

Group Allocation

|                      |                           |
|----------------------|---------------------------|
| Control <sup>1</sup> | Experimental <sup>2</sup> |
|----------------------|---------------------------|

### SECTION 1: DEMOGRAPHICS

1.1 Gender

|                   |                     |
|-------------------|---------------------|
| Male <sup>1</sup> | Female <sup>2</sup> |
|-------------------|---------------------|

1.2 Race

|                    |                    |                       |                     |
|--------------------|--------------------|-----------------------|---------------------|
| Black <sup>1</sup> | White <sup>2</sup> | Coloured <sup>3</sup> | Indian <sup>4</sup> |
|--------------------|--------------------|-----------------------|---------------------|

1.3 Age

|                      |                      |                      |                   |
|----------------------|----------------------|----------------------|-------------------|
| 18 – 29 <sup>1</sup> | 30 – 39 <sup>2</sup> | 40 – 50 <sup>3</sup> | > 50 <sup>4</sup> |
|----------------------|----------------------|----------------------|-------------------|

1.3.1 Age specified

|  |
|--|
|  |
|--|

1.4 Highest qualification

|                        |                          |                           |
|------------------------|--------------------------|---------------------------|
| ≤ Grade 3 <sup>1</sup> | Grade 4 - 7 <sup>2</sup> | Grade 8 - 10 <sup>3</sup> |
|------------------------|--------------------------|---------------------------|

1.4.1 Number of years of formal education

|  |
|--|
|  |
|--|

1.5 Home language

|                       |                        |                      |                    |
|-----------------------|------------------------|----------------------|--------------------|
| isiXhosa <sup>1</sup> | Afrikaans <sup>2</sup> | English <sup>3</sup> | Other <sup>4</sup> |
|-----------------------|------------------------|----------------------|--------------------|

*If other, please specify*

1.6 Are you currently employed?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

1.7 If yes, what work do you do?

|                       |                             |                         |                          |
|-----------------------|-----------------------------|-------------------------|--------------------------|
| Clerical <sup>1</sup> | Farm <sup>2</sup>           | Domestic <sup>3</sup>   | Education <sup>4</sup>   |
| Mechanic <sup>5</sup> | Shop assistant <sup>6</sup> | Hospital <sup>7</sup>   | Self-employ <sup>8</sup> |
|                       |                             | Unemployed <sup>9</sup> | Other <sup>10</sup>      |

*If other, please specify*

1.8 Can you tell the time from a clock face?

|                  |                 |                           |
|------------------|-----------------|---------------------------|
| Yes <sup>1</sup> | No <sup>2</sup> | Digital only <sup>3</sup> |
|------------------|-----------------|---------------------------|

1.9 Do you have a cell phone?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

1.10 How do you take your ARVs?

3TC

|                      |                        |
|----------------------|------------------------|
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |

d4T/ AZT

NVP/ EFV

|                      |                        |
|----------------------|------------------------|
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
|----------------------|------------------------|

## 1.11 LITERACY TEST

Give the patient a medicine label to read. Explain that this is not about their ARVs or any of their own medicines

1. How many teaspoons must you take when you start this medicine?
2. How many teaspoons must you take each time thereafter?
3. If you take this medicine at 12:30 pm when can you start eating your lunch? \*
4. You are usually told to take medication with water. Can you take this medicine with milk? \*
5. Will you keep any medicine to use next time you get sick?
6. How often must you take this medicine?
7. What can this medicine do to your teeth?
8. How should this medicine be stored?
9. Literacy rating

|                      |                        |
|----------------------|------------------------|
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
| Correct <sup>1</sup> | Incorrect <sup>2</sup> |
|                      |                        |

*\*these are weighted therefore total literacy rating out of 10*



**SECTION 2: HEALTH PASSPORT DATA**

**2.1 Body Mass Index**

2.1.1 Weight

2.1.2 Height

Body Mass Index

**2.2 Chronic medication for co-morbidities or opportunistic infections**

**2.3 Adverse Reactions**

**2.4 Regimen changes**

**2.5 Clinical Data**

**2.5.1. CD4 count**

**2.5.2 Viral load**

**2.6 Pharmacy refill dates**

## SECTION 3: EVALUATION OF HIV/AIDS KNOWLEDGE AND ARV INFORMATION

|   |                      |                    |    |    |
|---|----------------------|--------------------|----|----|
| 3.1.1. Language of PIL that is chosen for reading | English <sup>2</sup> | Xhosa <sup>1</sup> |    |    |
| 3.1.2 Regimen of ARVs                             | 1a                   | 1b                 | 1c | 1d |
| 3.1.3 Time taken to read the leaflet in minutes   |                      |                    |    |    |

### 3.2 Finding and Understanding of instructions

*EXP and CTRL: Ask patient the question and assess if answer is correct or incorrect.*

*EXP: Ask patient to locate the answer on the PIL. Then ask patient to explain in their own words.*

3.2.1. What are the names of the ARV medicines that you are taking?

Can you tell me the names?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.2. How often and when should efavirenz/ nevirapine be taken?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.3. Can a person spread HIV/AIDS to other people while taking ARVs through unprotected sex?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.4 Can you take your ARVs on an empty stomach?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.5 Like other medicines, ARVs have both good and unpleasant effects.

What are some of these unpleasant or side effects?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.6 What do ARVs do to the amount of HIV virus (viral load) in the body?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.7 Can the ARVs cure the HIV virus?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.8 When you are on ARVs, what must you do before you take other medicines?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.9 What should you do if you have a fever with or without chills (get hot, then cold)?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.10 How long do you have to take ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

3.2.11 If you experience stomach pain, nausea and vomiting after you have been on

ARVs, what should you do?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |

Can you tell me in your own words?

|                  |                      |                        |
|------------------|----------------------|------------------------|
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup> |
|------------------|----------------------|------------------------|

---

3.2.12 Where should you keep your ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.13 Can you tell me some of side effects that might happen in the first

6 weeks of starting ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.14 What happens to the good cells (CD4 cells) when you start taking the ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.15 Can you tell me some of the side effects that might happen after 3-6 months  
of taking ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.16 What should you do if you forget to take a dose of ARVs?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.17. If a friend runs out of his/her ARVs can you share your ARV's with that friend?

Can you tell me in your own words?

|                  |                      |                          |
|------------------|----------------------|--------------------------|
|                  | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup> | Located <sup>1</sup> | Not located <sup>2</sup> |
| N/A <sup>0</sup> | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.18 Are there any things that you should tell the doctor about before taking ARVs  
for the first time?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.19 Are there any places where you shouldn't keep your ARVs?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.20 How many times a day should you take Lamivudine (3TC)?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.21 If you see the sangoma who gives you medicine, can you take it with your  
ARVs or what must you do?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

3.2.22 If you are pregnant or trying to get pregnant , what should you do?

Can you tell me in your own words?

|                                    |                      |                          |
|------------------------------------|----------------------|--------------------------|
|                                    | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |
| N/A <sup>0</sup>                   | Located <sup>1</sup> | Not located <sup>2</sup> |
| Can you tell me in your own words? | Correct <sup>1</sup> | Incorrect <sup>2</sup>   |

---

### 3.3 No. of questions answered correctly (total questions=22)

3.3.1 CONTROL: Answered questions correctly without PIL

3.3.2 EXPERIM: Located information correctly

3.3.3 EXPERIM: Answered questions correctly with PIL

|  |
|--|
|  |
|  |
|  |

### 3.4 Rating for understanding of the leaflet

Both located and understood (total score =40)

|  |
|--|
|  |
|--|

### 3.5 Sources of information for patients

3.5.1 Where have you learnt about HIV/AIDS from?

|                                      |                  |                 |
|--------------------------------------|------------------|-----------------|
| Doctor <sup>1</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Nurse <sup>2</sup>                   | Yes <sup>1</sup> | No <sup>2</sup> |
| Pharmacist <sup>3</sup>              | Yes <sup>1</sup> | No <sup>2</sup> |
| Community Health worker <sup>4</sup> | Yes <sup>1</sup> | No <sup>2</sup> |
| Religious leader <sup>5</sup>        | Yes <sup>1</sup> | No <sup>2</sup> |
| Isangoma <sup>6</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Family <sup>7</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Friends <sup>8</sup>                 | Yes <sup>1</sup> | No <sup>2</sup> |
| School <sup>9</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Posters <sup>10</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Newspapers <sup>12</sup>             | Yes <sup>1</sup> | No <sup>2</sup> |

3.5.1 Where have you learnt about your ARVs from?

|                                      |                  |                 |
|--------------------------------------|------------------|-----------------|
| Doctor <sup>1</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Nurse <sup>2</sup>                   | Yes <sup>1</sup> | No <sup>2</sup> |
| Pharmacist <sup>3</sup>              | Yes <sup>1</sup> | No <sup>2</sup> |
| Community Health worker <sup>4</sup> | Yes <sup>1</sup> | No <sup>2</sup> |
| Religious leader <sup>5</sup>        | Yes <sup>1</sup> | No <sup>2</sup> |
| Isangoma <sup>6</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Family <sup>7</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Friends <sup>8</sup>                 | Yes <sup>1</sup> | No <sup>2</sup> |
| School <sup>9</sup>                  | Yes <sup>1</sup> | No <sup>2</sup> |
| Posters <sup>10</sup>                | Yes <sup>1</sup> | No <sup>2</sup> |
| Newspapers <sup>12</sup>             | Yes <sup>1</sup> | No <sup>2</sup> |

## SECTION 4: SELF EFFICACY

### Modified HIV-ASES test – Barford and Dowse

I am going to ask you about things that may happen when you have to take your ARVs. Sometimes, this could mean what happens when you are taking your medications, and other times it could mean how you deal with things like what you eat or whether you exercise or take vitamins. So, in these questions, when I ask you about your “treatment”, I am talking not only about your ARVs but also other things that you do to keep yourself healthy.

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).

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

12. Take your ARVs correctly even if side effects begin to interfere with daily activities?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

13. Integrate your ARVs into your daily routine?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

14. Take your ARVs every day even if it means taking them in front of people who do not know you have HIV?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

15. Take your ARVs even if your daily plans change e.g. if you have to go out of town?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

16. Take your ARVs even if you are not feeling well?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

17. Take your ARVs even if they interfere with (make you change?) your daily activities?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

18. Take your ARVs even if you are feeling healthy and the test results (CD4 count) are good?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

19. Take your ARVs even when you feel discouraged or are unhappy with your health?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

20. Take your ARVs even if it is a problem to get to the clinic?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

21. Take your ARVs even if your family or friends say the ARVs are not helping you?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

22. Get something good out of carrying on taking your ARVs, even if they are not making you feel better?

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|----|

# QUESTIONNAIRE: UNDERSTANDING OF ARV PIL

## 1 Month Interview

Omitted from Baseline Questionnaire:    Section 1.11    Literacy test

Addition from Baseline Questionnaire :    Section 5    Self-reported adherence

### SECTION 5: SELF REPORTED ADHERENCE

#### Modified Version Of The 8-Item Morisky Self-Reported Adherence Scale

9. Do you sometimes forget to take your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

10. Sometimes people miss taking medication for reasons other than forgetting. Over the past month (since your last clinic visit) were there any days when you did not take your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

11. Have you ever reduced or stopped taking your medication without telling your doctor, because you felt worse when you took it?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

12. When you travel or leave home, do you sometimes forget to bring along your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

13. Did you take your ARVs yesterday?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

14. When you feel healthy, do you sometimes stop taking your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

15. During last weekend, did you miss taking any of your ARVs?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

16. Some people find having to take ARVs everyday tiresome. Do you ever feel irritated about taking your ARVs every day?

|                  |                 |
|------------------|-----------------|
| Yes <sup>1</sup> | No <sup>2</sup> |
|------------------|-----------------|

9.6            Tablet count

|  |
|--|
|  |
|--|

9.7            In the researcher's opinion, was the participant adherent ?

| Non-adherent <sup>1</sup> | Poorly <sup>2</sup> | Moderately <sup>3</sup> | Mostly <sup>4</sup> | Totally <sup>5</sup> |
|---------------------------|---------------------|-------------------------|---------------------|----------------------|
| 0 - 20%                   | 21 - 49%            | 50 - 79%                | 80 - 99%            | 100%                 |



# QUESTIONNAIRE: UNDERSTANDING OF ARV PIL

## 3 Month Interview

In addition to the 1-Month Questionnaire: Section 6

### SECTION 6: ACCEPTABILITY OF PATIENT INFORMATION LEAFLET

#### PILs – opinions of content and layout

6.1 Do you like the way the leaflet looks?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.2 How easy was it to read the leaflet?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.3 Is the writing large enough?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.4 What do you think of the length of the sentences?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.5 Is there enough space between the lines?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.6 If you had just started taking ARVs, do you think a leaflet like this would be useful for you to take home?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.7 If you had just started taking these medicines and this was all the information you were given about them, do you think it would be enough?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

#### Usefulness of PIL to you and others

6.8 Did you use or refer to the PIL in the last 3 months?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

If so, what did you use it for?

---

6.9 What information did you find most useful?

---

6.10 What did you find least useful?

---

6.11 Is there other information you would like to see on the PIL?

6.12 At any stage in the last 3 months, have you had questions about your HIV/AIDS or your ARVs?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.13 If you had questions where did you look or who did you ask to try and find the answer?

6.14 Did the PIL help you understand more about HIV/AIDS?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.15 Did the PIL help you to understand more about how to take your ARV's?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.16 Did any of your family members read the PIL?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.17 Did any friends read the PIL?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

### **Reported understanding of text**

6.18 Are there any words in the text that you did not understand?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

Number of words not understood.

|  |
|--|
|  |
|--|

### **Labels**

6.19 Do you like the labels with pictures on them?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.20 Do you think the pictures helped you take your ARVs correctly?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

6.21 Did the labels with pictures help you to remember to take your ARVs at the right time?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

### **7. Evaluation of pictograms**

7.1 Do you like having pictures in the leaflet?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

7.2 Do you think the pictures help you understand and remember the information better?

|     |    |
|-----|----|
| Yes | No |
|-----|----|

7.3 Can you explain what the following pictograms mean?

|  |     |    |
|--|-----|----|
| 7.3.1 Take twice a day.                        | Yes | No |
| 7.3.2 Isangoma                                 | Yes | No |
| 7.3.3 Pharmacy                                 | Yes | No |
| 7.3.4 Spaza                                    | Yes | No |
| 7.3.5 Clinic                                   | Yes | No |
| 7.3.6 Supermarket                              | Yes | No |
| 7.3.7 Sharing Medication                       | Yes | No |
| 7.3.8 CD4 Pictogram                            | Yes | No |
| 7.3.9 Dizziness                                | Yes | No |
| 7.3.10 Lactic acidosis                         | Yes | No |
| 7.3.11 Rash                                    | Yes | No |
| 7.3.12 Do not store medication near the sun    | Yes | No |
| 7.3.13 Do not store medication in the car      | Yes | No |
| 7.3.14 Do not store medication near the fire   | Yes | No |
| 7.3.15 Do not store medication near the window | Yes | No |
| 7.3.16 Store medication away from children     | Yes | No |
| 7.3.17 Store medication in a cool dry place    | Yes | No |
| 7.3.18 Pregnant lady                           | Yes | No |
| 7.3.19 Headache and fever                      | Yes | No |
| 7.3.20 Pins and needles                        | Yes | No |

## **QUESTIONNAIRE: UNDERSTANDING OF ARV PIL**

### **6 Month Interview**

In addition to the 1-Month questionnaire to be conducted at the conclusion of the study:

#### **SCRIPT TO CONCLUDE 6-MONTH (FINAL) INTERVIEW**

*We have now come to the end of this study and today is the last time that I will see you. We would like to find out from you how you have felt being part of this study.*

Do you like the pictures in the PIL?

---

Would you like to get the PIL?

---

Do you think the labels with pictures would help you take your ARVs correctly?

---

Would you like to get the labels?

---

Do you think these PILs should be in all the ARV clinics in GHT/E Cape/SA?

---

#### **SCRIPT TO CONCLUDE 6-MONTH (FINAL) INTERVIEW**

*We have now come to the end of this study and today is the last time that I will see you. We would like to find out from you how you have felt being part of this study.*

#### **Experimental (probing necessary)**

Have you enjoyed being in the study? (did it take too long each time? did it embarrass you? were you interested in why we were doing it?)

Do you feel that you can help educate other people with the information you learnt in the PIL?

What information did you get when you first started taking ARVs?

Do you get any information about ARVs and HIV/AIDS at your follow up clinic visits?

What information do you think you should get from the HCP when you start ARVs?

Do you think these PILs should be in all the ARV clinics in GHT/E Cape/SA?

***Thank you so much for your participation in this study.***

# ANTIRETROVIRAL THERAPY (ARV)

## Patient information leaflet for Regimen 1a

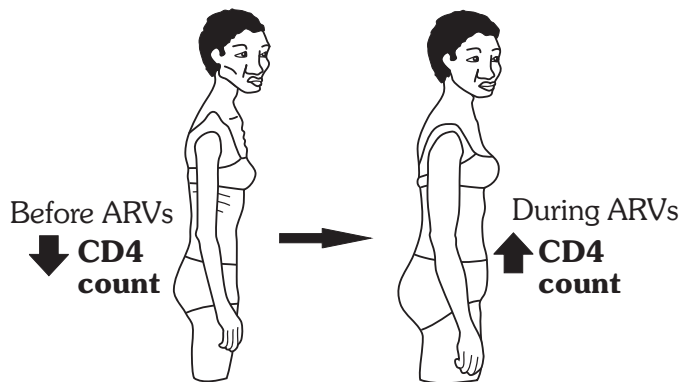
The information in this leaflet will help you take your ARVs properly and stay as healthy as possible.

### WHAT YOUR ARVs DO

#### ARVs fight HIV/AIDS :

- they stop the growth of HIV virus
- they help you become stronger
- they increase the CD4 count (good cells)
- they lower the amount of HIV virus in the blood

#### ARVs do not cure AIDS



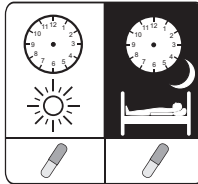
### BEFORE TAKING YOUR ARVs

#### Tell your doctor, nurse or pharmacist if you...

- are taking any other medicines
- have any allergies
- are pregnant or trying to fall pregnant
- are breast-feeding
- are on oral or injectable contraceptive
- have anything else wrong with you.

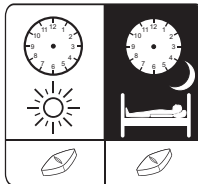
### HOW TO TAKE YOUR ARVs

#### Stavudine (d4T)



Take 1 tablet in the morning and 1 tablet at night

#### Lamivudine (3TC)



Take 1 tablet in the morning and 1 tablet at night

#### Efavirenz (EFV)



Take 1 tablet at night

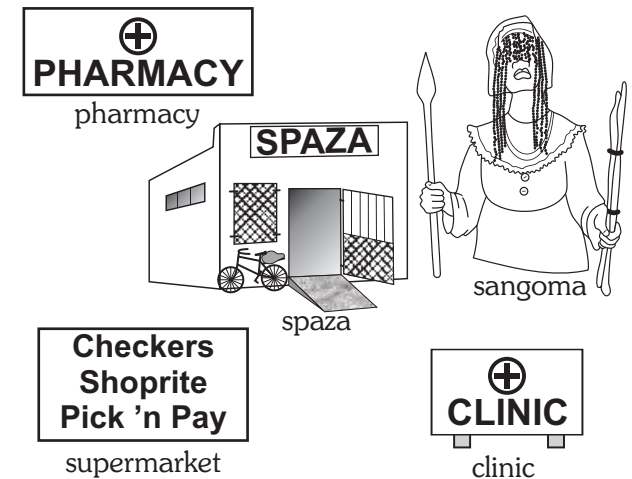
Take your ARVs with or without food

**You must not stop taking any of your medicines. Carry on taking all 3 of your ARVs.**

### WHILE TAKING YOUR ARVs

#### Are you taking other medicines?

You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or traditional remedies from the:

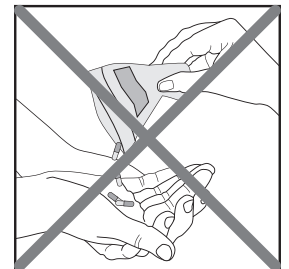


#### If you forget to take your medicine...

- take it as soon as you remember.

#### Do not share your medicines...

- with friends or family.



## SIDE EFFECTS

- Side effects are unpleasant effects that occasionally appear when taking ARVs, but they can be well managed and treated.
- You may not get any side effects. However if you experience any of the following tell the doctor or sister at the clinic.

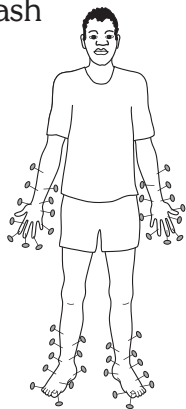
### In the first 6 weeks after starting ARVs:

- abnormal dreams
- dizziness
- headache
- nausea
- diarrhoea
- skin rash

### After 3 - 6 months of taking ARVs:

- tingling, burning, numbness or pain in the hands or feet (pins and needles)

### Go to the clinic AS SOON AS YOU CAN if you experience:



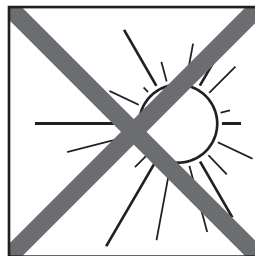
- stomach pain, nausea and vomiting



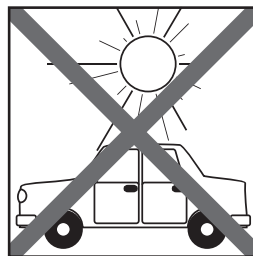
- severe rash on the body or in the mouth and a fever (hot)

## HOW TO STORE YOUR ARVs

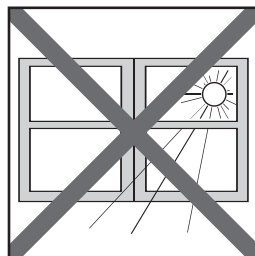
### Do not keep your ARVs...



in the sunlight



in the car

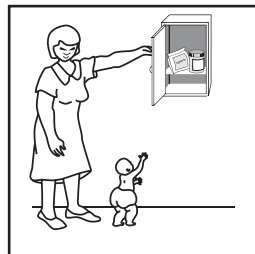


on a windowsill

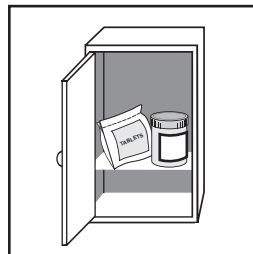


next to a fire

### Keep all medicines...



where children cannot reach them



in a safe, cool, dry place

## IMPORTANT !

### Go to the clinic AS SOON AS YOU CAN:

- if you are pregnant when taking Efavirenz

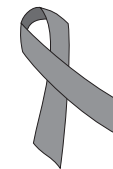


- if you experience fever (hot) with or without chills (cold)



## USE A CONDOM

You can still spread HIV/AIDS by having unprotected sex, even if you are taking ARVs.



You must use a condom every time you have sex to protect yourself and others.



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UNIVERSITY of CALIFORNIA,  
SAN DIEGO  
SCHOOL OF MEDICINE

July, 2009

# YOU MUST TAKE ARVs FOR THE REST OF YOUR LIFE

# ANTIRETROVIRAL THERAPY (ARV)

## Patient information leaflet for Regimen 1b

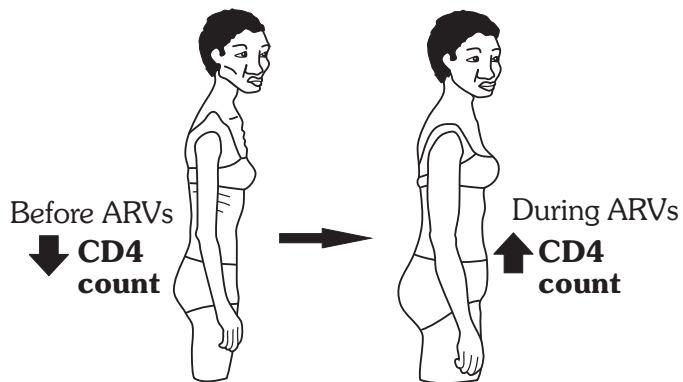
The information in this leaflet will help you take your ARVs properly and stay as healthy as possible.

### WHAT YOUR ARVs DO

#### ARVs fight HIV/AIDS :

- they stop the growth of HIV virus
- they help you become stronger
- they increase the CD4 count (good cells)
- they lower the amount of HIV virus in the blood

#### ARVs do not cure AIDS



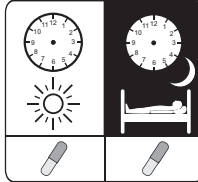
### BEFORE TAKING YOUR ARVs

#### Tell your doctor, nurse or pharmacist if you...

- are taking any other medicines
- have any allergies
- are pregnant or trying to fall pregnant
- are breast-feeding
- are on oral or injectable contraceptive
- have anything else wrong with you.

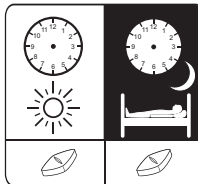
### HOW TO TAKE YOUR ARVs

#### Stavudine (d4T)



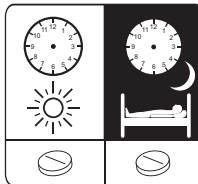
Take 1 tablet in the morning and 1 tablet at night

#### Lamivudine (3TC)



Take 1 tablet in the morning and 1 tablet at night

#### Nevirapine (NVP)



Take 1 tablet in the morning and 1 tablet at night.

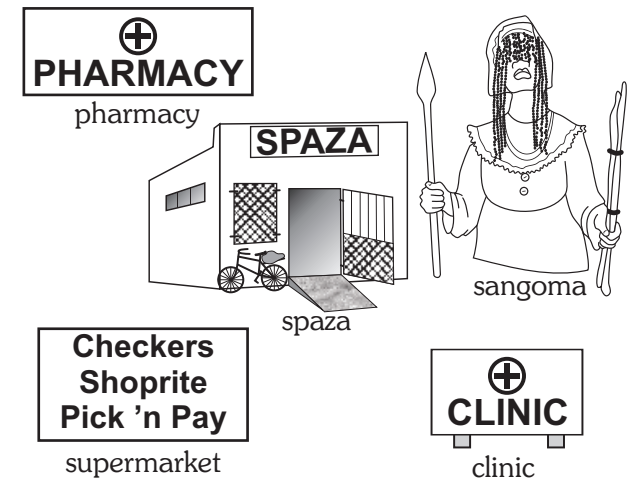
Take your ARVs with or without food

**You must not stop taking any of your medicines. Carry on taking all 3 of your ARVs.**

### WHILE TAKING YOUR ARVs

#### Are you taking other medicines?

You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or traditional remedies from the:

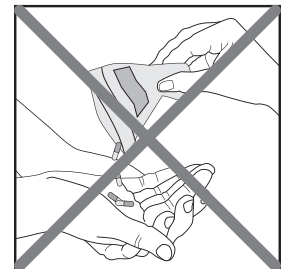


#### If you forget to take your medicine...

- take it as soon as you remember.

#### Do not share your medicines...

- with friends or family.



## SIDE EFFECTS

- Side effects are unpleasant effects that occasionally appear when taking ARVs, but they can be well managed and treated
- You may not get any side effects. However if you experience any of the following let the clinic sister know as soon as you can

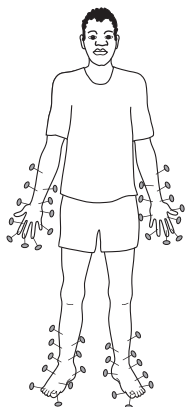
### In the first 6 weeks after starting ARVs:

- skin rash
- headache
- nausea
- diarrhoea

### After 3 - 6 months of taking ARVs:

- tingling, burning, numbness or pain in the hands or feet

### Go to the clinic AS SOON AS YOU CAN if you experience:



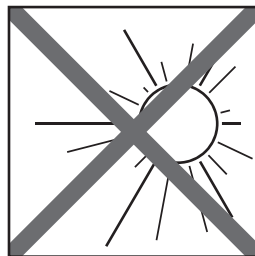
- stomach pain, nausea and vomiting



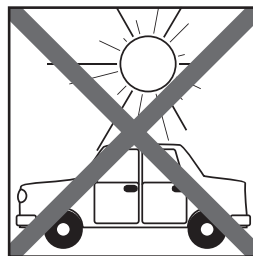
- severe rash on the body or in the mouth and a fever (hot)

## HOW TO STORE YOUR ARVs

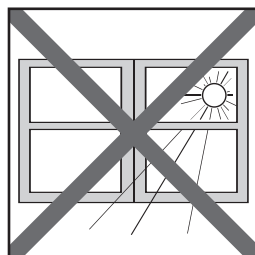
### Do not keep your ARVs...



in the sunlight



in the car

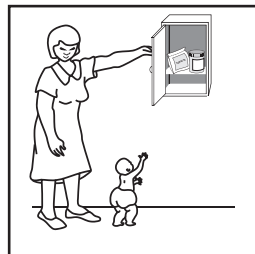


on a windowsill

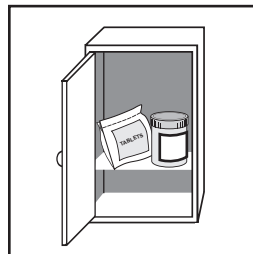


next to a fire

### Keep all medicines...



where children cannot reach them



in a safe, cool, dry place

## IMPORTANT !

**Go to the clinic AS SOON AS YOU CAN if you experience:**



- fever (hot) with or without chills (cold)

## USE A CONDOM



**You can still spread HIV/AIDS by having unprotected sex, even if you are taking ARVs.**



**You must use a condom every time you have sex to protect yourself and others.**



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July, 2009

# YOU MUST TAKE ARVs FOR THE REST OF YOUR LIFE

# ANTIRETROVIRAL THERAPY (ARV)

## Patient information leaflet for Regimen 1c

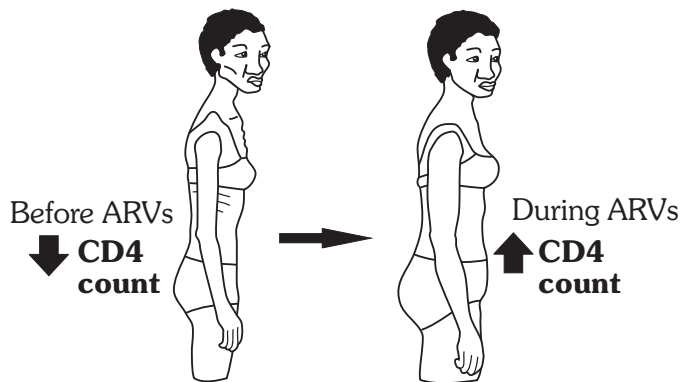
The information in this leaflet will help you take your ARVs properly and stay as healthy as possible.

### WHAT YOUR ARVs DO

#### ARVs fight HIV/AIDS :

- they stop the growth of HIV virus
- they help you become stronger
- they increase the CD4 count (good cells)
- they lower the amount of HIV virus in the blood

#### ARVs do not cure AIDS



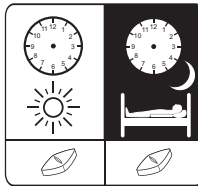
### BEFORE TAKING YOUR ARVs

#### Tell your doctor, nurse or pharmacist if you...

- are taking any other medicines
- have any allergies
- are pregnant or trying to fall pregnant
- are breast-feeding
- are on oral or injectable contraceptive
- have anything else wrong with you.

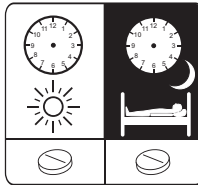
### HOW TO TAKE YOUR ARVs

#### Lamivudine (3TC)



Take 1 tablet in the morning and 1 tablet at night

#### Zidovudine (AZT)



Take 1 tablet in the morning and 1 tablet at night

#### Efavirenz (EFV)



Take 1 tablet at night

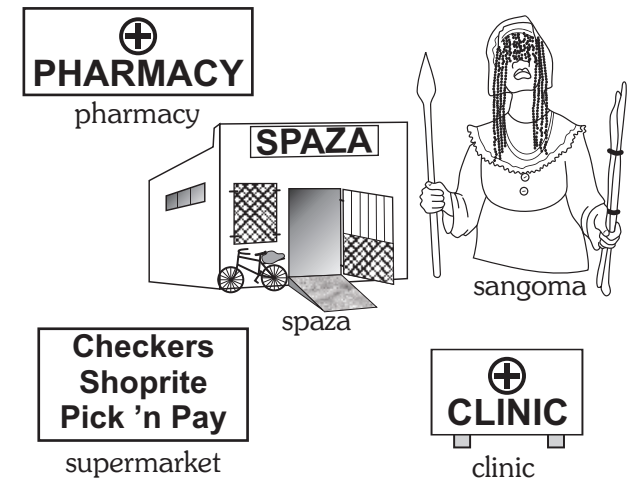
Take your ARVs with or without food

**You must not stop taking any of your medicines. Carry on taking all 3 of your ARVs.**

### WHILE TAKING YOUR ARVs

#### Are you taking other medicines?

You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or traditional remedies from the:

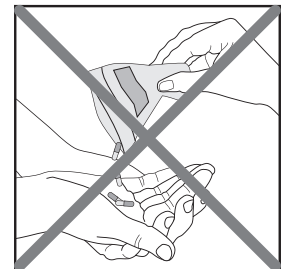


#### If you forget to take your medicine...

- take it as soon as you remember.

#### Do not share your medicines...

- with friends or family.





## SIDE EFFECTS

- Side effects are unpleasant effects that occasionally appear when taking ARVs, but they can be well managed and treated
- You may not get any side effects. However if you experience any of the following let the clinic sister know as soon as you can

### In the first 6 weeks after starting ARVs:

- nausea
- dizziness
- headache
- weakness/tiredness
- abnormal dreams
- skin rash
- diarrhoea

### After 3 - 6 months of taking ARVs:

- weakness, tiredness and dizziness

### Go to the clinic AS SOON AS YOU CAN if you experience:



- stomach pain, nausea and vomiting

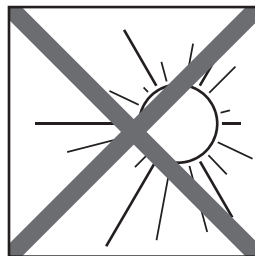


- weakness, tiredness and dizziness
- severe rash on the body or in the mouth and a fever (hot)

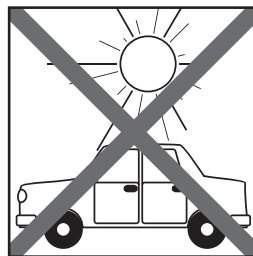


## HOW TO STORE YOUR ARVs

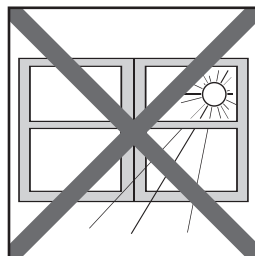
### Do not keep your ARVs...



in the sunlight



in the car

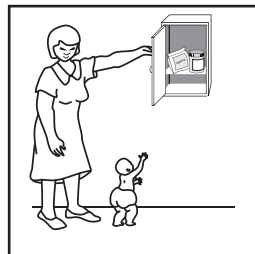


on a windowsill

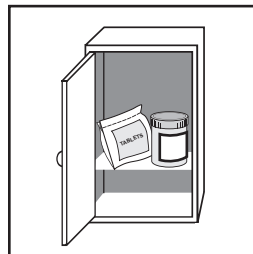


next to a fire

### Keep all medicines...



where children cannot reach them



in a safe, cool, dry place

## IMPORTANT !

### Go to the clinic AS SOON AS YOU CAN:

- if you are pregnant when taking Efavirenz



- if you experience fever (hot) with or without chills (cold)



## USE A CONDOM



**You can still spread HIV/AIDS by having unprotected sex, even if you are taking ARVs.**



**You must use a condom every time you have sex to protect yourself and others.**



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July, 2009

# YOU MUST TAKE ARVs FOR THE REST OF YOUR LIFE

# ANTIRETROVIRAL THERAPY (ARV)

## Patient information leaflet for Regimen 1d

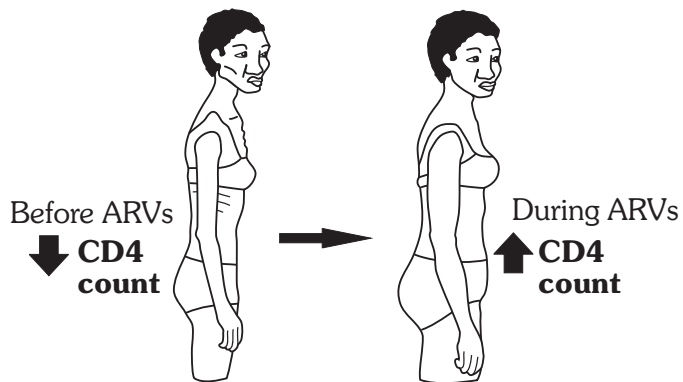
The information in this leaflet will help you take your ARVs properly and stay as healthy as possible.

### WHAT YOUR ARVs DO

#### ARVs fight HIV/AIDS :

- they stop the growth of HIV virus
- they help you become stronger
- they increase the CD4 count (good cells)
- they lower the amount of HIV virus in the blood

#### ARVs do not cure AIDS



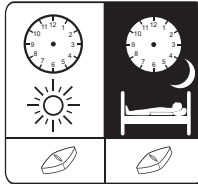
### BEFORE TAKING YOUR ARVs

#### Tell your doctor, nurse or pharmacist if you...

- are taking any other medicines
- have any allergies
- are pregnant or trying to fall pregnant
- are breast-feeding
- are on oral or injectable contraceptive
- have anything else wrong with you.

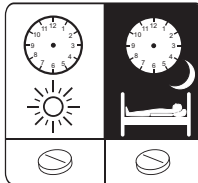
### HOW TO TAKE YOUR ARVs

#### Lamivudine (3TC)



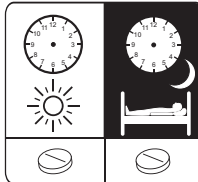
Take 1 tablet in the morning and 1 tablet at night

#### Zidovudine (AZT)



Take 1 tablet in the morning and 1 tablet at night

#### Nevirapine (NVP)



Take 1 tablet in the morning and 1 tablet at night.

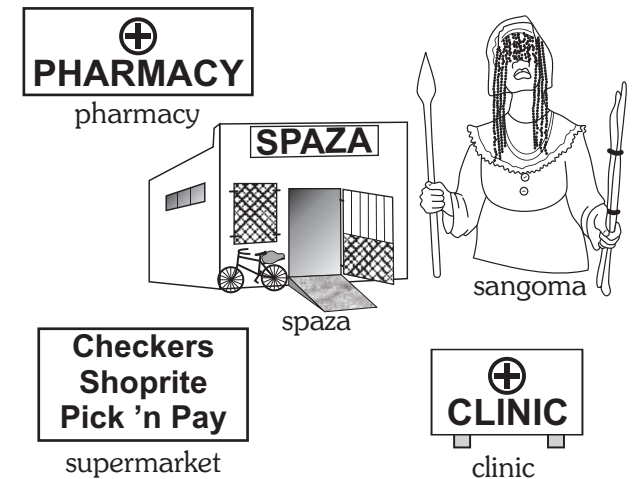
Take your ARVs with or without food

**You must not stop taking any of your medicines. Carry on taking all 3 of your ARVs.**

### WHILE TAKING YOUR ARVs

#### Are you taking other medicines?

You must tell your doctor, nurse or pharmacist if you are taking other medicines, herbal remedies or traditional remedies from the:

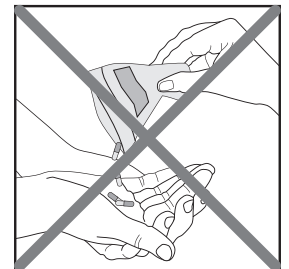


#### If you forget to take your medicine...

- take it as soon as you remember.

#### Do not share your medicines...

- with friends or family.



## SIDE EFFECTS

- Side effects are unpleasant effects that occasionally appear when taking ARVs, but they can be well managed and treated
- You may not get any side effects. However if you experience any of the following let the clinic sister know as soon as you can

### In the first 6 weeks after starting ARVs:

- skin rash
- dizziness
- nausea
- weakness/tiredness
- headache
- diarrhoea

### After 3 - 6 months of taking ARVs:

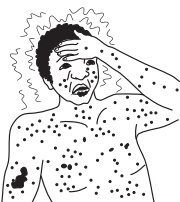
- weakness, tiredness and dizziness



### Go to the clinic AS SOON AS YOU CAN if you experience:



- stomach pain, nausea and vomiting

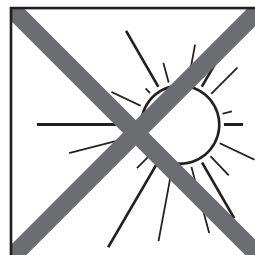


- weakness, tiredness and dizziness
- severe rash on the body or in the mouth and a fever (hot)

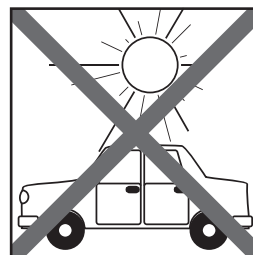


## HOW TO STORE YOUR ARVs

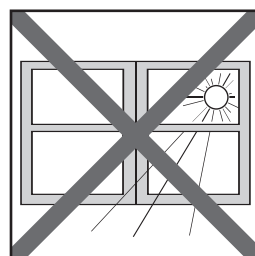
### Do not keep your ARVs...



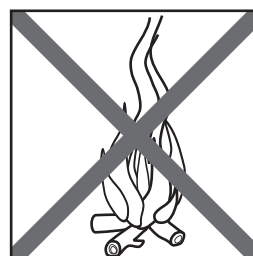
in the sunlight



in the car



on a windowsill

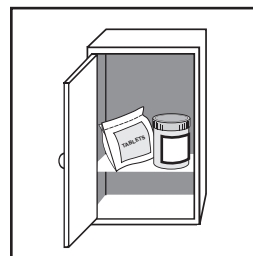


next to a fire

### Keep all medicines...



where children cannot reach them



in a safe, cool, dry place

## IMPORTANT !

**Go to the clinic AS SOON AS YOU CAN if you experience:**



- fever (hot) with or without chills (cold)

## USE A CONDOM



**You can still spread HIV/AIDS by having unprotected sex, even if you are taking ARVs.**



**You must use a condom every time you have sex to protect yourself and others.**



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# YOU MUST TAKE ARVs FOR THE REST OF YOUR LIFE

# UNYANGO NGEE-ANTIRETROVIRALS (ii-ARVs)

## Inkcazelo-sigulane nge-Regimen 1a

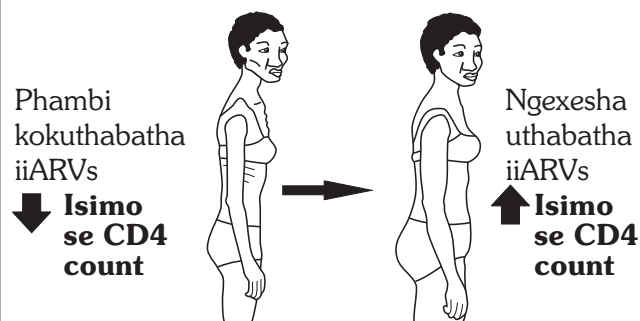
Le nkcazelo ikweliphetshana ingaluncendo kuwe ngedlela eyiyo yokuthabatha ii-ARVs ukuze uhlale usempilweni.

### II-ARVs ZENZA NTONI?

#### Ii-ARVs aziyinyangi iHIV/AIDS (ugawulayo nentsholongwane yakhe)

- inqambi iHIV ingakhuli zikunceda ukuba womelele ngakumbi
- zinyusa iCD4 count yakho (iiseli ezilungileyo)
- zithoba umthamo wentsholongwane kagawulayo egazini lakho

#### ii-ARVs aziyinyangi i-AIDS



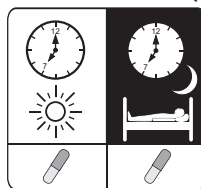
### PHAMBI KOKUBA USEBENZISE II-ARVs ZAKHO

#### Xelela ugqirha, usokhemesti okanye unesi ukuba:

- akhona amanye amayeza owathathayo
- kukho amayeza, ukutya okanye naziphi na ezinye izinto ezingavaniyo nomzimba wakho
- ukhulelwe okanye uzama ukukhulelwa
- uyancancisa
- uyacwangcisa ngeepilisi okanye ngenaliti
- kukho nantoni na enye engemanga kakuhle kuwe

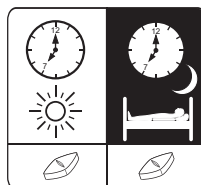
### INDLELA YOKUTHATHA II-ARVs ZAKHO

#### Stavudine (d4T)



Thatha ipilisi ibe nye kusasa, nenye futhi ebusuku

#### Lamivudine (3TC)



Thatha ipilisi ibe nye kusasa, nenye futhi ebusuku

#### Efavirenz (EFV)



Thatha ipilisi ibe nye ebusuku

Zithathe ii-ARVs nokutya okanye ngaphandle kokutya

**Akufuneki uwayeke nawaphi na kumayeza akho. Qhubeka ukuthatha zo-3 ii-ARVs zakho**

### NGELI XA USEBENZISA II-ARVs

#### Akhona amanye amayeza owathathayo?

Kufuneka uxelele ugqirha, unesi okanye usokhemesti wakho ukuba unamanye amayeza owasebenzisayo nowafumana kwezi ndawo.



ekhemesti



espaza



eggirheni



esuphamakethi



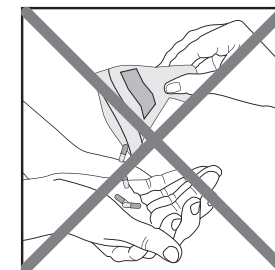
ekliniki

#### Ukuba uye walibala ukuthatha amayeza akho...

- wathathe ngoko nangoko wakukhumbula

#### Musa ukwabelana ngamayeza akho...

- nabahlobo bakho nosaphol wakho



## IZIPHUMO EBEZINGALINDELEKANGA

- iziphumo ezingalindelekanga zizinto eziyizevele ngelilixa utya amayeza, kodwa ke ziyalawuleka kwaye ziyanyangeka
- usenokungabi nazo ezi zinto zichazwe apha okanye uphathwe zezo zingachazwanga apha

### Kwiiveki ezi-6 zokuqala, usebenzisa ii-ARVs usenokuphathwe zezi zinto :

- amaphupha amabi
- isicaphucaphu
- isiyezi
- ukuhambisa kwesisu
- intloko ebuhlungu
- irhashala

### Emva kweenyanga ezi 3 ukuya kwezi 6 usitya ii-ARVs:

- inkantsi eminweni nasezinzwani

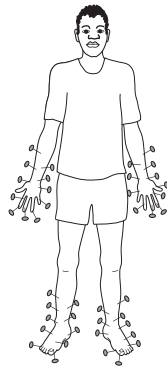
### Khawuleza uye ekliniki xa :



- unesisu sakho siyaluma, isicaphu-caphu, nokugabha ukutyhafa, ukudinwa nesiyezi

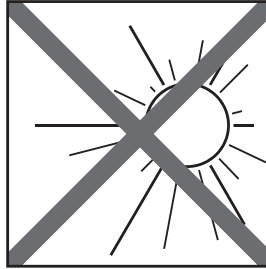


- irhashalala emzimbeni okanye emlonyeni kunye nefiva (ubushushu)

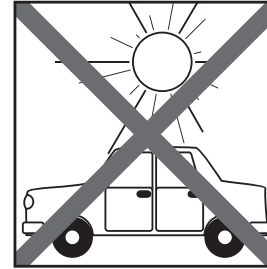


## INDLELA YOKUGCINA II-ARVs

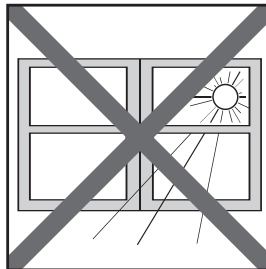
### Musa ukuzigcina ii-ARVs...



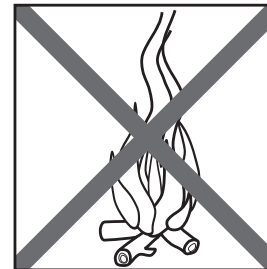
elangeni



emotweni

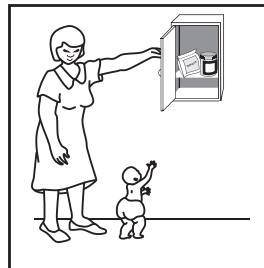


efestileni

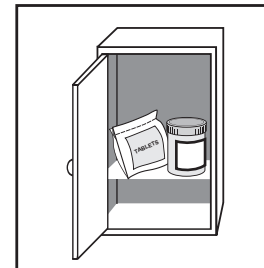


kufutshane nomlilo

### Gcina amayeza akho...



kwindawo abangenakufikelela kuyo abantwana



kwindawo ekhuselekileyo, epholileyo neyomileyo

## OKUBALULEKILEYO !

### Yiya ekliniki ngokukhawulezileyo :

- ukhulelwe ngexa usitya ii-Efavirenz



- ukuba ufunyenwe yifiva okanye yingqele



## SEBENZISE IKHONDOM



Usenokuyisasaza kwakhona iHIV/AIDS ngokulala neqabane lakho ngaphandle kokuzikhusela.



Kufuneka usebenzise ikhondom ngalo lonke ixesha ulala nomntu ukwenzela ukuzikhusela wena nabanye.



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Tel : 046 603 8381.



UNIVERSITY of CALIFORNIA,  
SAN DIEGO  
SCHOOL OF MEDICINE

July, 2009

# KUFUNEKA UZITYE II-ARVs UBOMI BAKHO BONKE



# UNYANGO NGEE-ANTIRETROVIRALS (ii-ARVs)

## Inkcazelo-sigulane nge-Regimen 1b

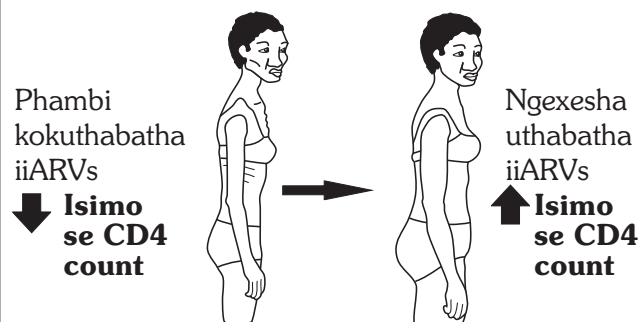
Le nkcazelo ikweliphetshana ingaluncendo kuwe ngedlela eyiyo yokuthabatha ii-ARVs ukuze uhlale usempilweni.

### II-ARVs ZENZA NTONI?

#### Ii-ARVs aziyinyangi iHIV/AIDS (ugawulayo nentsholongwane yakhe)

- inqambi iHIV ingakhuli zikunceda ukuba womelele ngakumbi
- zinyusa iCD4 count yakho (iiseli ezilungileyo)
- zithoba umthamo wentsholongwane kagawulayo egazini lakho

#### ii-ARVs aziyinyangi i-AIDS



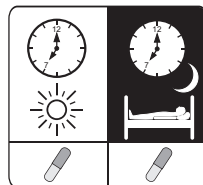
### PHAMBI KOKUBA USEBENZISE II-ARVs ZAKHO

#### Xelela ugqirha, usokhemesti okanye unesi ukuba:

- akhona amanye amayeza owathathayo
- kukho amayeza, ukutya okanye naziphi na ezinye izinto ezingavaniyo nomzimba wakho
- ukhulelwe okanye uzama ukukhulelwa
- uyancancisa
- uyacwangcisa ngeepilisi okanye ngenaliti
- kukho nantoni na enye engemanga kakuhle kuwe

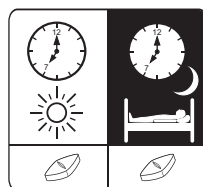
### INDLELA YOKUTHATHA II-ARVs ZAKHO

#### Stavudine (d4T)



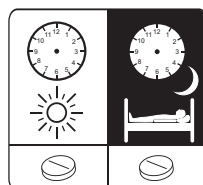
Thatha ipilisi ibe nye kusasa, nenyane futhi ebusuku

#### Lamivudine (3TC)



Thatha ipilisi ibe nye kusasa, nenyane futhi ebusuku

#### Nevirapine (NVP)



Thatha ipilisi ibe nye kusasa, nenyane futhi ebusuku

Zithathe ii-ARVs nokutya okanye ngaphandle kokutya

**Akufuneki uwayeke nawaphi na kumayeza akho. Qhubeka ukuthatha zo-3 ii-ARVs zakho**

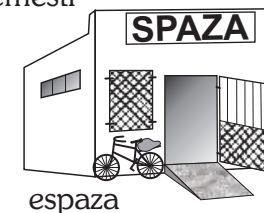
### NGELI XA USEBENZISA II-ARVs

#### Akhona amanye amayeza owathathayo?

Kufuneka uxelele ugqirha, unesi okanye usokhemesti wakho ukuba unamanye amayeza owasebenzisayo nowafumana kwezi ndawo.



ekhemesti



espaza



eggirheni



esuphamakethi



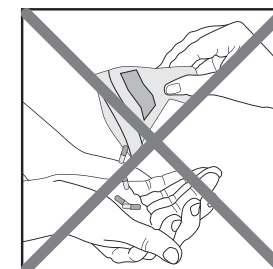
ekliniki

#### Ukuba uye walibala ukuthatha amayeza akho...

- wathathe ngoko nangoko wakukhumbula

#### Musa ukwabelana ngamayeza akho...

- nabahlobo bakho nosaphol wakho



## IZIPHUMO EBEZINGALINDELEKANGA

- iliziphumo ezingalindelekanga zizinto eziye zivele ngeli lixa utya amayeza, kodwa ke ziyalawuleka kwaye ziyanyangeka.
- usenokungabi nazo ezi zinto zichazwe apha, kodwa ukuba uthe waphathwa zizo xeleda ugqirha okanye unesi wakho

### Kwiiveki ezi-6 zokuqala, usebenzisa ii-ARVs usenokuphathwe zezi zinto:

- irhashala
- intloko ebuhlungu
- isicaphucaphu
- ukuhambisa kwesisu

### Emva kweenyanga ezi-3 ukuya kwezi-6 usitya ii-ARVs :

- inkantsi eminweni nasezinzwaneni

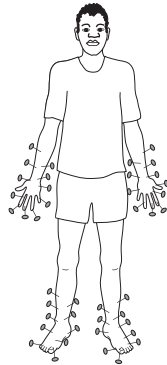
### Khawuleza uye ekliniki xa :



- unesisu sakho siyaluma, isicaphu-caphu, nokugabha

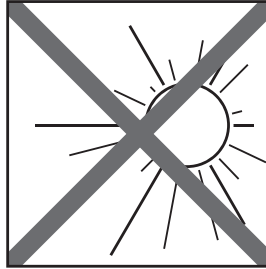


- irhashalala emzimbeni okanye emlonyeni kunye nefiva (ubushushu)

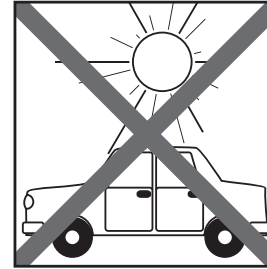


## INDLELA YOKUGCINA II-ARVs

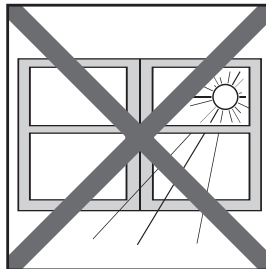
### Musa ukuzigcina ii-ARV...



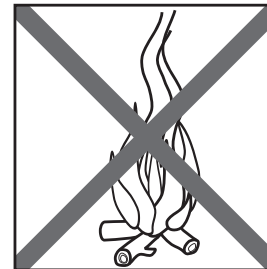
elangeni



emotweni

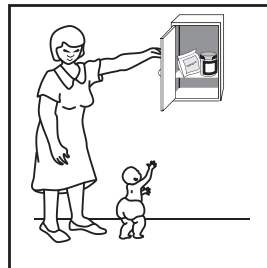


efestileni

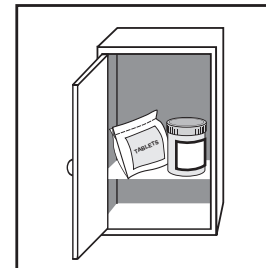


kufutshane nomlilo

### Gcina amayeza akho...



kwindawo abangenakufikelela kuyo abantwana



kwindawo ekhuselekileyo, epholileyo neyomileyo

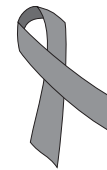
## OKUBALULEKILEYO !

### Yiya ekliniki ngokukhawulezileyo:



- ukuba ufunyenwe yifiva okanye yingqele

## SEBENZISE IKHONDOM



Usenokuyisasaza kwakhona iHIV/AIDS ngokulala neqabane lakho ngaphandle kokuzikhusela.



Kufuneka usebenzise ikhondom ngalo lonke ixesha ulala nomntu ukwenzela ukuzikhusela wena nabanye.



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July, 2009

# KUFUNEKA UZITYE II-ARVs UBOMI BAKHO BONKE

# UNYANGO NGEE-ANTIRETROVIRALS (ii-ARVs)

## Inkcazelo-sigulane nge-Regimen 1c

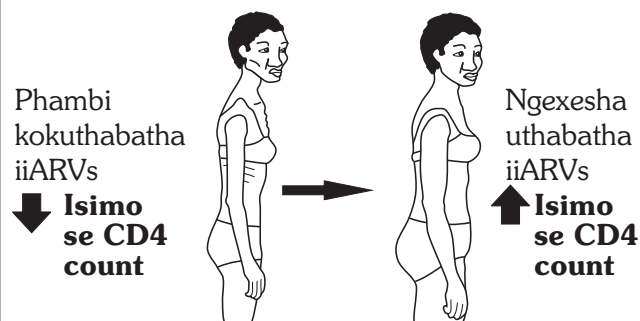
Le nkcazelo ikweliphetshana ingaluncendo kuwe ngedlela eyiyo yokuthabatha ii-ARVs ukuze uhlale usempilweni.

### II-ARVs ZENZA NTONI?

#### Ii-ARVs aziyinyangi iHIV/AIDS (ugawulayo nentsholongwane yakhe)

- inqambi iHIV ingakhuli zikunceda ukuba womelele ngakumbi
- zinyusa iCD4 count yakho (iiseli ezilungileyo)
- zithoba umthamo wentsholongwane kagawulayo egazini lakho

#### ii-ARVs aziyinyangi i-AIDS



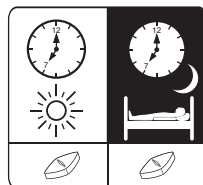
### PHAMBI KOKUBA USEBENZISE II-ARVs ZAKHO

#### Xelela ugqirha, usokhemesti okanye unesi ukuba:

- akhona amanye amayeza owathathayo
- kukho amayeza, ukutya okanye naziphi na ezinye izinto ezingavaniyo nomzimba wakho
- ukhulelwe okanye uzama ukukhulelwa
- uyancancisa
- uyacwangcisa ngeepilisi okanye ngenaliti
- kukho nantoni na enye engemanga kakuhle kuwe

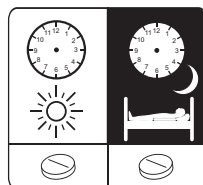
### INDLELA YOKUTHATHA II-ARVs ZAKHO

#### Lamivudine (3TC)



Thatha ipilisi ibe nye kusasa, nanye futhi ebusuku

#### Zidovudine (AZT)



Thatha ipilisi ibe nye kusasa, nanye futhi ebusuku

#### Efavirenz (EFV)



Thatha ipilisi ibe nye ebusuku

Zithathe ii-ARVs nokutya okanye ngaphandle kokutya

**Akufuneki uwayeke nawaphi na kumayeza akho. Qhubekeka ukuthatha zo-3 ii-ARVs zakho**

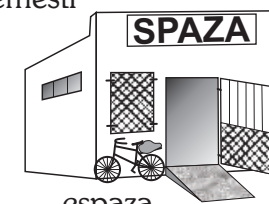
### NGELI XA USEBENZISA II-ARVs

#### Akhona amanye amayeza owathathayo?

Kufuneka uxelele ugqirha, unesi okanye usokhemesti wakho ukuba unamanye amayeza owasebenzisayo nowafumana kwezi ndawo.



ekhemesti



espaza



eggirheni



esuphamakethi



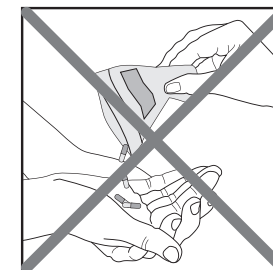
ekliniki

#### Ukuba uye walibala ukuthatha amayeza akho...

- wathathe ngoko nangoko wakukhumbula

#### Musa ukwabelana ngamayeza akho...

- nabahlobo bakho nosaphol wakho





## IZIPHUMO EBEZINGALINDELEKANGA

- iziphumo ezingalindelekanga zizinto eziyizevele ngelilixa utya amayeza, kodwa ke ziyalawuleka kwaye ziyanyangeka
- usenokungabi nazo ezi zinto zichazwe apha okanye uphathwe zezo zingachazwanga apha

### Kwiiveki ezi-6 zokuqala, usebenzisa ii-ARVs usenokuphathwe zezi zinto:

- isicaphucaphu
- iziyezi
- intloko ebuhlungu
- ubuthatthatka
- amaphupha amabi
- okanye ukudinwa
- ukuhambisa kwesisu
- irhashala

### Emva kweenyanga ezi-3 ukuya kwezi-6 usitya ii-ARVs :

- ukutyhafa, ukudinwa nesiyezi

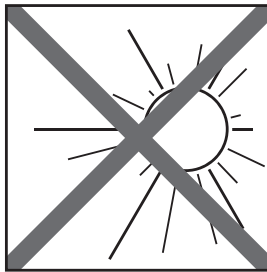
### Khawuleza uye ekliniki xa :

- unesisu sakho siyaluma, isicaphucaphu, nokugabha ukutyhafa, ukudinwa nesiyezi
- ubuthatthatka, ukudinwa nesiyezi
- irhashalala emzimbeni okanye emlonyeni kunye nefiva (ubushushu)

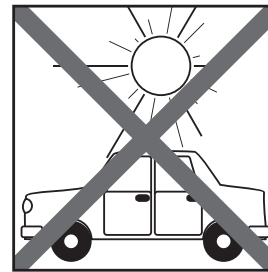


## INDLELA YOKUGCINA II-ARVs

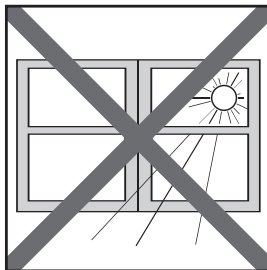
### Musa ukuzigcina ii-ARV...



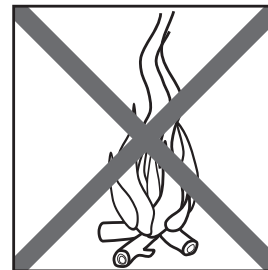
elangeni



emotweni

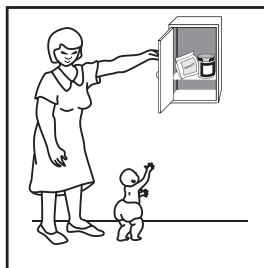


efestileni

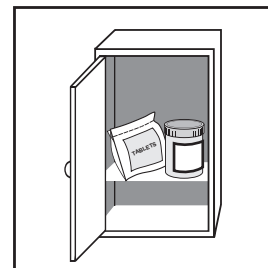


kufutshane nomlilo

### Gcina amayeza akho...



kwindawo abangenakufikelela kuyo abantwana



kwindawo ekhuselekileyo, epholileyo neyomileyo

## OKUBALULEKILEYO !

### Yiya ekliniki ngokukhawulezileyo :

- ukuba ukhulelwe ngexa usitya ii-Efavirenz



- ukuba ufunyenwe yifiva okanye yingqe



## SEBENZISE IKHONDOM



Usenokuyisasaza kwakhona iHIV/AIDS ngokulala neqabane lakho ngaphandle kokuzikhusela.



Kufuneka usebenzise ikhondom ngalo lonke ixesha ulala nomntu ukwenzela ukuzikhusela wena nabanye.



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July, 2009

# KUFUNEKA UZITYE II-ARVs UBOMI BAKHO BONKE

# UNYANGO NGEE-ANTIRETROVIRALS (ii-ARVs)

## Inkcazelo-sigulane nge-Regimen 1d

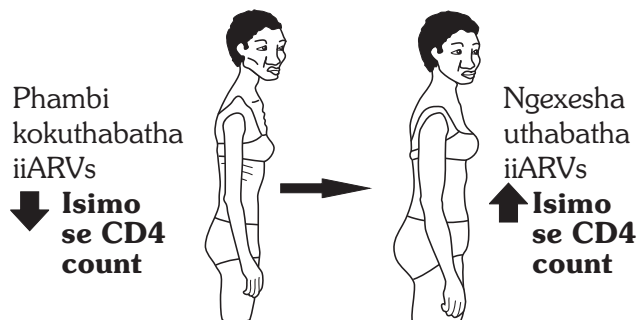
Le nkcazelo ikweliphetshana ingaluncendo kuwe ngedlela eyiyo yokuthabatha ii-ARVs ukuze uhlale usempilweni.

### II-ARVs ZENZA NTONI?

#### Ii-ARVs aziyinyangi iHIV/AIDS (ugawulayo nentsholongwane yakhe)

- inqambi iHIV ingakhuli
- zikunceda ukuba womelele ngakumbi
- zinyusa iCD4 count yakho (iiseli ezilungileyo)
- zithoba umthamo wentsholongwane kagawulayo egazini lakho

#### ii-ARVs aziyinyangi i-AIDS



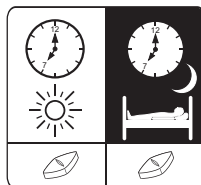
### PHAMBI KOKUBA USEBENZISE II-ARVs ZAKHO

#### Xelela ugqirha, usokhemesti okanye unesi ukuba:

- akhona amanye amayeza owathathayo
- kukho amayeza, ukutya okanye naziphi na ezinye izinto ezingavaniyo nomzimba wakho
- ukhulelwe okanye uzama ukukhulelwa
- uyancancisa
- uyacwangcisa ngeepilisi okanye ngenaliti
- kukho nantoni na enye engemanga kakuhle kuwe

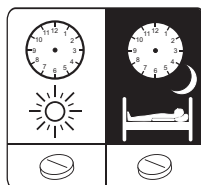
### INDLELA YOKUTHATHA II-ARVs ZAKHO

#### Lamivudine (3TC)



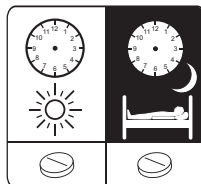
Thatha ipilisi ibe nye kusasa, nanye futhi ebusuku

#### Zidovudine (AZT)



Thatha ipilisi ibe nye kusasa, nanye futhi ebusuku

#### Nevirapine (NVP)



Thatha ipilisi ibe nye kusasa, nanye futhi ebusuku

Zithathe ii-ARVs nokutya okanye ngaphandle kokutya

**Akufuneki uwayeke nawaphi na kumayeza akho. Qhubeka ukuthatha zo-3 ii-ARVs zakho**

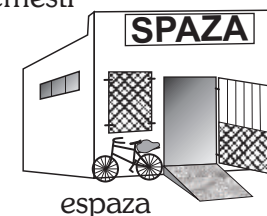
### NGELI XA USEBENZISA II-ARVs

#### Akhona amanye amayeza owathathayo?

Kufuneka uxelele ugqirha, unesi okanye usokhemesti wakho ukuba unamanye amayeza owasebenzisayo nowafumana kwezi ndawo.



ekhemesti



espaza



eggirheni



esuphamakethi



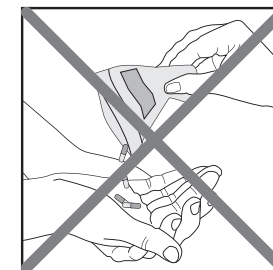
ekliniki

#### Ukuba uye walibala ukuthatha amayeza akho...

- wathathe ngoko nangoko wakukhumbula

#### Musa ukwabelana ngamayeza akho...

- nabahlobo bakho nosaphol wakho



## IZIPHUMO EBEZINGALINDELEKANGA

- iziphumo ezingalindelekanga zizinto eziyizevele ngelilixa utya amayeza, kodwa ke ziyalawuleka kwaye ziyanyangeka
- usenokungabi nazo ez zinto zichazwe apha okanye uphathwe zezo zingachazwanga apha

### Kwiivekieziyi 6 emveni ba uqalile ukuthatha ii-ARVs:

- irhashalala
- isicaphu-caphu
- intloko ebuhlungu
- ukuhambisa kwesisu
- iziyezi
- ukutyhafa okanye nokudinwa

### Emva kwenyanga ezi 3 ukuya kwezi 6 usitya ii-ARVs:

- ubuthatthatka, ukudinwa nesiyezi



### Iya ekliniki ngokukhowulezileyo xa usiva:



- isusu sakho siyaluma, isicaphucaphu, nokugaba

- ubuthatthatka, ukudinwa nesiyezi

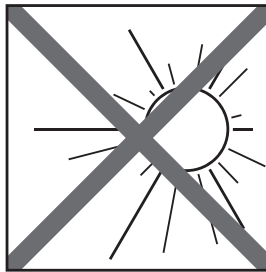


- irhashala emzimbeni okanye embonyeni kunye nengqele (ubushushu)

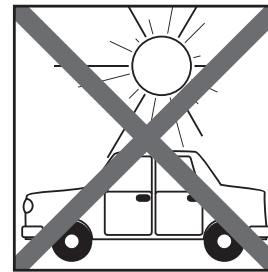


## INDLELA YOKUGCINA II-ARVs

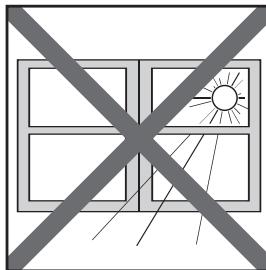
### Musa ukuzigcina ii-ARV...



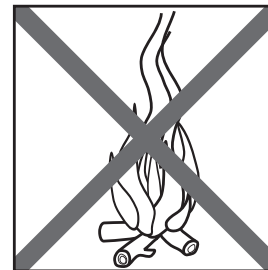
elangeni



emotweni

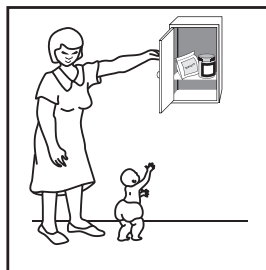


efestileni

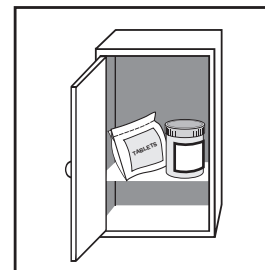


kufutshane nomlilo

### Gcina amayeza akho...



kwindawo abangenakufikelela kuyo abantwana



kwindawo ekhuselekileyo, epholileyo neyomileyo

## OKUBALULUKILEYO !

### Yiya ekliniki ngokukhawulezileyo :



- ba ufanyanwe yingqele, ikugadelisa okanye ingaku godolisi

## SEBENZISE IKHONDOM



Usenokuyisasaza kwakhona iHIV/AIDS ngokulala neqabane lakho ngaphandle kokuzikhusela.



Kufuneka usebenzise ikhondom ngalo lonke ixesha ulala nomntu ukwenzela ukuzikhusela wena nabanye.



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SAN DIEGO  
SCHOOL OF MEDICINE

July, 2009

# KUFUNEKA UZITYE II-ARVs UBOMI BAKHO BONKE