SELF-EFFICACY AND BELIEFS ABOUT MEDICATIONS: IMPLICATIONS FOR ANTIRETROVIRAL THERAPY ADHERENCE

by

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DECLARATION

Student number: 47538031

I declare that **SELF-EFFICACY AND BELIEFS ABOUT MEDICATIONS: IMPLICATIONS FOR ANTIRETROVIRAL THERAPY ADHERENCE** is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

March 2013

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Adegoke Olusegun Adefolalu Date

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ABSTRACT

The earlier optimism generated by the efficacy of antiretroviral drugs in human immunodeficiency virus (HIV) patients has been dissipated in the face of the enormous challenge of maintaining a nearly perfect adherence indefinitely. This study set to determine the influence of HIV adherence self-efficacy and beliefs about medicines on antiretroviral therapy adherence, with the aim of developing a framework for enhancing antiretroviral therapy (ART) adherence through focused intervention on modifiable factors from study variables that are strongly associated with ART adherence.

A descriptive correlational design was used to assess the predictive relationships of HIV adherence Self-Efficacy, Beliefs about Medicines and ART adherence among 232 HIV-infected patients in a large public health facility in Pretoria. Participants' medication beliefs were assessed using the Beliefs about Medicines Questionnaire, HIV adherence self-efficacy was assessed with HIV adherence self-efficacy scale (HIV-ASES) and ART adherence was assessed using the AIDS Clinical Trial Group questionnaire. Pearson correlation analysis was used to assess bivariate associations among the variables, and multiple regression analysis was used to examine the relationships among the independent variables and ART adherence.

Mean adherence for the 232 participants was 95% (SD=13.2). Correlation analysis revealed positive bivariate associations between perceived general harm and overuse of medications, and ART adherence ($p<0.05$); between specific necessity and concerns about ARVs, and perceived general harm and overuse of medications ($p<0.05$); between HIV adherence self efficacy and ART non-adherence ($p<0.05$). Multiple regression analysis showed significance for perceived general harm and overuse of medications on ART adherence ($F(1;231)=11,583;p<0,001$) with perceived general harmful ef-

fects and overuse of medications explaining 4.8% of the variance. There was significance for HIV adherence self-efficacy on ART non-adherence ($F(1;41)=4.440$; $p<0.041$), with HIV-ASES explaining 9,8% of the variance. Based on the results, a framework for enhancing ART adherence was developed. Activities in the framework consist of baseline screening for adherence facilitators and barriers using the beliefs about medicine questionnaire and HIV ASES, this is followed by focused interventions on identified barriers of ART adherence.

Key concepts: HIV adherence self-efficacy, beliefs about medicines, antiretroviral therapy adherence, antiretroviral therapy, human immunodeficiency virus.

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Very special thanks to the members of my family whose confidence in me has provided much needed strength in my quest for doctoral study. To my wife Toluwalase, and son Oluwaseun, thank you, for your words of encouragement have inspired me throughout this and other challenges.

Dedication

I dedicated this thesis to the glory of GOD almighty, and to all the HIV-infected persons, who are faced with the burden of taking an-tiretroviral drugs on a daily basis.

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List of abbreviations

ABC	Abacavir
ACTGAIDS	Clinical Trial Group
AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
AZT	Zidovudine
BMQ	Beliefs about Medicines Questionnaire
ddC	Zalcitabine
DAART	Directly administered antiretroviral therapy
ddI	Didanosine
D4T	Stavudine
DNA	Deoxyribonucleic acid
EDM	Electronic drug monitoring device
FDC	Fixed-dose combinations
HAART	Highly active antiretroviral therapy
HBM	Health Belief Model
ASES	Adherence Self-Efficacy Scale
HIV	Human immunodeficiency virus
HCT	HIV Counselling and Testing
HIV-ASES	HIV adherence self-efficacy scale
IDU	Injection drug users
iPrEx	Pre-exposure Prophylaxis Initiative
MMC	Medical male circumcision
MMT	Methadone maintenance therapy
mDOT	Modified directly observed therapy
MSM	Men who have sex with men

List of abbreviations

MARPS	Most at Risk Persons
NDOH	National Department of Health
NRTIS	Nucleoside reverse transcriptase inhibitors
NNRTIS	Non-nucleoside reverse transcriptase inhibitors
PAPM	Precaution Adoption Process Model
PI	Protease inhibitors
PLWHA	People living with HIV/AIDS
PMTCT	Prevention of Mother-To-Child Transmission of HIV
PrEP	Pre-exposure prophylaxis
RNA	Ribonucleic acid
StatSA	Statistics South Africa
SIV	Simian immune-deficiency virus
SCT	Social Cognitive Theory
STIs	Sexually transmitted infections
SPSS	Statistical Package for Social Sciences
SEM	Self-Efficacy Model
TDM	Therapeutic drug monitoring
TRP	Theory of Planned Behaviour
TRA	Theory of Reasoned Action
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNISA	University of South Africa
WHO	World Health Organization

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CHAPTER 1

ORIENTATION TO THE STUDY

1.1 INTRODUCTION

The Human immunodeficiency virus (HIV) and Acquired immune deficiency syndrome (AIDS) have become the most challenging public health concern of this generation. The pandemic has affected all age groups, causing premature deaths and depleting both human and capital resources especially in Sub-Saharan Africa leaving on its trail ethical, legal, and political issues together with economic and human rights implications. Although no definite cure has been found to treat this infectious disease, the introduction of antiretroviral therapy (ART) has enabled the disease to be managed as a chronic life-threatening disease producing substantial reduction in both AIDS-related morbidity and mortality (Abdool Karim, Naidoo, Grobler, Padayatchi, Baxter, Gray, Gengiah, Nair, Bamber, Singh, Khan, Pienaar, El-Sadr, Friedland & Abdool Karim 2010:700; Lawrence, Ndamage, Kayirangwa, Ndagije, Lo, Hoover, Hanson, Elul, Ayaba, Ellebrock, Rukundo, Shumbusho, Nash, Mugabo & Assimwe 2009:54; Wools-Kaloustian, Kimayo, Diero, Siika, Sidle, Yiannoustsos, Musick, Einterz, Fife & Tierney 2006:44).

While clinical outcomes of HIV-infected patients have been improved by highly active antiretroviral therapy (HAART), the earlier optimism generated by the efficacy of HAART in preserving the quality of lives of HIV/AIDS patients has been dissipated in the face of the enormous challenge of maintaining a nearly perfect adherence indefinitely (Simoni, Frick, Pantalone & Turner 2003:193). Although adherence to ART is a strong predictor of good clinical outcomes and survival among HIV-infected patients (Wang, Zhou, He, Luo, Li, Yang, Fennie & Williams 2009:759; Wools-Kaloustian et al 2006:44), the fact that high level of adherence is required in ART is very challenging and without this patients risk adverse outcomes for themselves and put extra burden on the already overstretched public health system (Rajasekran, Jeyaseelan, Vijila, Gomathi & Raja 2007:48). Furthermore, the complicated dosing requirements, adverse drug reactions and socio-economic factors often constitute challenges to patients and influence their adherence to treatment (Dahab, Charalambous, Hamilton, Fielding, Kielmann, Church-

yard & Grant 2008:63; Curioso, Kepka, Cabello, Segura & Kurth 2010:13; Amberbir, Woldemichael, Getachew, Girma, & Deribe 2008:265).

Treatment adherence is the act or quality of sticking to a particular advice as instructed by the health care provider (Kenreigh & Wagner 2005). It is broader than mere compliance with medications; it includes adhering to dietary instructions, clinic appointments and lifestyle adjustment. This is why long-term treatment adherence in chronic diseases such as HIV/AIDS is a very complex and dynamic phenomenon which involves the patients, health providers, the health system within which they operate and the broader socio-economic and political context around all the above (Miller, Ketlhapile, Rybasack-Smith & Rosen 2010:52).

Understanding the processes that influence adherence is helpful when trying to identify barriers and promote treatment adherence. The cognitive perspective of health behaviour provides a good framework in understanding some of these processes. This perspective assumes that attitudes and beliefs as well as expectations and outcomes determine patients' health behaviour (Munro, Lewin, Swart & Volmink 2007:104). Self-efficacy and beliefs about medications are cognitive variables from this perspective (Kagee 2008:421), and are constructs which are influential in terms of task choice, performance, effort, and perseverance as they pertain to the ability to successfully engage in behaviours that lead to desired outcomes (Skovdal, Campbell, Nhongo, Nyamukapa & Gregson 2011:309; Munro et al 2007:104). These cognitive variables have been found to be associated with medication adherence in chronic medical conditions like hypertension, diabetes, asthma (Ireland & Wilsher 2010:40; Neame & Hammond 2005:765).

The current study was designed to identify predictive relationships among self-efficacy, beliefs about medicines and ART adherence, and to explore cognitive factors that are strongly associated with adherence in order to suggest strategies for improving ART adherence among HIV patients through a framework development.

1.2 BACKGROUND INFORMATION ABOUT THE RESEARCH PROBLEM

1.2.1 The source of and background to the research problem

Adherence among patients on ART in developing countries, including South Africa, continues to pose challenges to the health care delivery system, although various studies in sub-Saharan Africa have shown that high levels of adherence, viral suppression and good clinical outcome are achievable in these resource-limited settings (Nachega, Hislop, Dowdy, Lo, Omer, Regensberg, Chaisson & Maartens 2006a:82; San Lio, Carbini, Germano, Guidotti, Mancinelli, Magid, Narciso, Palombi, Renzi, Zimba & Marazzi 2008:1614; Nachega, Hislop, Nguyen, Dowdy, Regensberg, Chaisson, Cotton & Maartens 2009:68; Mills, Nachega, Buchan, Orbinski, Attaran, Singh, Rachlis, Wu, Cooper, Thabane, Wilson, Guyatt & Bangsberg 2006:685; Hardon, Akurut, Comoro, Ekezie, Irunde, Gerrits, Kglatwane, Kinsman, Kwasa, Maridadi, Moroka, Moyo, Nakiyemba, Nsimba, Ogenyi, Oyabba, Temu & Laing 2007; Oyugi, Byakika-Tusiime, Charlebois, Kityo, Mugerwa, Mugyenyi & Bangsberg 2004:1101; Fox & Rosen 2010:11), it is very challenging to adhere to ART, and strict adherence is not common (Montessori, Press, Harris, Akagi & Montaner 2004:229).

A major review of studies on ART adherence puts it at 77% in Sub-Saharan Africa and estimates non-adherence in adult population at 33-88% depending on the measure of adherence employed (Mills et al 2006:685). In other studies across sub-Saharan Africa ART adherence varies widely from 25-56% (Amberbir et al 2008:265; Uzochukwu, Onwujekwe, Onoka, Okoli, Uguru & Chukwuogo 2009:4; Malangu 2008:49; Peltzer, Du Preez, Ramlagan & Anderson 2010:111). These percentages are low considering that adherence of 95% is necessary to achieve optimum benefit of ART (Nachega et al 2006a:81). Low adherence levels are linked to development of resistant virus, rapid disease progression, poor quality of life and premature mortality (Graham, Masese, Gitau, Jalalian-Lechak, Richardson, Peshu, Mandaliya, Kiarie, Jaoko, Ndinya-Achola, Overbaugh & McClelland 2010:1541; Nachega et al 2006a:83; Wools-Kaloustian et al 2006:44).

The consequences of non-adherence in HIV management is so costly and researchers have advocated that health behaviour theories needed to be well examined to enhance the understanding of how relevance they are concerning adherence to medication in

chronic condition such as HIV/AIDS (Gill, Hamer, Simon, Thea & Sabin 2005:1247; Peltzer et al 2010:111).

Adherence self-efficacy is the personal belief regarding the capabilities to plan and perform a desired behaviour to comply with prescribed medications and health instructions in managing a disease condition (Bandura 2004:144). Adherence self-efficacy is a known predictor of a wide range of health behaviour of patients on chronic medication including medication adherence (Kott 2008:60; Sleath et al 2010:628; Zebracki & Drotar 2004:142; Johnson et al 2007:367; Rudy, Murphy, Harris, Muenz & Ellen 2009:188).

Beliefs about medicines is another variable from the cognitive perspective of health behaviour, it describes a person's beliefs about the potential costs and benefits of taking medication and it is an important factor that has influence on medication use behaviour (Horne, Weinman & Hankins 1999:20).Various studies across a range of chronic medical conditions have identified similarities in beliefs that influence medication adherence. These studies have found low rates of adherence to be consistently related to doubts about personal need for medications (Magadza, Radloff & Srinivas 2009:369; Neame & Hammond 2005:764; Porteous, Francis, Bond & Hannaford 2010:228; Ireland & Wilsher 2010:39).

Whereas studies from developed countries where the socio-economic dynamics are quite different to what obtains in sub-Saharan Africa countries have already documented positive association among adherence self-efficacy, beliefs about medicines and medication adherence in diseases like HIV, asthma, diabetes, glaucoma and depression; and that poor adherence is likely to occur in patients with low self-efficacy (Horne 2006:67; Rudy et al 2009:190; Zebracki & Drotar 2004:142; Johnson, Neilands, Dilworth, Morin, Remien & Chesney 2007:367; Sleath et al 2010:628; Gifford, Bormann, Shively, Wright, Richman & Bozzette 2000:394), few studies have examined this relationship in developing countries (Kagee 2008:420; Peltzer et al 2010:111).

An extensive search of the literature for previous studies was conducted using databases such as ProQuest, PubMed, MEDLINE, NiPAD, SocINDEX and PsycINFO as well as Google Scholar search engine using keywords such as self-efficacy, antiretroviral therapy adherence and beliefs about medications. By using these search terms over 250 research papers were generated, the researcher narrowed down the search to re-

search articles that dealt with adherence to chronic medications, self-efficacy in the context of chronic medical conditions and medication beliefs among patients who were on chronic treatment for medical ailments. In addition, descriptive, methodological and contextual factors from each research article were done to gain better understanding of work done in this area.

The researcher identified that relationships among adherence self-efficacy, antiretroviral therapy adherence and beliefs about medications have not been examined thoroughly in South Africa setting that has the largest ART program worldwide despite a rapidly growing body of literature addressing issues associated with adherence to ART. Given the dearth of research on the combination of variables that relate to patients' adherence behaviour and intentions to adhere in South Africa, studies that consider some of these explanatory factors simultaneously are urgently needed as psychosocial variables that are amenable to intervention, such as self-efficacy and belief about medicines, may improve the body of knowledge in the area of ART adherence (Reynolds, Testa, Marc, Chesney, Neidig, Smith, Vella, Robbins and the ACTG teams 2004:148).

1.3 RESEARCH PROBLEM

According to cognitive perspective of health behaviour, persons who are likely to perform certain health behaviour are those who believe that such behaviour is going to benefit them (Munro et al 2007:104). Rather than identifying the characteristics of adherent or non-adherent patients as previous studies have done, there is need to better understand the interaction of the individual with the disease and its treatment modalities. Extending knowledge of HIV/AIDS to an understanding of the process and predictors of behaviour change may provide an insight about the successful self-management of this chronic disease (Gauchet, Tarquinio & Fischer 2007:147).

Further research is therefore needed as psychosocial variables that are amenable to intervention such as self-efficacy and belief about medicines provide a good framework for understanding ART adherence. However, more information regarding the role of these variables in adhering to ART needs to be established by research in our local setting. It was anticipated that the results of this study would offer additional support to existing body of knowledge that self-management behaviour improves with beliefs of self-

efficacy and need for medication; and the expectation that by performing the behaviour a positive outcome will result.

As research has indicated that adherence needed for maximal benefit in ART differ significantly from those of other chronic medical conditions (Simoni, Frick, Pantalone & Turner 2003:185-198). By implication, HIV-infected patients on ART need to demonstrate self-management skills and good knowledge of their disease as well as having a high level of self-confidence in adhering to their medications. These relationships however have not yet been tested empirically in South African patients. It is clearly in the interest of ART adherence monitoring to know the cognitive factors that will predict high and low adherence for purposes of focused intervention.

The researcher is an HIV clinician and previously served as Technical advisor on HIV treatment programmes with an international donor organisation in Pretoria where he witnessed the various challenges faced by patients in adhering to ART and was persuaded that cognitive perspective of health behaviour could be used to gain better understanding of ART adherence. The researcher was therefore motivated to conduct an investigation into the influence of adherence self-efficacy and beliefs about medicines on ART adherence among HIV-infected patients within the Tshwane area. Identifying the predictive relationships of these variables will enhance the patients' and the health providers' understanding of cognitive factors associated with ART adherence in the local setting where the study was based.

Based on the introduction, background information and the description of the problem stated above, the researcher arrived at this research question: How can adherence self-efficacy and Beliefs about Medicines be utilized in HIV/AIDS service delivery to develop strategies that would enhance adherence to ART in South Africa, thereby minimizing development of adverse outcomes in patients in forms of loss of virologic control and subsequent viral rebound; development of viral resistance and the transmission of resistant virus to others; and repeated patients hospitalizations with high economic importance to the already overwhelmed public health system?

1.4 AIM OF THE STUDY

This study aimed to provide a framework for ART adherence improvement through focused intervention on modifiable factors that are strongly associated with ART adherence.

1.4.1 Research purpose

The purpose of this study was to determine the influence of adherence self-efficacy and beliefs about medicines on ART adherence among patients on lifelong treatment. The information obtained would be used to provide a framework for enhancing adherence to antiretroviral therapy.

1.4.2 Research objectives

The specific objectives of this research are to:

1. Explore the cognitive variables of adherence self-efficacy and beliefs about medicines that influence adherence among patients on ART.

2. Determine the inter-relationships among adherence self-efficacy, beliefs about medicines and ART adherence.

3. Describe the modalities of enhancing adherence to ART through focused interventions on the identified factors that are strongly associated with ART adherence.

4. Develop a framework for the improvement of ART adherence based on the factors identified in this study.

1.5 SIGNIFICANCE OF THE STUDY

HIV/AIDS is a chronic life threatening disease that constitutes the largest burden of disease in South Africa (NDOH 2010:10). The management of the disease is complex and

requires a team approach involving the patient, doctors, nurses, adherence counselors, and many others. As part of the multidisciplinary team, HIV patients have a role to play in the management of their disease. They are expected to take their medications regularly, maintain healthy diet, observe some dietary restrictions and avoid risky behaviours, and all these are based on the constructs of the cognitive perspective of health behaviour.

Since adherence in persons with HIV/AIDS varies within each person, identifying variables to improve adherence monitoring offers an additional perspective about HIV/AIDS management and ART adherence monitoring in South Africa.

Identifying the cognitive factors that are predictive of ART adherence will make significant contributions to the field of adherence monitoring in HIV/AIDS management in South Africa. Exploring cognitive variables that are strongly associated with ART adherence would assist in identifying factors that require focused interventions to improve adherence among HIV-infected patients. Interventions could then be manipulated to promote these factors among patients on ART. In addition, identification of these factors will enable for baseline screening for adherence predictors prior to ART initiation. Health providers could then use patients' responses to prioritize them for further education to assist in improving their adherence.

1.6 DEFINITION OF TERMS

1.6.1 Acquired immune deficiency syndrome (AIDS)

AIDS is this study refers to the late stage of HIV infection when a person's immune system which serves as the body's natural response to infections is severely damaged due to decrease in the number and functions of CD4+ T-lymphocytes cells. This causes a severe immunodeficiency state that leaves the body susceptible to a variety of potentially fatal infections which are otherwise non virulence (Wilkinson & Gotch 2001:188).

1.6.2 Antiretroviral therapy (ART)

Antiretroviral (ARV) are drugs used in the treatment of HIV/AIDS, they are meant to interrupt the life cycle of HIV; and they do so at different points to reduce the replication of

the virus (Montessori et al 2004:229).The drugs that make up ART usually consist of at least two classes of antiretroviral agents (Boyd & Pett 2008:66; Palmer 2003:59). Antiretroviral therapy in this study is refers to the combination of three or more antiretroviral agents used for maximal suppression of viral replication in the treatment of HIV/AIDS.

1.6.3 Antiretroviral therapy adherence

Treatment adherence is the act or quality of sticking to a particular advice as instructed by the health care provider (Kenreigh & Wagner 2005). ART Adherence in this research refers to the extent to which HIV-infected patients behaviour corresponds to the prescribed medical advice in terms of antiretroviral use.

1.6.4 Beliefs about medicines

Describes a person's beliefs about the potential costs and benefits of taking medication and it is an important factor influencing medication use behaviour (Horne et al 1999:20). ''Beliefs about medicines'' in this study is a construct that describes a patient's beliefs about the potential costs and benefits of taking antiretroviral therapy. The measure to gauge these beliefs is the "beliefs about medicine questionnaire".

1.6.5 Human immune-deficiency virus (HIV)

HIV is a retrovirus of the lentiviruses family; infections with lentiviruses are often characterized by a long period of clinical latency, persistent viral replication and follow a chronic course of disease. The HIV comprises of two species namely HIV-1 and HIV-2 which researchers believe to have originated as zoonotic infection from primate host that harbour certain lentiviruses called the simian immune-deficiency (Rubbert, Behrens & Ostrowski 2007:60).

1.6.6 HIV adherence self-efficacy

Self-efficacy is a personal belief regarding the capabilities to carry out a specific task to achieve a desired outcome, it describes an individual's belief that he can alter a behaviour or action required to achieve positive health outcomes in managing a disease con-

dition (Bandura 2004:144; 1977:193). HIV adherence self-efficacy in this research is described as one's belief in the ability to plan and perform a desired behaviour leading to ART adherence.

1.6.7 HIV-infected person

This is a person whose HIV specific antibodies or viral antigens have been demonstrated in their blood or body fluids through standardized tests. These markers are found in HIV-infected individuals and their presence is used to make the diagnosis of HIV infection (Preiser & Korsman 2007:41). An HIV-infected person in this study is one who has been diagnosed with the prescribed standardized laboratory tests.

1.7 FOUNDATION OF THE STUDY

1.7.1 Meta-theoretical assumptions

The term 'meta- theory' explores the underlying assumptions of theory and attempts to understand the consequences of such assumptions on the act of theorizing and the practice of empirical research (Wallis 2010:78). It does not take a specific event, phenomenon, or series of empirical real world practices as its object of analysis. Meta-theoretical assumption typically addresses issues such as the nature and the structure of scientific theories, the nature of scientific growth, the meaning of truth, explanations and objectivity (Wallis 2010:98-99). Meta-theoretical assumptions reflect the researcher's view, they are beliefs which origin is philosophical in nature, and therefore not meant to be tested but are accepted to be true for the researcher. Meta-theory defines the context in which theoretical and methodological concepts are constructed, theories and methods refer directly to the empirical world, while meta-theories refer to methods themselves (Overton 2007:154). The theoretical assumptions are deducted from the meta-theoretical assumptions and can be formulated into central statements or hypothesis which could be validated through research. The cognitive perspective of health behaviour was used in this study; this study draws from the Self-Efficacy Model and the Health Belief Model (HBM).

1.7.2 Theoretical framework

Health behaviour theories provide ground for target interventions aimed at changing behaviour or establishing good health habits, and ways by which health behaviour can be modified to achieve the desired outcome is increasingly becoming the focus of research in medication adherence. The broad overarching theoretical framework behind this research was aimed at explaining how HIV patients on ART conceptualize threats to their health (HIV/AIDS disease); how they conceptualize one specific solution to the health threat (treatment or medication use) and why actual medication use behaviour may or may not take place. There are several theories related to health behaviour that apply to an individual that could be used to describe and guide interventions related to cognitive factors and medication adherence in the HIV-infected persons. The cognitive perspective of health behaviour guided this study; theories that emphasize cognitive variables and processes were applied in understanding health behaviour among patients on ART.

The meta-theoretical assumption of this research is based on the assumption that possessing a high level of self-efficacy towards ART adherence and positive beliefs about medicines increase the likelihood that an individual would be more motivated to actively achieve high adherence to ART and good clinical outcome. Two theories from the cognitive perspective of health behaviour, the Self-Efficacy Model and the Health Belief Model (HBM) were used in this study. These two models were chosen for this study because they contain the cognitive variables under investigation in the current research.

1.7.2.1 Self-Efficacy Model

Self-efficacy, a concept articulated by Bandura postulates that although social cognitive theory acknowledges that knowledge of health risk and benefits of treatment are necessary to perform health behaviour; these are not enough, additional self-influences are necessary to achieve changes that will result in the desired health behaviour (Bandura 2004:145). Self-efficacy is an individual's personal belief regarding their capabilities to carry out a specific task to achieve a desired outcome. Self-Efficacy Model begins with a perception of the existence of a problem followed by the belief that the desired result can be achieved with one's actions, thus creating an incentive to persevere (Bandura 2004:145). The Adherence Self-Efficacy Scale (ASES) is designed to measure self-

efficacy for adherence to HIV treatment plans; this includes taking ART and other self care behaviour.

1.7.2.2 Health belief model (HBM)

HBM is a psychosocial approach to explaining health behaviour that deals with value expectancies related to health. The model was introduced by psychologists Rosenstock, Hockbaum, Leventhal and Kegeles in the 1950s and has been used widely by various researchers. It is a cognitive and interpersonal approach that view human as a rational being who behave in certain ways to minimize what they perceived as threat (e.g. disease symptoms) and enhance what are perceived as benefits (e.g. adherence to treatment) (Bandura 2004:145). HBM postulates that health seeking behaviour is influenced by a person's perceptions of threat posed by a health problem and the perceived benefits of taking action to minimise such threat (Kagee 2008:420). Beliefs about Medicines, a construct that was developed from the elaboration of HBM by Horne et al (1999:1-24) describes a person's beliefs about the potential costs and benefits of taking medicines. The Beliefs about Medicines Questionnaire (BMQ) that was developed as a measure to gauge patients' beliefs about medicines, is used to score beliefs about medicines.

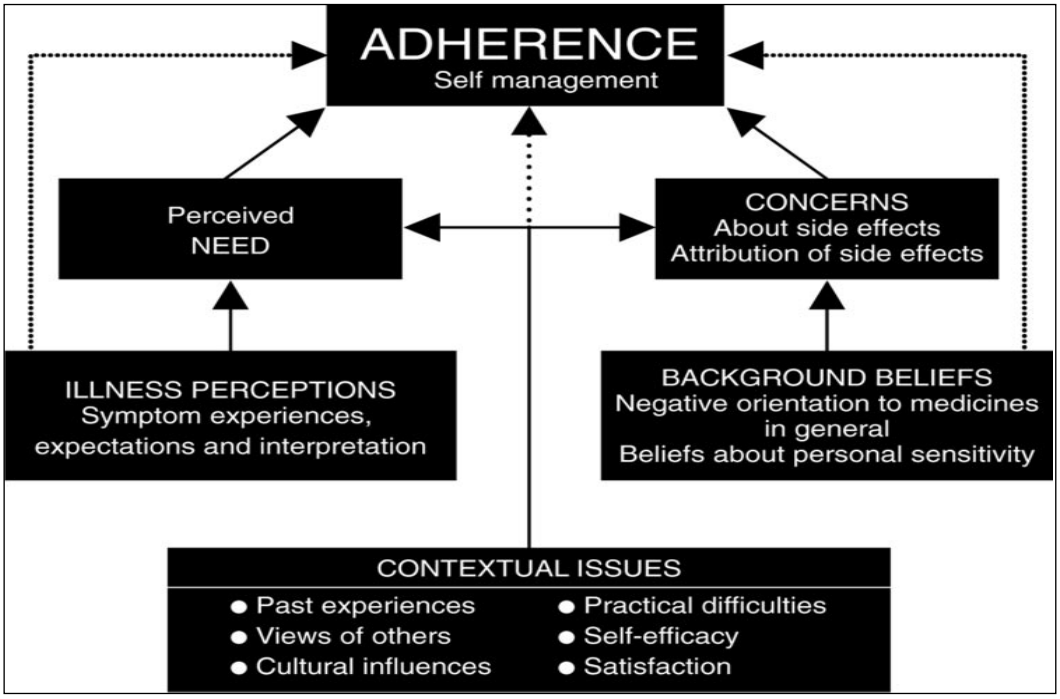

Figure 1.1 Analytical representations of cognitive variables of adherence

(Adapted from Horne 2006:71S)

As shown in Figure 1.1, ART adherence is influenced by self-efficacy, beliefs about medications, perceived severity of the disease and individual's past experience. The cognitive perspective of health behaviour assisted the researcher to understand how HIV-infected patients on ART interpret and evaluate situations around them as well as their self-conception as to whether they will have self-efficacy in adhering to treatment. Prediction of medication adherence is very complex, and health-related knowledge and beliefs alone are insufficient to achieve behaviour change especially in chronic condition like HIV/AIDS. In this study, the researcher examined a theoretical framework encompassing health beliefs/attitudes, ART self-efficacy and demographic characteristics in relationship to antiretroviral therapy adherence. This research examined the relationships between two individual factors (self-efficacy and beliefs about medicines) and the health behaviour (HIV medication adherence) in an attempt to identify the potential area for focused interventions that could be used in enhancing ART adherence.

1.8 RESEARCH DESIGN AND METHOD

1.8.1 Research paradigm

Quantitative research involves collection of numerical data that can be subjected to statistical analysis which results in quantifiable information (Terre Blanche & Durrheim 2008:7). According to Baum (1995:466), some public health issues need quantification while others are more qualitative in nature; methodologies for health research need to be diverse and chosen to suit the problem being investigated. The variables under investigation in this study consist of cognitive mechanisms that are quantifiable; the researcher therefore adopted an objective and detached epistemological stance towards the study variables and followed positivist approach in undertaking this research.

1.8.2 Research design

A non-experimental quantitative research methodology was employed using descriptive correlational design. Correlational research is a measure of the association or covariation of two or more dependent variables and is used in exploring causal relationships (Walker 2005:573). This research design was used to assess the predictive relationships of adherence self-efficacy, beliefs about medicines and ART adherence in

HIV-infected patients. The chosen research design is best suited for this research as it involves examining relationships among variables without introduction of any intervention (Terre Blanche & Durrheim 2008:7).+-9

1.8.3 Power of the study and sample size

Power of a study is the ability of the study to demonstrate an association or causal relationship between two variables, given that an association exists. In quantitative research it is necessary to specify the desired study power and to calculate the sample size needed to achieve this power when planning the study to avoid conducting a study with insufficient power. Traditionally, researchers consider a study power of 80% to be the minimum, although higher values are commonly used (Harvey & Lang 2010:736). An exact binomial test with a nominal two-sided significance level will have 87% power to detect the difference between the Null hypothesis proportion π_0 of 0.6 and the Alternative proportion π_A of 0.7 when the sample size is 232 (Chernick & Liu 2002:149-155). The sample size for this study was 232 patients, which represented 10% of the study population.

1.8.4 Population and sample selection

The study population consisted of male and female, older than 18 years, of all races and socio-economic groups who were on ART at a large district hospital within the Tshwane Metropolitan area. This hospital is part of the Comprehensive Care, Management and Treatment program of the Gauteng Department of Health. This area was selected because it is an area where the researcher believes one can find the entire population groups in South Africa representing a heterogeneous population. According to hospital records, there were 2312 adult patients on ART in the hospital at the time of this study (Antiretroviral Clinic Statistics 2011).

Systematic random sampling method was employed in selecting 232 patients on ART at the study setting using the inclusion criteria of (a) 18 years and above, (b) Free of severe opportunistic infections (c) No cognitive impairment as determined by the mini-mental state examination (d) Ability to understand English or any of the South African official languages (e) Have been on ART for at least one year. The file numbers of all the 2312 patients were listed in ascending order and every tenth person on the list was

selected to participate in the study until the desired sample size was reached. Where a selected respondent declined to participate in the study or ineligible the next person on the list was included.

1.8.5 Data collection procedures

Two research assistants were trained to assist in recruitment of study respondents and administration of questionnaires. In order to ensure consistency in data collection, role-play was used to ensure standard procedures of obtaining informed consent, completion of questionnaires, and handling questions before or in the process of administration of the questionnaires. The research assistants were also informed of the need to resolve difficult issues with the principal investigator before or during the administration of the questionnaires. The questionnaires were written in English and the research assistants were able to communicate effectively with respondents and clarify their queries.

Patients on ART at the study setting were informed about the study and that they were all potential participants. The risk, benefits, time commitment and eligibility for the study were also explained. Informed consent was obtained from selected respondents and appointment fixed for the completion of the questionnaires. The study made use of questionnaires that were completed with the assistance of the researcher and his assistants. Completions of the questionnaires were conducted in separate rooms and data were collected using four quantitative instruments combined into one (Annexure D). These are: the Demographic Data Questionnaire (developed by the researcher); The HIV Treatment Adherence Self-Efficacy Scales (HIV-ASES); the Beliefs about Medicines Questionnaire (BMQ) and the AIDS Clinical Trial Group (ACTG) Questionnaire Adherence. Permission to use the ACTG and HIV-ASES is granted for HIV research purposes by the Center for AIDS Prevention Studies (CAPS) at University of California, San Francisco (Center for AIDS Prevention Studies 2011). The researcher obtained permission to use the BMQ from the copyright holder (Annexure F).

1.8.6 Content validity of the research instruments

Content validity is based on the extent to which a measurement reflects the specific intended domain of content; it focuses on the adequacy with which the domain of the characteristics is captured by the measure (Vogt, King & King 2004:232). To ensure that all the measures in this study represent the facets of the constructs under investigation, the following steps were taken by the researcher:

- An extensive review of relevant literature on the constructs being investigated; this enabled the researcher to conceptually define the domains of the characteristics i.e. specifying what the variables are and what they are not.
- Ongoing refinement of definitions of the constructs being investigated.
- Consultation with members of the target population to increase the chance that items are content valid for their intended purpose.
- Consultation with subject matter experts in the field of this research for content validity of the instruments.
- Development of the items for administration in survey form before actual data collection commences.

1.8.7 Measurement of variables

The variables measured in this study include demographic characteristics assessed by the demographic data questionnaire; the ability to carry out tasks that results in adherence to ART was measured with the HIV adherence self-efficacy scale, the Beliefs about medicine questionnaire measured specific and general beliefs of patients on antiretroviral medicines and other medications used in chronic medical conditions. Finally, ART adherence was measured with the ACTG questionnaire.

1.8.8 Data analysis

The data collected were captured into Excel spreadsheet and analysed with the Statistical Package for Social Sciences (SPSS) version 19.0 manufactured by IBM. Before data analysis each questionnaire was checked for completion by the research assistants to ensure that they were answered correctly and subsequently scrutinized twice by

the researcher before the data was eventually entered into the Excel spreadsheet using double entry method, checked for errors, cleaned and then exported into the SPSS programme for processing and analysis. The data that differed during double entry were cross-checked against the questionnaires concerned. Before data analysis each variable was examined separately through various SPSS functions for accuracy of data entry, missing values, and fit between their distributions and the assumptions of multivariate analysis. Accuracy of data entry was confirmed by checking univariate descriptive statistics for strange data such as values out of range, means, standard deviations and univariate outliers.

Descriptive statistics including means, percentages and frequency distribution were used to summarize the demographic data, HIV-ASES, BMQ and ACTG questionnaire. Measures of variability were applied to characterize the differences that exist among the scores and the central tendency of the data. Pearson correlation analysis was used to assess the bivariate associations among the variables, and multivariable logistic regression was used to determine predictors of medication adherence. The significance of each independent variable as well as the combined significance of the independent variables to the dependent variable was explained by the variance observed in the dependent variable. Variables that were included in the model are summary scores from the BMQ and HIV-ASES that are significantly associated with adherence as measured by ACTG questionnaire.

1.8.9 Pilot study

Pilot study assists researchers in identifying possible problems in the proposed study and allows for revision of the methods and instruments before data collection (Van der Riet & Durrheim 2008:94). The researcher carried out a pilot study at a separate clinic that was not included in the final study sample. The four instruments were tested among randomly selected 30 participants that had similar characteristics to the sample selected for this study for contents clarity before being administered to the selected sample. The respondents were asked to give constructive feedback with regard to clarity of the questions, comprehension and time necessary to answer all the questions in the questionnaire. The respondents did not experience difficulty in completing the questionnaires but made some valuable comments described below which were considered during the administration of the questionnaires to the 232 patients selected for this study.

The following were the comments made by the 30 participants who participated in the pilot study:

Question 9 on the demographic data questionnaire: What is/are the most likely way(s) that you became infected with HIV? When asked about the modality of acquiring HIV infection, about half of the respondents indicated they did not know. This prompted the researcher to include an option “Don’t know” in the revised questionnaire.

Question 14 on the demographic data questionnaire: What is the number of pills you swallow every day? Participants queried what the number of pills meant; as there were some participants who had co-morbidities e.g. asthma, diabetes, hypertension etc. who were also on ART. They wanted to know if they should add up all the ARVs and other pills. In the revised questionnaire the researcher specified the number of pills to mean ARVs only to avoid confusing the participants.

Furthermore, the participants in the pilot study identified some similarity between questions 4 & 7 in the HIV-ASES questionnaire. Question 4 asked: ‘’How confident are you that you can stick to your treatment schedule even when your daily routine is disrupted?’’ Question 7 asked: “How confident are you that you can continue with your treatment even if doing so interferes with your daily activities?” The researcher clarified the ambiguity noted here with the participants during the administration of the questionnaires to the 232 selected individuals. Sticking to treatment schedule mentioned in question 4 meant continuing taking medication as prescribed in terms of dosing, scheduling and dietary instructions. To continue with treatment mentioned in question 7 meant continuing taking medication without emphasizing sticking to dosing, scheduling and dietary instructions.

Some participants indicated they did not know the meaning of T-cells in question 8, where participants were asked how confident they were in continuing with their treatment plan prescribed by their physician even if their T-cell drops significantly in the next three months. The researcher changed T-cell to CD4 in the revised questionnaire that was eventually used in this study since all HIV-infected patients on ART know what CD4 means; they are informed of it during the counselling process.

1.9 ETHICAL CONSIDERATIONS

All the respondents gave consent to participate in the research; and completed study questionnaires after their clinic appointment to avoid inconveniences. They did not receive any monetary incentive and were informed that they could withdraw from the study at any time with no consequences. The author throughout the study observed strict confidentiality and anonymity. Identification numbers were used for the questionnaires that bear no link with respondents' names or hospital numbers. Collected data were stored electronically and protected with password. The sample respondents were not identified in published or disseminated results. Name and phone numbers of the researcher and his supervisor were provided in the event that any concerns regarding the research arise. Counselling services were readily available for any participant who developed emotional trauma as a result of participating in the study. Furthermore, ethical clearance was obtained from the Department of Health Studies Higher Degree Committee at UNISA and permission was sought from the management of the health institution where the study was carried before the study commenced.

1.10 STRUCTURE OF THE THESIS

This thesis is presented in five chapters and outlined as follows:

Chapter 1: Orientation to the study

This chapter provides the introduction and background information about the research problem, the statement of the research problem, aim of the study, the research purpose guiding the study and the objectives. In addition, the chapter also discussed the significance of the study, definition of terms used, foundation of the study which include meta-theoretical assumptions and theoretical framework. Finally, the research methodology and ethical considerations are also discussed in this chapter.

Chapter 2: Literature review

Includes the literature review on epidemiology of HIV/AIDS, clinical aspect of HIV and antiretroviral therapy, theories associated with adherence in chronic medical conditions, adherence in ART, factors associated with ART adherence, consequences of non-

adherence in ART, adherence monitoring in ART and strategies and tools for enhancing adherence. The chapter concludes by highlighting some limitations of previous studies done on adherence to ART.

Chapter 3: Methodology

The chapter covers the methodological approach including aims and objectives of the study, research design, sampling and study population, Research instruments, data collection technique, pilot study, internal and external validity of the study, reliability of research instruments, data management, procedure for data analysis and ethical consideration for the study.

Chapter 4: Analysis, presentation and description of the research findings

The chapter describes the results of the study findings including the descriptive and analytical statistics conducted.

Chapter 5: Discussion, conclusions and recommendations

Chapter 5 includes the discussion of the study findings, conclusion of the study and gives recommendation and future directions for research.

1.11 CONCLUSION

Antiretroviral therapy results in viral suppression, improved immune function and delay disease progression in HIV/AIDS patients. However, this treatment is indefinite and achieving high level of adherence is difficult. Various studies conducted in developed nations have identified some cognitive correlates and predictors of adherence to ART, but few studies have been conducted among people living in sub-Saharan Africa, where over two-thirds of people living with HIV reside and particularly in South Africa with the largest ART program worldwide.

This study aimed to explore the cognitive correlates of adherence to ART in people living with HIV in South Africa. The research examined the relationship between ART ad-

herence self-efficacy, beliefs about medicines and adherence to ART. The meta-theoretical assumption of this study is based on the assumption that an individual living with HIV may adhere to ART because of the beliefs they have about medications and personal belief regarding their capabilities to carry out specific tasks in adhering to medications.

The confidence in a person's ability to carry out specific task in adhering to medications may depend on his or her beliefs about the medications. The researcher investigated whether beliefs about medicines correlates with adherence to ART among people living with HIV, whether beliefs about medicines correlates with ART adherence self-efficacy, and whether ART adherence self-efficacy correlates with adherence to ART and determine whether ART adherence self-efficacy mediates the relation between beliefs about medicines and adherence to ART.

Achieving high levels of adherence is difficult in chronic medical conditions; identifying the predictive relationships of the study variables has enhanced our understanding of cognitive factors associated with the management of HIV/AIDS, which is a good source for focused intervention in enhancing ART adherence.

CHAPTER 2

LITERATURE REVIEW

2.1 INTRODUCTION

Literature review identifies gaps in knowledge on the topic which is being researched and serves as the foundation on which the new knowledge generated in research activity is based. According to Kaniki (2008:19), a research project cannot exist in isolation; it has to be done within the context of prior knowledge. In other words, literature review puts the research into context, provides the readership with the necessary background information that would allow for proper understanding and comprehension of the topic under investigation.

An extensive search of the literature for previous studies was conducted using databases such as ProQuest, PubMed, MEDLINE, NiPAD, SocINDEX and PsycINFO as well as Google Scholar search engine using keywords such as self-efficacy, antiretroviral therapy adherence and beliefs about medications. In addition, a thorough literature review of other relevant journals, books, articles, research reports, policy documents and other information sources was done to identify available knowledge on ART adherence and cognitive variables associated with adherence.

The following areas are covered in the literature review: theoretical framework of the research, epidemiology of HIV/AIDS, clinical aspect of HIV and antiretroviral therapy, theories associated with adherence in chronic medical conditions, adherence in ART, factors associated with ART adherence, consequences of non-adherence in ART, adherence monitoring in ART, and strategies and tools for enhancing adherence.

2.2 THEORETICAL FRAMEWORK

2.2.1 Cognitive perspective of health behaviour

Health behaviour theories provide ground for target interventions aimed at changing behaviour or establishing good health habits (Horne 2006:71S), and ways by which health

behaviour can be modified to achieve desired outcome is increasingly becoming the focus of research in medication adherence. The broad overarching theoretical framework behind this research was aimed at explaining how HIV patients on ART conceptualize threats to their health (HIV/AIDS disease); how they conceptualize one specific solution to the health threat (treatment or medication use) and why actual medication use behavior may or may not take place. There are several theories related to health behavior that apply to an individual that could be used to describe and guide interventions related to cognitive factors and medication adherence in the HIV-infected persons. The cognitive perspective of health behaviour guided this study; theories that emphasize cognitive variables and processes were applied in understanding health behaviour among patients on ART.

Cognitive perspective of health behaviour focuses attention on ways in which patients conceptualize health threats and appraise factors that facilitate adherence or serve as barriers (Sabate 2003:140). Although this perspective has been criticized for not adequately addressing the issue of behavioural skills needed for adherence among patients and for paying little attention to the origin of beliefs and how such beliefs influence other behaviours (Munro et al 2007:104), the cognitive perspective of health behaviour provides a good theoretical framework for organizing thoughts about adherence and other health behaviours in patients on lifelong ART. The theoretical framework for this research is based on two theories from the cognitive perspective of health behaviour, which are the Self-Efficacy Model (SEM) and the Health Belief Model (HBM).

2.2.1.1 Self-Efficacy Model

Self-efficacy is an individual's personal belief regarding their capabilities to carry out a specific task to achieve a desired outcome. However, such behaviours are likely to be carried out by the patient if the patient believes he can perform such, meaning that self-efficacy is required for a person to perform a behaviour that is expected to result in a desired outcome. The Self-Efficacy Model begins with a perception of the existence of a problem followed by the belief that the desired result can be achieved with one's actions, thus creating an incentive to persevere (Bandura 2004:145).

Bandura's Self-Efficacy Model is defined by constructs such as: self-efficacy, outcome expectation, self-care behavior and outcome. The Self-Efficacy Model provides a

framework for predicting self-efficacy and self-care behaviors for a given task. Behaviour change is said to occur as a result of the person's belief about how capable one is of performing the behavior leading to the desired outcome. HIV-infected patients on ART will choose to adhere to their medication if they believe that doing so will result in getting better and living quality life. Self-care behavioral skills in persons with HIV/AIDS can be a major challenge as it requires high level of self-efficacy (Saberi & Johnson 2011:6); self-care, defined as the daily regimen tasks that an individual performs to manage HIV/AIDS is not limited to taking pills; it involves behaviors such as sticking to healthy diet, regular exercise, avoidance of risky behaviour and medication adherence.

Self-efficacy is a known predictor of a wide range of health behaviour of patients on chronic medication including medication adherence (Kott 2008:60; Ogedegbe, Mancuso, Allegrante & Charlson 2003:523; Sleath, Blalock, Robin, Hartnett, Covert, DeVellis & Giangiacomo 2010:628; Zebracki & Drotar 2004:142; Hewlett et al 2001:1228), and has also been shown to influence adherence to ART (Johnson, Neilands, Dilworth, Morin, Remien & Chesney 2007:367; Rudy, Murphy, Harris, Muenz & Ellen 2009:188). In this study, it is conceptualized that self-efficacy in ART can be depicted as an individual's ability to continue taking ARV despite the various challenges that could be encountered in doing so.

2.2.1.2 Beliefs about medicines

The Health Belief Model (HBM) has been used in explaining variation in adherence to treatment in chronic medical conditions. Researchers have postulated that beliefs about medicines which is a component of the HBM is an important factor influencing medication use behaviour (Horne et al 1999:20). The Model postulates four key elements that determine a patient's adherence to treatment: firstly, the threat of the illness (perceived severity and susceptibility); secondly, positive outcome expectancy (perceived benefits from treatment); thirdly, barriers to using the treatment (e.g. expected disadvantages of treatment); and fourthly, intent (intention to adhere to the treatment regimen) (Kagee 2008:420). According to self-regulatory theory, patients' treatment perceptions and illness representations influence medication adherence (Reynolds 2003:117-124). Therefore, patients on chronic treatment often undertake a cost-benefit analysis, considering whether their beliefs about the necessity of medications for maintaining health outweigh their concerns about the potential adverse effects of taking them (Lennerling & Forsberg

2012:44; Gonzalez, Penedo, Llabre, Duran, Antoni, Schneiderman & Horne 2007:51). This perspective led to the development of the Beliefs about Medicines Questionnaire (BMQ) by Horne et al (1999) who reason that a separate, specific measure to gauge patients' beliefs about medicines would add to the explanatory power of the HBM. The authors argue that an enhanced understanding of patient's beliefs about their medications could inform the development of interventions to improve adherence and optimize the benefits they derive from such medicines (Horne et al 1999:20).

The use of medication is strongly influenced by patient's perception on the benefits of taking such medication (Redding et al 2000:183; Gauchet, Tarquinio & Fischer 2007:145). One could easily assume that positive or negative medication beliefs would influence medication use behaviour, but variables such as medication cost and the level of patient trust in the prescriber may also influence non-adherence in persons with favourable attitudes towards their medications (Gauchet et al 2007:145). Patients often conceptualize the use of medication as *necessary* to achieve specific health goal. In this research, the perceived health benefits of medication use are operationally defined as the perceived necessity of medication for the target condition; the target condition is HIV disease. The perceived necessity of medication is also driven by interaction of two variables in patients namely; the perception that they are *susceptible* to the target condition and the *perceived severity* of the condition should it occur (Munro et al 2007:104). Each of the two variables is considered to be necessary but insufficient for an individual to perceive that a medication is necessary for their health, and hence the model postulates that the interaction between these two rather than their main effects will be associated with the necessity for adhering to ART by patients.

Health belief model also postulates *perceived effectiveness* of the medication to treat the target condition as a predictor of medication use behaviour (Munro et al 2007:104; Kagee 2008:420). Perceived necessity for medication is also influenced by concerns about the long-term safety of and dependence upon medications; patients' concerns about medications are often generalized, thinking that all medications have some form of negative qualities which is also true of ART (Liu-Seifert et al 2007:12; Guimarães et al 2008:167; Menezes de Pádua et al 2007:23). Various studies across a range of chronic medical conditions have identified similarities in beliefs that influence medication adherence; these studies have found low rates of adherence to be consistently related to doubts about personal need for medications (Neame & Hammond 2005:764; Porte-

ous, Francis, Bond & Hannaford 2010:228; Ireland & Wilsher 2010:39). Given that perceived need for ART includes the beliefs that use of a medication is necessary to maintain or improve one's health, concerns about the long-term harm of medications logically have a negative association with those beliefs (Gauchet et al 2007:145).

Cognitive intervention in ART is aimed at changing the patient's behaviour and attitudes through assisting the individual in changing unrealistic expectations or behaviour through education to learn how to do things in a new or different ways. People can control or influence the events that affect their lives by integrating cognitive, social, and behavioural sub-skills related to beliefs of personal efficacy in performing these skills (Bandura 2004:144). Cognitive perspective of health behaviour focuses on effective self-management behaviour of health habits that keep people healthy for the rest of their life (Bandura 2004:151). HIV-infected patients need to have confidence in their ability to perform the required self-management activities (self-efficacy) and hold positive beliefs about their medications. They must believe that exhibiting self-care behaviour and holding the right beliefs about their medications lead to good clinical outcomes which translate to quality health. This research is based on the assumptions that possessing a high level of self-efficacy towards ART adherence and positive beliefs about medicines will increase the likelihood that an individual would be more motivated to actively achieve high adherence to ART and good clinical outcome.

Prediction of medication adherence is very complex, and health-related knowledge and beliefs alone are insufficient to achieve behaviour change especially in chronic condition like HIV/AIDS. The cognitive perspective of health behaviour assisted the researcher to understand how HIV-infected patients on ART interpret and evaluate situations around them as well as their self-conception as to whether they will have self-efficacy in adhering to treatment. In this study, the researcher examined a theoretical framework encompassing health beliefs/attitudes, ART self-efficacy and demographic characteristics in relationship to antiretroviral therapy adherence as shown in Figure 2.1 below.

This research examined the relationships between two individual factors (self-efficacy and beliefs about medicines) and the health behaviour (HIV medication adherence) in an attempt to identify the potential area for focused interventions that could be used in developing a framework for enhancing ART adherence.

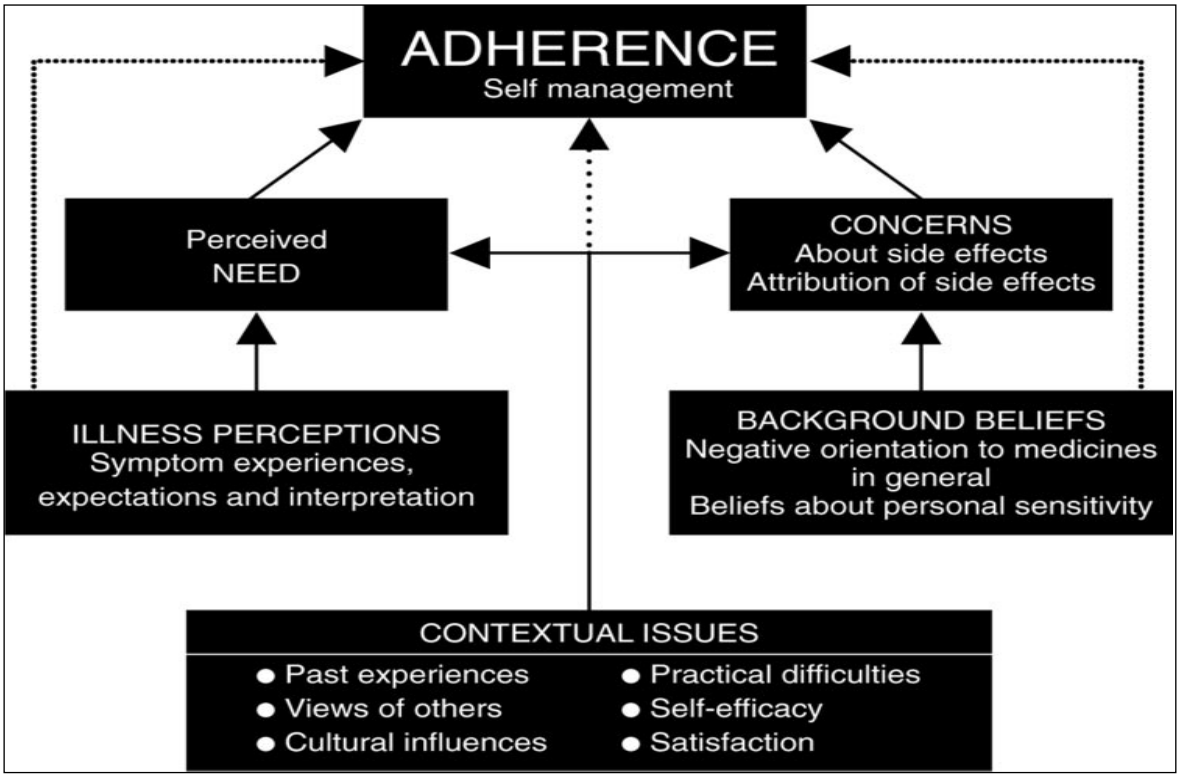

Figure 2.1 Theoretical framework: ART adherence is influenced by self-efficacy, beliefs about medications, perceived severity of the disease and individual's past experience

(Adapted from Horne 2006:71S)

2.3 EPIDEMIOLOGY OF HIV/AIDS

The HIV and AIDS have become the most challenging public health concern of this generation especially in sub-Saharan Africa that is saddled with over two-thirds of the global HIV/AIDS caseload despite having limited resources (UNAIDS 2010). At present, an estimated 35 million people are living with HIV/AIDS worldwide of which 31 million are adults, 16 million women, and over 2.5 million are children. The estimated number of AIDS-related deaths was around 2 million in year 2009 alone. In Sub-Saharan Africa, an estimated 22.5 million people live with HIV/AIDS, and since 1981 when the first case of AIDS was discovered, over 60 million people have been infected with HIV and close to 25 million people have died of AIDS-related complications (UNAIDS 2010).

Most sub-Saharan African countries including South Africa have reported decline or stabilization in the rate of new infections but according to recent statistics, about 5.7 mil-

lion South Africans are living with HIV (UNAIDS 2010), which makes South Africa epidemic the highest globally. AIDS-related death is nearly 450,000 annually in South Africa and the number of AIDS orphans in the country is over 1.9 million (StatSA 2009; WHO/UNAIDS 2009). There is no doubt that HIV/AIDS places huge economic burden on the government of South Africa considering the cost of HIV Counselling and Testing (HCT) services, antiretroviral therapy, treatment of opportunistic infections associated with HIV, loss of manpower and the enormous human resources involved in the provision of HIV/AIDS services. Therefore, reduction in the prevalence of HIV/AIDS, the rate of new infection and comprehensive management of the present caseload of the disease are global priorities that are particularly relevant to South Africa (Sawers & Stillwaggon 2010:216-217).

Key drivers of the HIV epidemic in sub-Saharan Africa include multiple and concurrent sexual partners, intergenerational sex, commercial and transactional sex, serodiscordant couples, low rates of male circumcision, lack of consistent condom use, high rate of sexually transmitted infections, especially genital herpes and high level of alcohol abuse (Simon, Ho & Abdool Karim 2006:490). Effective HIV prevention is therefore a major strategy to reverse the continued global spread of the disease and to safeguard a sustainable response to the enormous growing needs for HIV/AIDS care and treatment.

2.4 CLINICAL ASPECT OF HIV

2.4.1 Pathogenesis of HIV

The HIV is a retrovirus of the lentiviruses family; infections with lentiviruses are often characterized by a long period of clinical latency, persistent viral replication and follow a chronic course of disease (Rubbert, Behrens & Ostrowski 2007:60). HIV comprises of two species namely HIV-1 and HIV-2 which originated as zoonotic infection from primate hosts that harbour certain lentiviruses called the simian immune-deficiency virus (SIV). This virus is sexually transmitted among primates but does not result in frank immunodeficiency despite lifelong infection and levels of viraemia that exceed those in HIV-infected human subject (Kaur & Johnson 2003:80). HIV-1 originated from Central Africa from chimpanzee lentivirus and HIV-2 from monkey, it is assumed that human beings became infected during the slaughtering of these animals for the consumption of their meat (Volberding & Deeks 2010:49; Rubbert et al 2007:60).

HIV-1 was first isolated in 1983 (Barre-Sinoussi, Chermann, Rey et al 1983:870); it is found worldwide and is made of four groups the M (major), N (non-M, non-O), O (outliers) and P. Most of the HIV-1 infections are caused by the M type which is further subdivided into 10 subtypes A to J. The subtype-C is the commonest HIV-1 in Central and Southern Africa regions and in the Western Europe and America the subtype-B is the commonest (Volberding & Deeks 2010:50). HIV-2 on the other hand was isolated in 1986, is made of subtypes A to E, mostly confined to West Africa and is mainly acquired through heterosexual intercourse (Clavel, Guetard, Brun-Vezinet et al 1986:344). Under the electron microscope HIV-1 and HIV-2 look similar, the differences are in the molecular weight of their proteins and their accessory genes. Although actual immune deficiency may be less severe in HIV-2, both HIV-1 and HIV-2 replicate using the CD4 T cells (Rubbert et al 2007:60).

The diameter of an HIV-1 viral particle is about 100nm and is made up of two copies of the single-stranded RNA viral genome packed inside a protein core, this protein core comprises of the structural proteins namely; p24 (capsid), p17 (matrix), p7 (nucleocapsid) and the p55 (Gag-Pol precursor protein). The viral particle is also made up of the polymerase proteins which are p66/p51 (reverse transcriptase), p11 (protease) and the p31 (endonuclease/integrase) used in the early stage of the virus life during replication (Greenberg & Cammack, 2004). A lipid envelope surrounds the HIV capsid, this envelope is derived from the cell that has been infected by the virus and contains the gp120 (outer glycoproteins), gp41 (transmembrane glycoproteins) and the gp160 (precursor glycoproteins) (Wilson et al 2007:51:19).

The cells that express CD4 receptor are the ones that are usually infected by HIV although some cells like neurons that do not express CD4 may also be infected by HIV (Wilkins 2011:387-389). Cells that express CD4 that are targets of HIV include T-helper cells and other white blood cell like monocytes and macrophages; glial cells in the central nervous system; Langerhans cells in skin and mucous membrane and the chromaffin cells in the intestine. In addition to the CD4 receptor, certain human cell surface proteins are necessary for HIV entry into the human body. These proteins are called co-receptors and two of them have been identified for HIV-1 to be fused to its target cell. The first is CCR-5, a chemokine receptor which is expressed by monocytes and lymphocytes and mediates the entry of syncytium-inducing (NSI) monocytotropic strains

of the HIV-1 (Greenberg & Cammack 2004:334). The second chemokine receptor is CXCR-4 which is expressed on T-lymphocytes and mediates the entry of syncytium-inducing T-cell tropic strains of HIV-1. This means that monocytotropic strains of HIV can infect both monocytes and primary lymphocytes which express CCR-5 but cannot infect T-cell which lack CCR-5. Conversely the T-cell tropic strains of HIV-1 cannot infect monocytes which lack the CXCR-4 (Wilkins 2011:388).

2.4.1.1 The life cycle of human immuno-deficiency virus

The virus binds to the T-Helper cells with the aid of two proteins; these are the gp120 on the surface of the HIV itself and the CD4 on the surface of the T-Helper cells (Rubbert et al 2007:60). Thereafter the virus fuses with the plasma membrane of the T-Helper cell and releases its genetic material a single stranded RNA into the host. Once the viral RNA is released into the cytoplasm of T-helper the viral reverse transcriptase enzyme uses it to produce a single complementary strand of DNA using the nucleotides from the host cell. The single-stranded virally encoded DNA acts as a template for the production of a complementary DNA strand, forming a double stranded DNA molecule which then migrates into the nucleus of the host and incorporates into the genome of the host with the aid of the enzyme integrase, this incorporated virus is called the provirus. The virus at this stage is not infectious and can be latent for several months, which is the reason why antibodies are not produced immediately after infection since the immune system has to wait for macrophages to present the viral antigens for it to start producing antibodies (Greenberg & Cammack 2004:334).

The latter stage of the cycle includes the transcription of the DNA provirus into RNA which are divided into two parts; the mRNA which is used as template for translation of viral proteins and the viral RNA which forms the viral genetic material (Wilson, Naidoo, Bekker, Cotton & Maartens 2007:20; Boyd & Pett 2008:66). An HIV enzyme called protease cleaves p24, p17, p9 and p7 *gag* proteins. New viruses then bud from the cell and each may then go to infect and destroy other T-cells weakening the immune system of the host (Wilson et al 2007:21).

2.4.1.2 The natural history of HIV infection

Immediately following infection, the acute viral syndrome of primary HIV infection follows; this is the interval between infection and development of antibody response by the host. The virus titre rises and the patient experience a flu-like symptoms often characterized by fever, rash and swollen glands. These usually appear within days or weeks following infection although not all patients exhibit these mononucleosis symptoms (Volberding & Deeks 2010:50)

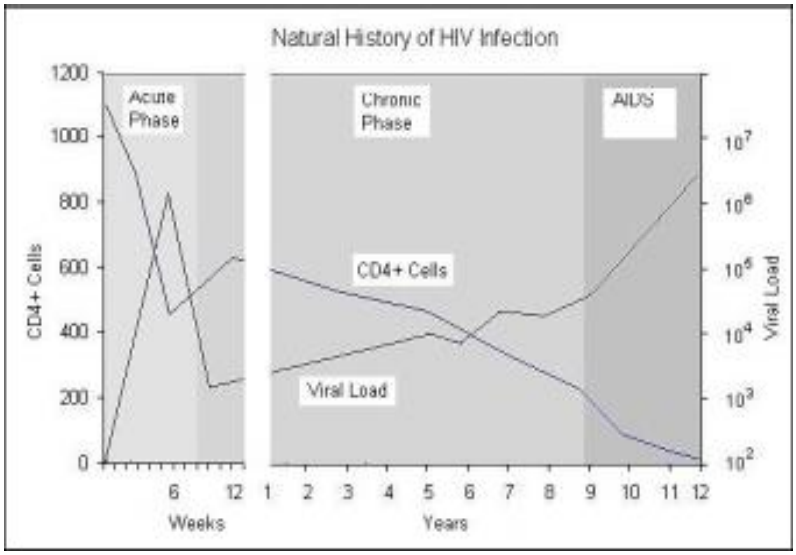

Figure 2.2 Natural history of HIV infection

(Kamps & Hoffman 2007:25)

There is an initial fall in the number of CD4 cell and a minimal rise in the CD8 cells, this number quickly return to normal shortly thereafter. A strong defence against the virus is mounted by both cytotoxic B and T lymphocytes and this greatly reduces the amount of virus in circulation (Wilkins 2011:387-389). Over 10 billion new viral particles are produced daily at this stage and they are cleared rapidly from the blood stream. Most of the viruses produced at this stage are from recently infected proliferating CD4 cells, these infected cells are destroyed by either the immune system or the virus itself. At this stage the rate of CD4 production can still compensate for the loss of cells. This is the most infectious phase of the HIV disease and most individuals exposed to HIV will seroconvert within one to four weeks (Wilkins 2011:387-389).

Following acute infection a state of equilibrium may be reached between host immune system and viral replication and the patient may not show any clinical symptoms for

years. This clinical latency stage though devoid of symptoms, viral replication and CD4 destruction in the host continues (Wilkins 2011:387-389). The immune response of the cytotoxic B and T lymphocytes clears the virus from the blood but it persists in lymph nodes especially in association with dendritic cells. Because CD4 T helper cells are the target of HIV, the immune system will fail to control the infection. In addition, the dendritic cells are supposed to present antigen to CD4 cell; in doing this they bring the virus (antigen) into contact with the CD4 cells thereby further destroying the CD4 cells (Wilkins 2011:387-389).

The cytotoxic T CD8 and the virus continue to destroy the T cells and the T cells also decline through apoptosis. This results in fall in CD4 cell, rise in viral load and decline in immune system activity. This loss in immune activity enables benign organisms such as the fungi and protozoa to cause diseases. At the stage the CD4 is usually below 200 cells/cm and mortality is high if patients are not commenced on ART. The CD4 cells decline as a result of direct or indirect destruction of CD4 cells in the peripheral immune system (Napolitano 2003:160). After many of the T-Helper cells have been destroyed, the immune system of the host would have been weakened to the point of developing opportunistic infections and is therefore said to have acquired immune-deficiency syndrome (AIDS). The CD4 cell count is therefore often used as a prognostic factor or in determining when to initiate treatment, as it gives the extent of damage to the immune system of the patient (Wilson et al 2007:51).

2.4.1.3 Modes of HIV transmission

Unprotected heterosexual intercourse has been described as the major route of HIV transmission worldwide and is closely followed by homosexual intercourse (UNAIDS 2010). The risk of acquisition of HIV from an infected person varies and some other factors affect the transmission of HIV through heterosexual intercourse, some of the factors include STIs, viral load of source patient, male circumcision (Wilkins 2011:387). The risk of HIV transmission also increases in cases of multiple concurrent sexual partners and as proportion of unprotected sexual acts increases (UNAIDS 2010; Wilson et al 2007:62).

High rates of HIV infection have been reported among men who have sex with men (MSM) in all regions of the world (Ndiaye et al 2009:250; Baral, Sifakis, Cleghorn &

Beyrer 2007:1905). A systematic review of data from 38 low and middle income countries found that MSM are 19 times more likely to have HIV than the general population (Baral et al 2007:1905). Receptive anal intercourse carries the highest risk of HIV infection and the presence of STI also increase the risk. Most HIV-1 infections contacted through sexual intercourse result from exposure to virus in semen, what remains unclear is whether transmitted strains originate as RNA virions in seminal plasma or as integrated proviral DNA in infected seminal leukocytes. A recent study done among six transmitting pairs of men who have sex with men showed that virus found free in seminal plasma of the transmitting partner consistently bore the closest resemblance to the virus found in the newly infected individual. The authors acknowledge that these results provide the most compelling experimental confirmation that cell-free HIV RNA in seminal plasma, and not cell-associated HIV DNA in seminal cells, is the origin of sexually transmitted virus between MSM (Butler et al 2010:18)

Injection drug use also carries a high risk for HIV transmission, about 3 million of the estimated 13-16 million injection drug users (IDU) population worldwide are living with HIV/AIDS (Mathers et al 2008:1742; Aceijas et al 2004:2296). It is estimated that between 5-10% (2-4 million cases) of all HIV infections globally are attributable to injection drug use (Mathers et al 2008:1739). There is wide variation in the incidence of HIV transmission among injecting drug users (IDU) worldwide, Eastern Europe, East and South East Asia and Latin America have the largest estimated populations (40%) of injecting drug users who are HIV positive (Mathers et al 2008:1742). About 10% of new HIV infection in Africa, Southeast Asia and the Caribbean occur in children, an estimated 370,000 new HIV infections in children was reported in 2009 and about 90% of these HIV infections were acquired in-utero, during delivery or through breastfeeding (UNAIDS 2010).

2.4.2 Prevention

2.4.2.1 Sexual transmission

This involves activities to promote abstinence, including delay of sexual activity or secondary abstinence, fidelity, reducing multiple and concurrent partners, and related social and community norms that impact these behaviours. According to Kennedy, Medley, Sweat and O'Reilly (2010:620), these activities should provide individuals being target-

ed with the relevant motivation and skills needed to adopt safer behaviors rather than solely focusing on improving knowledge or awareness of HIV. Provision of both male and female condoms made available widely through health facilities, social marketing and retail outlets with emphasis on consistent and correct use has been shown to reduce HIV transmission (Kennedy et al 2010:620).

Research has shown that sex workers experience higher rates of HIV infection than most other population groups, however, worldwide less than 50% of sex workers have access to a package of prevention services (Bertozzi, Laga, Bautista-Arredondo & Coutinho 2008:831-844; UNAIDS 2009). Even where services are theoretically available, sex workers face substantial obstacles to accessing HIV prevention, treatment care and support, particularly where sex work is criminalized. Therefore, an effective preventive strategy addressing sexual workers has been described as highly necessary to curb the spread of HIV by this high-risk group (UNAIDS 2009).

Medical male circumcision (MMC), the surgical removal of the penis foreskin is an effective intervention to reduce the risk of male heterosexually acquired HIV infection. Already three randomized control trials have indicated that MMC in adult reduces men‘s risk of HIV acquisition by at least 60%, a potential protective effect equivalent to a vaccine (Auvert et al 2005:11; Bailey, Moses, Parker et al 2007:651; Gray, Kigozi, Serwadda et al 2007:664). In addition, observational studies indicate that MMC may be even more protective among Most at Risk Persons (MARPs) engaging in sex with women (Auvert et al 2005:11). Based on modelling studies done on MMC, it has been predicted that the benefits of the procedure are likely to be significant in populations with high HIV prevalence and low MMC uptake, with one HIV infection averted for every five to fifteen MMC performed (UNAIDS 2007; UNAIDS 2009). Although the ultimate effect may only be apparent in ten to twenty years from now; as HIV prevalence decreases among circumcised men, there is an indirect protective effect against HIV for women, women‘s uncircumcised male sexual partners, and ultimately the whole population (UNAIDS 2009).

The Pre-exposure Prophylaxis Initiative (iPrEx) study on oral pre-exposure prophylaxis (PrEP) for HIV prevention among MSM using oral co-formulated emtricitabine 200 mg/tenofovir 300 mg (truvada) or placebo found that a daily dose of oral truvada reduced HIV infection risk among men and transgender women who have sex with men

(MSM) by an average of 43.8% (Grant, Lama et al 2010:2597). Although the research findings are promising in the prevention of HIV, the authors cautioned that their data on the biological activity of the PrEP drug has to be confirmed through further studies.

Microbicides are being tried as a protective measure for HIV transmission especially for use by women. Microbicides are medical products that can be applied vaginally to prevent sexual transmission of HIV; it could be in forms of gels or tablets. Although microbicides have shown promising results, more research is still needed before it can be made available as a means of HIV prevention. Tenofovir gel, one of such microbicides that have been researched has shown new dimension in preventing HIV infection and could help empower women to take control of their own risk of HIV infection, it demonstrated overall protection of 39% among women and increased to 54% in women that used the gel consistently (Abdool Karim et al 2010:1171).

Some researchers have even proposed highly active antiretroviral treatment (HAART) to be used as a form of prevention for HIV transmission since research has shown that transmission is very low at viral load less than 400copies/ml (Simoni et al 2006:S30). In a mathematical modelling by Granich et al (2010:1) they predicted that if adults are started on treatment immediately irrespective of CD4 count, the incidence and mortality of HIV would be reduced to less than one case per 1000 people within ten years, although the authors acknowledge that the cost; ethical and human rights consequences make this option a distant choice in most developing nations for now (Granich et al 2010:1).

2.4.2.2 Prevention for Injecting and non-injecting drug users

The use of illicit drugs promotes behaviours that increase the risk for HIV infection. The nature of the drug being abused, its quantity as well as the route of administration is important in determining drug use that promotes high risk behaviors for HIV infection (Kerr et al 2005:546). People who inject drugs are at risk for acquiring and transmitting HIV through high-risk sexual behaviours, including but not limited to unprotected sex and engaging in sexual behaviours under the influence of drugs or in exchange for drugs. Substance abuse treatment has been shown to reduce the frequency of drug use which in turn reduces HIV risk behaviours, it also improves adherence to treatment regimens of disease condition (Xing, Sun, Cao et al 2012:758). Methadone maintenance therapy

(MMT) is associated with reduced HIV risk behaviours including reduced frequency of injecting and sharing of injection equipment, reductions in the number of sex partners, and exchanges of sex for drugs or money (Xing, Sun, Cao et al 2012:758; Zaric, Brandeau & Barnett 2000:1022:Tran, Ohinmaa, Duong, Do, Nguyen, Mills, Houston & Jacobs 2012:286).

2.4.2.3 Prevention of mother-to-child transmission (PMTCT)

An estimated 25% of HIV-infected mothers will infect their babies if no intervention were made (Coovadia 2009:319), but with the introduction of ART to prevent mother to child transmission, the risk in-utero and during delivery has been drastically reduced (Kilewo et al 2009:400), the main concern in resource-limited settings at present is the high risk of postnatal transmission of HIV in the infant (Wilfert & Fowler 2007). Although infant feeding options have shown promising results in the reduction of mother to child transmission (Nduati, John, Mbori-Ngacha, Richardson, Overbaugh, Mwatha, Ndinya-Achola, Bwayo, Onyango 2000:1171), higher infant mortality have been reported among infants who were formula fed compared to breastfed infants. In a Botswana study, infant mortality at 7 months was significantly higher for the formula fed group than for the breastfed plus zidovudine group (9.3% vs 4.9%). This demonstrates the risk of infant formula in sub-Saharan Africa with widespread unsafe practices in preparation of the infant formula (Thior, Lockman, Smeaton, Shapiro, Wester, Heymann, Gilbert, Stevens, Peter, Kim, Van Widenfelt, Moffat, Ndase, Arimi, Kebaabetswe, Mazonde, Makhema, McIntosh, Novitsky, Lee, Marlink, Lagakos, Essex & the Mashi Study Team 2006:798).

Recently the use of extended prophylaxis with nevirapine or with nevirapine and zidovudine for the first 4-6 weeks of life in HIV-exposed infants have been advocated as research has shown that it significantly reduces postnatal transmission of HIV infection (WHO 2012; Kumwenda, Hoover, Mofenson et al 2008:122). Experts have advocated for the use of HAART among HIV-infected pregnant women and this is also recommended by South African national guidelines on ART (NDOH 2010b).

2.5 ANTIRETROVIRAL THERAPY

Antiretrovirals (ARV) are drugs used in the treatment of HIV/AIDS, the mechanism of actions of the drugs are based on the life cycle of the virus. Therefore, ARV is meant to interrupt the life cycle of HIV; and it does so at different points to reduce the replication of the virus. ARVs were introduced in early 1980 when a nucleoside reverse transcriptase inhibitor (NRTI) called zidovudine was introduced as a mono-therapy with very little benefit as viral replication was minimally suppressed and resistance was quick to develop (Clumeck & De Wit 2000:8). The development of more drugs in the same class with zidovudine in early 1990s made dual therapy available but this also failed to suppress viral replication effectively. The introduction of non-nucleoside reverse transcriptase inhibitors (NNRTI) and protease inhibitors (PIs) in mid 1990s allowed for the combination of ARV of different classes which effectively suppressed viral replication resulting in reduction of morbidity and mortality associated with HIV/AIDS (Clumeck & De Wit 2000:9).

2.5.1 Goals of antiretroviral therapy

The main objective of antiretrovirals is to decrease the plasma HIV RNA and maintain it below the limit of detection, viral level < 400 copies/ml is arbitrarily assumed to be a point at which viral level is below detection (Clumeck & De Wit 2000:7) although low level of viral replication has been documented in people with HIV RNA levels between 50-500 copies/ml (Gross et al 2001:2113). The suppression of viral replication achieved by ART reduces the destruction of CD4 cells and damage to the immune system which in turn slows down the progression of the disease. This effect is shown in the rising CD4 cells and reduction in the viral load. In addition, there is restoration or preservation of immunologic function, improved quality of life and reduced HIV-related morbidity and mortality (Severe et al 2010:261).

2.5.2 Challenges of taking antiretroviral

Research has documented that using multi-therapies of ART regimens have significantly improved quality of lives of HIV patients and improved survival (Reddi, Leeper, Grobler et al 2007:13; Wool-Kaloustian et al 2006:43). However, high levels of adherence are very important for this to be realized. The ART regimen is so complex; it con-

sists of 3 or more drugs that have to be taken in combination. In addition, it involves timing of the medication intake, dietary and fluid restrictions all which influence medication adherence (Curioso, Kepka, Cabello, Segura & Kurth 2010:13).

The pill burden is a major challenge for patients taking ART as some of these patients may also have co-morbidities like asthma, diabetes, hypertension and arthritis. They are therefore required to take treatment for these and some other prophylaxes against opportunistic infections, multi vitamins and even be on treatment for tuberculosis. The pill burden, therefore becomes enormous and constitutes a major challenge in the administration of ART (Frank 2002:S10).

The side-effects of ART are another major challenge of taking the medications and this has been reported as the reasons why some do not adhere to their treatment (Frank 2002:S10). The stigma and discrimination associated with HIV/AIDS within the society unlike any other chronic illnesses constitute one of the greatest challenges facing people on ART (Elliott, Utyasheva & Zack 2009:29). Due to this stigma, taking ART without considering what onlookers would say or think is a great concern for people living with HIV/AIDS (PLWHA) as some would rather take the drugs in secrecy which otherwise may affect their compliance to the treatment (Hardon et al 2007:662; Weiser et al 2003:285).

2.5.3 Initiation of antiretroviral therapy

The decision to initiate ART requires weighing the benefit of treatment on the morbidity and mortality of HIV/AIDS, the adverse drug reactions, cost of the treatment, drug interaction and the ability of the patient to maintain a lifelong therapy on HAART (Thompson et al 2010:322). Therefore, HAART regimens need to be individualized after a full baseline assessment, HIV resistance testing, hepatitis screening, cardiovascular risk assessment, screening for diabetes and renal problems. For women it is advisable to discuss issue of pregnancy, and there is also need for psychosocial history of the patients to identify psychiatric problems, alcohol use and recreational drug use. ART regimens have to be chosen taking into consideration the patient's working and family life, especially the cost implication of the drugs to ensure continuous uninterrupted supply so that adherence could be optimized (Volberding & Deeks 2010:53).

Total CD4 cell counts are used worldwide as an indicator of when treatment should be initiated; this is often combined with the viral load. Using CD4 percentage has been advocated by clinicians as it has some additional prognostic value independent of the total CD4 count. The limitation of this is that it may result in deferral of treatment in some patients with CD4 count less than 350 cells/mm^3 but high CD4 percentages, or support initiation of ART earlier in patients with CD4 count higher than 350 but low CD4 percentages (Gazzard et al 2008:570).

Starting ART at CD4 below 350 cells/mm^3 or in symptomatic disease is associated with higher risk of disease progression and death (Thompson et al 2010:322). Recent trends in ART have shifted the therapeutic risk-benefit balance towards earlier treatment of HIV/AIDS (Severe et al 2010:263). The WHO recommends ART to be started in all HIV-infected patients with CD4 ≤ 350 cells/mm^3 and those who are in WHO clinical stage III or IV whose CD4 test is not available (WHO 2010:29). According to the British HIV Association guidelines, HIV-infected patients should be initiated on ART when the CD4 cell count is ≤ 350 cells/mm^3 (Gazzard et al 2008:570). The International AIDS Society of the USA guidelines recommend initiation of ART for all symptomatic HIV-infected individuals irrespective of CD4 cell count and for asymptomatic individuals; treatment should be started at CD4 ≤ 500 cells/mm^3. For patients with CD4 > 500 cells/mm^3 and have co-morbidities, it is suggested that ART initiation should be highly considered (Thompson et al 2010:322).

Studies have shown that initiating ART at CD4 between 350 – 500 cells/mm^3 was beneficial to patients as it decreased death rates and incident of TB, what is not fully clear is the benefit of initiating ART at CD4 above 500 cells/mm^3 (Thompson et al 2010:323; Severe et al 2010:262). It is now fully acknowledged that older age is associated with higher risks of AIDS and non-AIDS death, therefore early ART initiation is highly indicated among elderly HIV-infected population. Pregnant women should also be treated early at least by the second trimester to reduce the chances of vertical transmission and therapy should continue after delivery of the baby (Severe et al 2010:262).

Several current guidelines on ART have advised that the following factors be considered when initiating ART in a patient: co-morbid conditions (e.g. cardiovascular disease, liver disease, psychiatric disease, renal diseases, or tuberculosis); potential adverse drug effects; potential drug interactions with other medications; pregnancy or pregnancy

potential; results of genotypic drug resistance testing; gender and pretreatment CD4 T-cell count if considering nevirapine; HLA-B*5701 testing if considering abacavir; patient adherence potential; and convenience (e.g. pill burden, dosing frequency, and food and fluid considerations (Gazzard et al 2008:570; WHO 2010:41; Severe et al 2010:262).

2.5.3.1 Initiation of ART in South Africa

South Africa with the huge burden of the epidemic and limited resources has placed the cut-off point at CD4 of ≤ 250 cells/mm^3 for all patients with the exception of infants who qualify for ART irrespective of CD4 counts. Pregnant women and HIV patient with TB co-infection also qualify for ART at CD4 ≤ 350 cells/mm^3. In addition, HIV patients in WHO stage IV and those with MDR/XDR TB are to be initiated on ART irrespective of CD4 count (NDOH 2010a:6).

The eligibility for ART in South Africa for children includes both clinical and social criteria. For children between the ages of one to five years, they have to be initiated on ART if they are symptomatic at WHO stage III or IV. In addition, if their absolute count is < 750 cells/mm^3 or CD4 < 25%, they also qualify for ART (NDOH 2010b:26). For those who are five years or older, they qualify for ART if they are symptomatic at WHO stage III or IV and if their CD4 < 350 cells/mm^3 (NDOH 2010b:26).

The social criteria are hinged on the potential for adherence on ART. The national guidelines in South Africa dictate that at least one person is identified as a caregiver who is able to supervise the child and ensure that the medication is taken according to prescription. Furthermore, it is recommended that the HIV status of the child is disclosed to another adult living in the same house with the identified caregiver so that there is someone else who can assist with the treatment (NDOH 2010b:26). The baseline clinical and laboratory work up necessary before the treatment is commenced are measurement of the child's weight and height, staging of the disease, screening for TB, Full blood count test, CD4 count test and viral load testing. In addition to these, the health care worker may proceed to do some other specific tests depending on the regimen proposed for the child (NDOH 2010a:12).

For HIV-infected adult, following the establishing eligibility for ART, all patients have to be screened for TB, have CD4 test and viral load done together with full blood count.

Women of child bearing age are screened to rule out pregnancy, and WHO stage of the HIV disease is also determined. Serum creatinine test is compulsory if patient is going to start tenofovir, alanine transaminase test is also necessary if nevirapine will be included in the regimen and at least serum haemoglobin should be done before zidovudine is initiated in an HIV-infected adult (NDOH 2010a:15).

2.5.4 Antiretroviral drugs (ARV)

The six classes of ARV that are commonly used are the nucleoside reverse transcriptase inhibitors (NRTIs), the non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitors, integrase inhibitors and chemokine co-receptor antagonists. The later three are not readily available in resource-limited settings at present, South Africa ART regimens follow the WHO guidelines and they are informed by available resources. Standard therapy of combination ART includes two nucleoside reverse transcriptase inhibitors (NRTIs) and at least one PI. Another is two NRTIs plus on NNRTIs (WHO 2010:31).

2.5.4.1 Nucleoside reverse transcriptase inhibitors (NRTIs)

These were the first ARV used to treat HIV infections (Clumeck & De Wit 2000:8). NRTIs target the HIV reverse transcriptase enzyme and prevent the synthesis of viral DNA, therefore inhibiting the elongation of new DNA chain and stopping the viral replication process (Grigsby, Pham, Mansky, Gopalakrishnan & Mansky 2010:41). Dual-NRTIs have the class advantage as the established “backbone” of ART regimens when used in combination with other classes of ARV in the management of HIV/AIDS (Grigsby et al 2010:41). The major drawback is the potential of the dual-NRTIs causing lactic acidosis with hepatic steatosis which have been reported for most of the drugs in this class (Montessori, Press, Harris, Akagi & Montaner 2004:229). Examples of NRTIs include zalcitabine (ddC), zidovudine (AZT), stavudine (d4T), lamivudine (3TC), didanosine (ddI) and abacavir (ABC). Tenofovir is a newer NRTI which is used in combination with other antiretrovirals, it retains its viral suppressive activity against most NRTI-resistant HIV strains (Grigsby et al 2010:41). Addition of tenofovir to failing ART regimen has been shown to result in durable viral load suppression in treatment-experienced patients (WHO 2010:32; Grigsby et al 2010:41).

2.5.4.2 Non-nucleoside reverse transcriptase inhibitors (NNRTI)

NNRTI targets the reverse transcriptase enzyme binding in a reversible and non-competitive manner to a unique site on the enzyme that eventually alters its ability to function. When the NNRTIs were developed, their use was initially hampered by being given as mono-therapy which resulted in rapid resistance development (Clumeck & De Wit 2000:8). They have good oral bioavailability and their half-life is long which allows for once-daily dosage for efavirenz or once or twice-daily dosing for nevirapine (Clumeck & De Wit 2000:8). Safety of efavirenz in pregnancy is yet to be fully established although recent studies suggest it may be safe in early pregnancy (Bera et al 2010:287). They also have very good viral suppressive effect when given in combination with other ARVs, but have low threshold for resistance. This high degree of cross-resistance within the class limits the use of NNRTI (Clumeck & De Wit 2000:8). NNRTI have several drug-drug interactions since they induce cytochrome P450 enzyme causing other drugs to be metabolized faster and therefore reducing the concentration of such drug. Common NNRTI are nevirapine, delavirdine and efavirenz.

2.5.4.3 Protease inhibitors (PIs)

The enzyme protease is responsible for cleaving the polyproteins precursors that give rise to the viral envelope, core protein and enzymes; protease inhibitors inhibits this enzyme and halts the production of matured infectious virons. Some of the common PIs are saquinavir, indinavir, ritonavir, nelfinavir, amprenavir and lopinavir. These drugs are very efficient when used with the NNRTIs and NRTIs leading to profound and durable viral suppression (Clumeck & De Wit 2000:8). The major drawbacks of PIs are short half-lives, variability in oral absorption, dietary requirements and drug restrictions. The metabolic disorders associated with protease inhibitors may preclude their lifelong use because of the risk of artherogenesis and thrombogenesis. PIs also interact with other drugs metabolized by P450 because they act as inhibitor of P450 leading to elevated levels of many drugs that are metabolized by P450 (Volberding & Deeks 2010:51).

2.5.4.4 HIV fusion inhibitors

The first drug in this class is enfuvirtide; it acts by inhibiting the fusion of HIV and CD4 cells. This drug targets a structural transition in the viral envelope glycoprotein gp41 re-

quired for membrane fusion and virus entry (Boyd & Pett 2008:67). Enfuvirtide has a potent antiretroviral activity but its major drawback is the twice-daily administration by subcutaneous injection (Boyd & Pett 2008:68). It requires extensive patient counselling on injection technique and how to maintain strict adherence as injection site reactions may affect patients' compliance with the drug. Enfuvirtide is yet to be available in most sub-Saharan Africa countries.

2.5.4.5 HIV integrase inhibitors

The drugs in this class act by inhibiting the HIV integrase enzyme which is necessary for the incorporation of viral DNA into the host cell genome. Raltegravir is the first in this class and by blocking HIV integrase enzyme it inhibits HIV replication (Pommier, Johnson & Marchand 2005:236). The drug is used in combination with other ARVs and is very potent in treating HIV patients who have developed resistance to older medications. Currently the drug is indicated in treating patients who have developed resistance to other ARV as salvage therapy (Yilmaz, Gisslen et al 2009:e6877). Like the fusion inhibitors, raltegravir is mainly available in resource rich settings and yet to be available in public health sectors in most developing countries.

2.5.4.6 Chemokine co-receptor antagonist

Chemokine co-receptor antagonist prevents the entry of HIV-1 into host cells by blocking the CCR5 co-receptor. Maraviroc is a member of this class of antiretroviral agents and works by blocking CCR5, a protein on human immune system cells that the virus uses as a portal to enter and infect the cell. Maraviroc binds specifically and selectively to CCR5 on the surface of the CD4 cell and blocks HIV-1 binding. In a study that compared maraviroc with placebo, it was demonstrated that the drug is associated with significant reduction in HIV viral load and increase in CD4 count among patients (Gulick, Lalezari et al 2008:1437). Maraviroc has been used in ART with good results although the drug has been linked to increase in frequency of upper respiratory tract infection and persistent cough among patients (Ghebremedhin 2012:4).

2.5.5 Drugs combinations in ART

Antiretroviral are used in combination to achieve maximal and durable viral suppression, the result in what is now called highly active antiretroviral therapy (HAART). The criteria used for the selection of drugs are often based on the properties of the drugs and how appropriate the regimen will be for the patient (Gazzard et al 2008:571). The first line regimen according to World Health Organization recommendations consist of two NRTIs plus NNRTI, one of the two NRTIs should be tenofovir or zidovudine (WHO 2010:31-32). The British HIV Association (BHIVA) also recommends efavirenz to be part of all first line regimens (Gazzard et al 2008:571). The second line regimen according to the WHO consists of a ritonavir-boosted protease inhibitor plus two NRTIs after considering what was used in the first line regimen (WHO 2010:53).

Abacavir when used in combination with zidovudine and lamivudine was earlier shown to be as efficacious as the combination indinavir, zidovudine and lamivudine (Clumeck & De Wit 2000:8). Recent data suggest that this combination is less potent than combining two NRTIs with either an NNRTI or PI (WHO 2010:39). High virological failure was reported and therefore triple NRTIs are no longer recommended in ART although some clinicians advocate for the combination of zidovudine/lamivudine/tenofovir with or without abacavir in exceptional cases when a PI or NNRTI-based regimen cannot be given to a patient (Gazzard et al 2008:574).

Combination of two NRTIs plus a boosted PI has been proven to be clinically beneficial in ART. When PIs are boosted with low-dose ritonavir they produce sustained viral suppression, significant CD4 cell rise and have high genetic barrier to resistance (Gazzard et al 2008:573). Ritonavir prolongs the half life of the PIs which makes it possible for reduction in pill burden and dosing frequency, in addition adherence is better achieved with less pill and dosing frequency (Bangsberg, Moss & Deeks 2004:697).

There are various regimens being used for patients with extensive antiretroviral experience who are falling their current therapy. The failure is often due to viral resistance to the drugs. Tenofovir has a distinct and unique drug resistance profile, the class-resistance that affects the NRTIs does not affect tenofovir; therefore it is useful in non-cross-resistant HAART regimens in salvage therapy, particularly with children and adolescents (Grigsby et al 2010:41).

2.5.6 Response to antiretroviral therapy

Long-term remission of HIV disease is readily achieved by combination of ART. Once ART has maximally suppressed HIV replication, the CD4 count slowly increases which results in improved immune functioning. Consequently, there is resolution of established opportunistic infections, decrease in risk of new infections, improved quality of life and weight gain in some patients who have become emaciated as a result of advanced disease (Janssens et al 2007:1137; Ware et al 2009:43). The clear linear relationship between virologic, immunologic and clinical outcomes is not straightforward in some cases, virologic non-responders and immunologic non-responders have described (Moore et al 2005:290). Virologic non-responders are patients with increasing CD4 cell count in the absence of viral suppression while immunologic non-responders are those with good viral suppression without increase in CD4 cell count. This discordance has been widely reported among poorly adherent patients and is associated with a higher risk of mortality (Moore et al 2005:290).

Treatment with HAART should result in prompt viral load decrease within two to four weeks of initiating therapy, and it is expected to reach a level below 400 copies/mL within four to 12 weeks and a target of below 50 copies in 24 weeks. Decline in viral load of at least 1_{log} from pre-treatment levels after 6-8weeks of starting antiretroviral therapy, decline in viral load to < 5,000 RNA copies/ml by 12weeks after starting antiretroviral therapy and viral load of < 50 copies are criteria used to determine treatment success in HIV/AIDS when triple therapy is instituted (Volberding & Deeks 2010:51).

The suppression of plasma viral loads to less than the limit of quantification is expected to lead to improvement in CD4 cell counts. The decrease in viral load is expected to go hand in hand with CD4 cell count, in the short term the impact of ART is more apparent in the viral load than the CD4 count because of the time delay in the two responses (Gross et al 2001:2114). This is the reason why immunologic response is not usually used in adherence studies, although some authors have reported that adherence is the most significant factor associated with increase in CD4 count (Gross et al 2001; Paterson et al 2000). The earlier misconception that CD4 count less than 350 cells/µL represented an irreparable damage to the immune system precluding a CD4 response to ART was disproved by Wood et al (2004:261-268). The study found that significant CD4 increase was possible in patients with advanced stage of HIV/AIDS who adhered to

treatment. Wood et al (2004:261-268) revealed that adherent patients with advanced HIV disease showed an increase in CD4 count as low as 50 cells/µL to 200 cells/µL.

Despite the high efficacy demonstrated by HAART, complete eradication of the HI virus is not possible. This inability of the ARVs to completely suppress the virus results in the selection of drug-resistant variants and therefore limits the long-term success of HAART (Volberding & Deeks 2010:51). Numerous factors contribute to failure of HAART, including suboptimal drug potency and pharmacokinetics, poor adherence to complex ART regimens, emergence of drug-resistant strains and compromised immunologic function in the patient (Clotet 2004:123; Duong et al 2004:221).

2.6 COGNITIVE-BEHAVIOURAL THEORIES AND MEDICATION ADHERENCE

Contemporary theories of health behaviour at the individual and interpersonal levels are referred to as cognitive-behavioural theories, key concepts of these theories stipulates that behaviour is mediated by cognition i.e. knowledge and attitude of a person affect the person's action (Rimer & Glanz 2005:12). In addition, cognitive-behavioural theories recognize knowledge alone as being insufficient to produce behavioural change; a person's perception, motivation, skills and social environment are influential in his behavioural change (Rimer & Glanz 2005:12). Individual level theories explore behaviour and focus on intrapersonal factors such as knowledge, attitude, beliefs, motivation, self-concept, past experience and skills. At the interpersonal level theories of health behaviour take into consideration that an individual exist within a society and is influenced by the social environment. Thoughts, behavior and opinion of people around an individual influence the feelings and actions of such person and the person also have reciprocal effects on those people (Rimer & Glanz 2005:12). Some of the theories frequently used in behavioural interventions are the health belief model, social cognitive theory, trans-theorectical model and theory of planned behaviour.

2.6.1 Health Belief Model

This is a psychosocial approach to explaining health behaviour. This model was introduced by psychologists Rosenstock, Hockbaum, Leventhal and Kegeles in the 1950s and has been used widely by various researchers. The model deals with value expectancies related to health. It is a cognitive and interpersonal approach that view human

as a rational being who behave in certain ways to minimize what they perceived as threat (e.g. disease symptoms) and enhance what are perceived as benefits (e.g. adherence to treatment) (Bandura 2004:145). The HBM comprises of some interactive states of belief, which collectively affect adherence.

2.6.1.1 Perceived susceptibility

This means that a person will seek preventive medical care if the individual believes he/she is at risk of developing a disease. Therefore, the perceived susceptibility of a disease brings to light the fact that the individual could actually get the disease (Redding, Rossi, Rossi, Velicer, Prochaska 2000:181).

2.6.1.2 Perceived seriousness

This implies that people tend to be more proactive in prevention of serious diseases than the ones perceived to be less serious. In other words susceptibility and seriousness combine to form what an individual perceives as a threat of a disease (Redding et al 2000:182). Perceived seriousness of HIV/AIDS are the consequences of being infected with the disease which are pain, disability, lifelong therapy on ARV and ultimately death (Dahab et al 2008:63).

2.6.1.3 Perceived benefits

The perceived benefit derived from health behaviour describes how effective an individual thinks the health behaviour will be. Health behaviour that results in an immediate benefit may be perceived as very effective since the effect is rapid and noticeable (Redding et al 2000:182).

2.6.1.3 Perceived barriers

These have influence on the action to be taken by a person, and include factors which an individual perceived as obstacles to the health action. An individual may feel that treatment takes too much time, requires too much effort or is too difficult to obtain. According to (Redding et al 2000:182), when perceived threat of a disease is high and

perceive benefits outweigh the perceived barriers, then there is high likelihood of health action being taken.

Health belief model also recognizes other factors that could influence health behaviour of a person. These include **predisposing factors** such as the individual values, beliefs, attitudes and perception of the disease. Another one is **enabling factors** such as issues around availability and accessibility of health resources. The last one is **reinforcing factors** that have to do with peer support, feedback and assurance given by health care worker to the patients to ensure treatment compliance (Redding et al 2000:182).

Perceived susceptibility to and severity (health consequences) of a disease are postulated to be driven by knowledge, attitude and practices of individuals (Bandura 2004:144). Similarly, background belief about the disease and the symptoms experienced are postulated to affect an individual's perceived susceptibility to and severity of the disease (Bandura 2004:144). In the context of South Africa, the general knowledge of the high prevalence of HIV/AIDS in South Africa and the health consequences of the disease is also perceived to influence perceived personal susceptibility to and severity of HIV/AIDS (Dahab et al 2008:63).

Medication use behaviour is also influenced by the direct experience of medication adverse effects (Munro et al 2007:104). The experience of adverse drug reactions requires the occurrence of the adverse event and the causal attribution of the event to one or more of the ARVs. A patient with prior adverse drug reactions to medication which is an indication of personal negative experience with medications may logically strengthen such belief to attribute adverse event easily to ARVs. Therefore, medication use behaviour of such patient is influenced by belief of potential adverse effects of the medications (Munro et al 2007:104).

The patient's perception of their relationship with their health provider is also postulated to influence their medication use behaviour. Health providers potentially have substantial influence over the level of knowledge that patients have about the target condition and the adverse health consequences of that condition as well as about the medications themselves (Skovdal, Campbell, Nhongo, Nyamukapa & Gregson 2011:309). In addition, the patients' trust that their health providers are competent and knowledgeable about HIV/AIDS will influence the acceptance of and belief in the advice and education

that they receive regarding the threat to their health from the target condition and the risks and benefits of the proposed medication to reduce that threat (Skovdal et al 2011:309). Further to this, the patients' perception of health providers' concern about their welfare, being involved in decision-making process regarding management of their health, and good communication with the health providers are all influential in patients' medication use behaviour (Gauchet, Tarquinio & Fischer 2007:141–150).

2.6.2 The social cognitive theory

Social cognitive theory (SCT) explains human behaviour in terms of a dynamic, reciprocal and continuous interaction between the individual and the environment (Bandura 1988:276). The common theoretical basis of cognitive theory is learning as human behaviour is learned, therefore, SCT proposes that behaviour is the result of cognitive processes that people develop through the social acquisition of knowledge (Bandura 1988:299). This theory focuses on the concept of behavioural capability, which states that before an individual acts in a given circumstance the person needs to know what to do and how to do it. Bandura's conceptual model of reciprocal determinism addresses the personal determinant of health; he postulates that a person engages in cognitive, vicarious, self-reflective, and self-regulatory processes to achieve a set goal (Bandura & Adams 1977:288; Rosenstock et al 1988:176). He goes further to say people effect change in themselves through their actions in anticipatory, proactive ways by exercising control over their behaviour through their thought processes, motivation, and action (Bandura 2004:145). Without aspirations, Bandura claims people remain unmotivated and uncertain about their capabilities.

Individuals with health promoting behaviour possess self-beliefs, enabling them to exercise control over their thoughts, feelings, and actions (Clark & Dodge 1999:84). Therefore, people who engage in self-management of health habits reduce major health risks and live healthier and more productive lives (Clark & Dodge 1999:86). According to Bandura (2004:145), although SCT acknowledges that knowledge of health risk and benefit of treatment are necessary to perform health behaviour, this in itself is not enough, additional self-influences are necessary to achieve changes that will result in the desired health behaviour, this concept is called self-efficacy.

Cognitive technique in counselling by health care worker assist the patient to learn relevant information about HIV/AIDS and the courses of action to make in taking decision about their disease and solving problems (Skovdal et al 2011:309). The support groups in HIV/AIDS use cognitive and behavioural strategies to empower patients to handle problem and establish supportive relationships. Issues around disclosure of HIV status, relaxation skills, anxiety management and treatment education are skills taught in these groups that may result in better adherence to treatment (Skovdal et al 2011:309). The two cognitive processes that influence behaviour have been described as outcome expectation and self-efficacy expectations.

2.6.2.1 Outcome expectation

An outcome expectation is the belief that a particular behaviour will result in a specified outcome or effect, and outcomes can either be positive or negative. This theory postulates that an individual will choose an action that he or she believes will maximize a positive outcome and minimize a negative outcome (Redding et al 2000:185). Cognitive intervention in ART is aimed at changing the patient's behaviour and attitude through assisting the individual in changing unrealistic expectations or behaviour through education to learn how to do things in a new or different ways.

2.6.2.2 Self-efficacy

Self-efficacy, a concept articulated by Bandura postulates that although social cognitive theory acknowledges that knowledge of health risk and benefit of treatment are necessary to perform health behaviour, this in itself is not enough, additional self-influences are necessary to achieve necessary changes that will result in the desired health behaviour (Bandura 2004:145). It describes the belief in one's ability to take control of behaviour and the confidence that one can perform a specific task. Self-efficacy has become a major focus area in the process of assessing patient performance of certain skills that are required to manage their disease condition with the aim of improving their quality of life. Self-efficacy theory has been increasingly recognized in health behaviour and has become one of the key constructs in social cognitive theory. Persons with high self-efficacy or self-confidence that they can perform certain health behaviour such as adhering to medication are more likely to carry out such behaviour (Redding et al 2000:187).

Central to Bandura's work is the Self-Efficacy Model, a paradigm of the person engaging in behaviour with a consequent outcome (Bandura & Adam 1977:288). According to Bandura, self-efficacy describes the belief in one's ability to take control of behaviour and the confidence that one can perform a specific task. Self-efficacy influences how a person thinks, feels, acts and is motivated. Furthermore, self-efficacy affects a person's choice of setting, the effort expanded on a particular task and the emotional reactions to situations (Jones, Owens, Lydston, Tobin, Brondolo & Weiss 2010:1503). Self-efficacy describes an individual belief that he can alter the behaviour or action required to achieve positive health outcomes in managing the disease. In this study it is conceptualized that self-efficacy in ART can be depicted as an individual's ability to continue taking ARV despite various challenges associated with ART.

Bandura describes four sources of information that influence self-efficacy: performance mastery, vicarious experience, verbal persuasion, and physiological symptoms. Integration of information from one or more different sources forms a self-efficacy judgment (Bandura 1988:285). ***Performance mastery*** refers to knowledge and skill gained through experience and perseverance (Bandura 1988:285). ***Vicarious experience*** occurs from observing others complete a task successfully contributing as a source of modeling self-efficacy in performing that task (Bandura 1988:284). ***Verbal persuasion***, the most often used source of self-efficacy by health care professionals, is used to try to convince persons that they can succeed at a task. Verbal or social persuasion serves to reinforce feelings of efficacy when facing the minor failures mentioned above (Bandura 1988:285). ***Physiological symptoms*** also serve as sources of information toward an individual's self-evaluation of competence. A person's physical reaction to difficult situations can influence how prepared that person feels to effectively handle the situation (Bandura 1988:285).

2.6.2.3 Observational learning or modelling

Other influences that are recognized by the Cognitive theory are observational learning or modelling which describes how a person acquires skills and information through the actions of other people (Redding et al 2000:185). Through observation, a person can learn from other people's actions and go further to develop an understanding of and be prepared for the consequences of such actions. The support groups that are formed

among HIV-infected patients may serve as a good model where people learn how to do certain things by observing others within the group (Skovdal et al 2011:309).

2.6.2.4 Reinforcement

This is another influence in Cognitive theory, here the response to a person's behaviour can influence whether or not that behaviour will be repeated. Reinforcement can be positive or negative. When health behaviour is positively reinforced, it makes it more likely that the individual will repeat such behaviour. On the other hand lack of response or negative reinforcement of a person's behaviour tends to make repetition of such behaviour less likely (Redding et al 2000:185). The behavioural theory of adherence is based on the operant conditioning such as reinforcement of action that leads to adherence. For example, reward for completion of medication in form of compliment or if the patient feel healthier after complying with instructions of health giver. Negative reinforcement has limited role in ART adherence, but may be applicable in patient who continuously fail to adhere and developed resistant strain of the virus with very little resources available to initiate other regimens of ARV.

2.6.3 Trans-theoretical model (stages of change)

This theory was developed by Prochaska and DiClemente (1983:390-395), and is also called Stages of Change theory. The basic premise of the model is that behaviour change is not a once off event but a process in which an individual attempting to change his behaviour moves along a series of motivational changes namely; pre-contemplation, contemplation, determination, action, maintenance and relapse (Rimer & Glan 2005:15). The stages of change model is not linear but circular in nature, a person does not progress automatically from one stage to the next, but he or she enters the change process at any stage, progresses or relapses to an earlier stage and starts the process all over (Redding et al, 2000:188). Trans-theoretical Model has been used in various behavioural interventions at both individual and organizational levels; persons at different stages in this process often have varying informational needs and only benefit from intervention designed specifically for the stage they are in (Rimer & Glanz 2005:15).

In the **pre-contemplation** stage, the person has not given a thought about the particular health behaviour to be taken and therefore has no intention of adopting such behav-

iour. At the **contemplation** stage the person is said to be seriously considering taking the health behaviour but has not taken any action about it. The person proceeds to make a plan to adopt the health behaviour at the **determination** stage. During the **action** phase, the person makes an initial behavioural change and this phase usually covers the first six months of adopting the health behaviour. After a period of six months the individual enters the **maintenance** phase and this is sustained for a period of time (Redding et al 2000:188).

The patients who started ART often comply at the early stage; this trans-theoretical model applies to those who become non-adherent after complying with treatment on previous occasions. **Relapse** stage describes the reversion back to the earlier stage after failing to maintain the health behaviour; this is often referred to as a secondary stage of change. The relapse may occur any time after action is taken to adopt the specified behaviour.

2.6.4 The precaution adoption process model (PAPM)

This model comprises of seven stages beginning from lack of awareness to adoption or maintenance of desired health behaviour. At the first stage, a person is unaware of the health risk; the individual may become aware in Stage 2 but remained unengaged. In Stage 3 the individual is faced with the decision to act, and may decide to act (Stage 4), of decide not to (Stage 5). Stage 6 is action stage, and Stage 7 is maintenance of the action taken in earlier stage (Rimer & Glanz 2005:19). In the Precaution Adoption Process Model, an individual moves sequentially through all the stages without skipping any of them, though it is possible to move backwards from some later stages to earlier ones, people do not return to the first two stages once completed. This model recognizes that the barriers faced by people who are unaware of health risks or hazards differ from those who are aware of such risks but decided not to take action (Rimer & Glanz 2005:19). In PAPM, interventions that target stages that precede active decision making have been advocated to address adherence in medical conditions.

2.6.5 The theory of reasoned action/planned behaviour

The theory of planned behaviour (TRP) and the associated theory of reasoned action (TRA) stipulate that the determinant of behaviour is behavioural intention (Rimer & Glanz 2005:19:16). Theory of reasoned action predicts behaviour from intention and

explores the relationship between beliefs, attitudes, intentions and behaviour (Redding et al, 2000:183). The modified version of the TRA is the theory of planned behaviour which includes one additional construct, perceived behavioural control; this construct has to do with people's beliefs that they can control a specific behaviour (Redding et al 2000:183). The perceived control construct was added to TRA to gain better understanding of situations where behaviour or behaviour intention is influenced by factors which are beyond a person's control (Rimer & Glanz 2005:19:16).

TRA predicts behaviour from intention; this intention is influenced by three factors which are subjective norms, attitudes and self-efficacy (Redding et al 2000:183). According to TRA, behavioural intention is influenced by an individual's attitude towards such behaviour and by the individual's beliefs about whether people who are significant in the life of such individual approve or disapprove of the behaviour (subjective norm), while self-efficacy is the confidence a person has that certain behaviour can be performed (Redding et al 2000:183).

Two beliefs in TRA that influence behavioural intentions are the normative and behavioural beliefs, normative beliefs are based on social expectations which are often considered the rule; they influence subjective norms while beliefs about the behaviour influence the attitude. Attitudes are usually conceptualized in terms of values, a person's attitudes toward health behaviour are said to be determined by the outcome expectations of performing such behaviour and the extent to which the individual values the outcome (Redding et al 2000:183). According to TRA, an individual will perform certain health behaviour to reduce health risks if convinced such behaviour will prevent the risks and extent to which the individual perceives the benefit of performing the behaviour will outweigh the cost (Redding et al 2000:183).

The current study was guided by the self-efficacy model and the health belief model. These two models were chosen for this study because they contain the cognitive variables under investigation in the current research.

2.7 ADHERENCE AND ANTIRETROVIRAL THERAPY

Adherence is the act or quality of sticking to a particular instruction or advice. In the management of chronic medical ailments, adherence is considered non-judgmental and is preferred over the term "compliance," which is an act of conforming, yielding or acquiescing (Castro 2005:e338). Compliance implies a lack of patient participation; carries negative connotations and suggests blame for the patient. In the context of chronic medical conditions the word adherence translates to a collaborate process between the patient and health care provider (Castro 2005:e338). Medication adherence in actual word is described as the extent to which the individual's behaviour corresponds to the prescribed medical advice of the health care provider (Kenreigh & Wagner 2005). The treatment of HIV/AIDS extends beyond knowledge development in patients; a partnership between patients and healthcare providers is required, with the patient assuming the major responsibility of self-care leading to adherence and good clinical outcome (Sanjobo, Frich & Fretheim 2008:142).

2.7.1 Adherence to antiretroviral therapy

Based on the definition of adherence, non-adherence is not limited to missing medication intake; it includes other acts like not following instructions regarding dietary or fluid restrictions and not taking medication at the prescribed time. It is difficult to predict which patient will adhere to treatment; past adherence is the only predictor of future adherence (Ickovics & Meade 2002:S100). Adherence levels change over time; clinical experience and research indicate that adherence is a "moving target", the longer a patient stays on ART the poorer the adherence is likely to become (Cauldbeck et al 2009:7; Ickovics & Meade 2002:S100). In the study done by Orell et al (2003:1369-1375), it was shown that adherence should not be a barrier in ART initiation in developing countries with limited resources if there is adequate access to ART, proper patient education, social support, and issues around social barriers are well addressed.

Generally, adherence rates are shown to be high among patients who are taking medications for acute medical conditions compared to those with chronic medical condition (McDonald, Garg & Haynes 2002:2870). In addition to this, adherence levels among patients with chronic diseases, no matter how impressive initially have been reported to drop dramatically after six months (Van Dulmen et al 2007:55). Numerous interventional

studies have been done in the past to address the problem of non-adherence among patients (Amico, Harman & Johnson 2006:295; Van Dulmen et al 2007:55; Munro et al 2007:104). The unfortunate thing is that most of these interventions seem to have modest impact (Amico et al 2006:295; Simoni et al 2003:193; Munro et al 2007:104). There is a big challenge for behavioural sciences in developing interventions aimed at enhancing ART adherence, the lack of appropriate theories to explain and predict non-adherence among patients on chronic medications may have a role to play in the slow progress made in this field of knowledge (Kagee 2008:424; Van Dulmen et al 2007:55).

Various studies have been done to establish the levels of adherence to ART although most of these were done in the developed world. The earlier studies on adherence and its impact on outcome were done using electronic monitoring, pill counts, and self-reports and they all demonstrated inverse relationship between adherence and viral load (Paterson et al 2000:22; Bangsberg et al 2006:226; Gross et al 2001:2112).

2.7.2 Adherence required for optimal results in antiretroviral

The study of Paterson et al (2000:21-30) has been used widely in establishing the level required for optimal adherence (> 95%) necessary to maintain viral suppression. In the study, the authors revealed virologic failure (HIV RNA > 400 copies/mL) in 22% of patients with adherence level of 95% and above, 61% in patients with adherence level of 80-94.9% and 80% virologic failure in patients whose adherence level fell below 80% (Paterson et al, 2000:26). Any adherence below 95% in ART has been linked to treatment failure, the risk of developing resistance to ARV is also shown to be highest between 80-90% level of adherence (Bangsberg, Moss & Deeks 2004:697), this is because the virus is not likely to develop resistance at low concentration of the drugs but at high drug concentration which is suboptimal for suppression of viral replication the chances of viral resistance are high (Clotet 2004:123; Bangsberg, Moss & Deeks 2004:697).

The earlier estimates of adherence levels necessary for viral suppression were done among patients receiving the unboosted PIs regimens which have been described as less potent than the NNRTI regimens (Gazzard et al 2008:573; Thompson et al 2010:326). Recent studies on adherence levels required to maintain good viral suppression with NNRTI-based regimens revealed that viral suppression was still achievable in

patients with adherence level below 80% (Nachega et al 2007:567; Bangsberg 2006:940). The study of Nachega et al (2007:567) done in South Africa showed that there was improvement in patients' virologic outcomes as adherence to NNRTI-based regimens went beyond 50%. In addition, 73% patients achieved maximal viral suppression with adherence levels of 90-100% (Nachega et al 2007:567). This study shows that the NNRTI-based regimens may be appropriate alternative to the PI-based regimens where adherence between 70-94% is anticipated, although the authors warned that adherence should be enhanced in any patients on HAART irrespective of the patterns of adherence among populations groups.

HIV patients have been shown to adhere better than the general population; the average adherence to chronic medications among the general population is 50% which is far below self-report adherence rate between 55-77% reported among patients on ART (Mills et al 2006:687). Despite this, non-adherence is common among patients on ART, which is estimated between 30-50% among patients and more than 10% of patients usually miss one or more of their daily doses of antiretroviral drugs (Chesney 2000:S172).

The level of adherence among adolescents has been reported to be lower than adults and elderly patients on ART (Protopopescu et al 2009:602). In a study done in the USA among adolescents on ARV, only 28% took prescribed ARVs in the previous month (Murphy et al 2003:253). Another cohort study in nine countries within the Southern Africa region also reported poor adherence among adolescents (Nachega et al 2009:67). A recent survey done among HIV patients in India also revealed poor adherence among people who were aged below forty years (Cauldbeck et al 2009:7). The explanatory factors responsible for this discrepancy may be due to the fact that older individuals are more likely to have prior experience taking medication for age-related diseases and may have already become accustomed to such. Another reason may be related to the fact that lifestyle adjustments necessary for successful adherence are often less burdensome for adults compared to young patients.

Several studies in sub-Saharan Africa have reported low adherence among patients on ART, in a sample of 109 patients on ART in Botswana only 54% of the patients were adherent by self-report, although this increased marginally to 56% when provider assessment was used (Weiser et al 2003:284). In another study in Ethiopia conducted

among 400 patients on ART, 24% were non-adherent when combined indicators of dose, time and dietary instructions were used, the authors go further to report that this rate increased to 27% after reassessment 3 months later (Amberbir 2008:268). A Nigerian study that assessed ART adherence among patients on subsidized ART programme reported an alarming 75% of the study participants as non-adherent to their medications, patients in this study cited various reasons for their actions, ranging from ARVs side-effects and non-availability of ARVs to forgetfulness (Uzochukwu, Onwujekwe, Onoka, Okoli, Uguru & Chukwuogo 2009:4).

A more recent KwaZulu-Natal study among 735 HIV-infected patients, found 30% of patients to be non-adherent to dose, schedule and dietary instructions (Pelzer, Du Preez, Ramlagan & Anderson 2010:111). Another South African study by Malangu (2008:49) revealed that only about 50% of patients on ART reported taking at least or over 95% of their prescribed ARVs. A major review on studies conducted on ART adherence that involved 72 developed countries and 12 developing countries, five of which are Africans, estimates adherence level among people living with HIV/AIDS in Sub-Saharan Africa at 77%, surprisingly higher than 55% in North America. The authors state further that non-adherence to ART in adult population range between 33 to 88%, depending on the measure of adherence employed (Mills et al 2006:685). These percentages are low considering that adherence of 95% is necessary to minimize development of viral resistance and to achieve optimum benefit of ART (Paterson et al 2000:26).

The results obtained from some of the adherence studies in resource-limited settings should be interpreted with caution as there is possibility of the results skewing towards better adherence. The reason for this is because large majority of participants in these studies received free ARVs, free information and support from dedicated clinical staff, a beneficial experience which does not reflect the true situation of things in most resource-constraint settings.

2.7.3 Consequences of non-adherence to ART

Adherence to ART has been described as the most crucial for the expected positive clinical outcome in patient initiated on ART. Adherence to combination ARV therapy has been shown to inhibit HIV replication which has resulted in the steady decline in HIV/AIDS related morbidity and mortality (Janssens et al 2007:1137; Duong et al

2004:218; Ware et al 2009:43). Lower levels of adherence have been demonstrated to achieve treatment goals in chronic medical conditions like hypertension and diabetes where moderate adherence has been considered adequate for treatment outcomes (Simoni et al 2003:185). This is quite different in HIV/AIDS management where adherence level greater than 95% has been described as the requirement for maximal virological suppression especially ART regimens that contain the protease inhibitors (Bangsberg et al 2003:1930; Paterson et al 2000:26). Although recent studies indicate moderate adherence at 80-90% may suppress viral replication with the non-nucleotide reverse transcriptase inhibitors (Bangsberg 2006:940; Nachega et al 2007:569); this finding has to be interpreted with caution as risk of viral resistance and mortality is high at such adherence levels (Nachega et al 2006a:81).

Unlike other chronic diseases in which non-adherence is somehow tolerated, the high rate of viral replication and mutation in HIV means that high levels of adherence has to be maintained all times (Clotet 2004:123). Non-adherence to ART results in inadequate suppression of viral replication in the body which allows the virus to continuously replicate and deplete the T-Helper cells; this destroys the immune system and allows the disease to progress at a faster rate. Non-adherence has also been shown to be associated with repeated hospital admissions, development of opportunistic infections, poor quality of life, loss of productivity and premature mortality (Graham et al 2010:1541; Moore et al 2005:290; Nachega et al 2006a:83; Wools-Kaloustian et al 2006:44). Development of resistance to ART is another implication of non-adherence because the virus is prone to developing resistance to ARV when exposed to suboptimal concentrations of the drug (Boyd & Pett 2008:67; Clotet 2004:123). These resistant strains can be transmitted to other persons thereby decreasing treatment options and worsening of the HIV epidemic.

Hogg et al (2002:1051-1058) found that patients whose adherence level is below 75% were three times more likely to die compared to those whose adherence level is above 75%. In another study by Garcia de Olalla et al (2002:105-110), the authors revealed that patients with adherence level below 90% were 3.87 times more likely to die compared to those with adherence above 90%. Likewise, Nachega et al (2007:564-573) reported that patients whose adherence fell below 80% were three times more likely to die than those with adherence above 80%. The results of these studies have to be interpreted with caution bearing in mind that many of the patients in these studies were initi-

ated on ART with advanced stage of HIV/AIDS and with very low CD4 counts. The most important lesson from these studies is that poor adherence in advanced stages of the disease carries a high risk of mortality.

2.7.4 Factors influencing adherence in ART

The management of HIV/AIDS with ART has resulted in significant clinical outcomes; but the complicated dosing requirements, ART adverse drug reactions and socio-economic factors often constitute a challenge to patients (Dahab et 2008:63; Curioso, Kepka, Cabello, Segura & Kurth 2010:13; Amberbir et al 2008:265). Although various studies in sub-Saharan Africa have shown that high levels of adherence, viral suppression and good clinical outcome are achievable in these resource-limited settings (Nachega et al 2006a:82; San Lio et al 2008:1614; Nachega et al 2009:68; Mills et al 2006:685; Hardon et al 2007:662; Oyugi et al 2004:1101; Fox & Rosen 2010:11), it is very challenging to adhere to ART, and strict adherence is not common (Montessori, Press, Harris, Akagi & Montaner 2004:229).

Many studies have been done on factors associated with adherence in patients taking antiretroviral medication, while some focused on socio-demographic characteristics like race, age, income and level of education; some focused on health beliefs of patients; others concentrated on the interaction between patients and health care providers (Malangu 2008:49; Ware et al 2009:43; Dahab et al 2008:63; Curioso et al 2010:13; Amberbir et al 2008:265). Although some of the factors identified in these studies are somehow predictive of adherence, none of them has been shown to be associated with adherence across studies.

2.7.4.1 Patient-based factors

Socio-demographic factors such as age, gender, and socio-economic status, level of education, income and ethnicity have been used in studies to understand their influence on adherence (Rougemont, Stoll, Elia & Ngang 2009:21; Gordillo, Del Amo, Soriano, & Gonzalez-Lahoz 1999:1765). It has not been possible to predict adherence based on demographic characteristics as no consistent correlation has been found between demographic characteristics and patient adherence level (Rougemont et al 2009:21; Cauldbeck et al 2009:7). Although socio-demographic factors were not consistently cor-

related with treatment adherence in several studies, they can be used to identify particular populations that may benefit more extensively from targeted interventions that address specific barriers (Gordillo et al 1999:1766; Cauldbeck et al 2009:7).

Medication adherence is affected by patients' beliefs about disease origin and transmission which often form the basis for stigmatization in HIV/AIDS. Psychosocial factors like drugs and alcohol use, social stability, depression and psychiatric illness have also been used in other studies to find out if there are correlation between any of them and adherence to ART (Berg, Cooperman, Newville & Arnsten 2009:247; Howard et al 2002:2179; Murphy et al 2003:253; Gordillo et al 1999:1764). What studies have found are barriers to adherence such as substance abuse, unstable housing, depression, mental illness, fear of disclosure of HIV status, decreased quality of life, work and family responsibility and past history of non-adherence (Glass et al 2010:200; Protopopescu et al 2009:603; Mills et al 2006:687). The importance of these findings in ART initiation is that denying an individual the benefit of ART based on the assumption that the person will not adhere due to his or her demographic characteristics is a futile exercise as no data are available to substantiate such action (Ickovics & Meade 2002:S99).

Socioeconomic factors have also being implicated as part of barriers to adherence to ART in a number of studies, the cost of ART, and availability and accessibility to medications were the most significant barriers to adherence reported in various studies in Africa (Weiser et al 2003:284; Hawkins & Murphy 2007:1041; Iliyasu et al 2005:292; Mukhtar-Yola, Adeleke, Gwarzo & Ladan 2006:142; Hardon et al 2007:661; Tuller et al 2009). There are indirect costs associated with ART which influence adherence; these are the time taken off work, the time spent in hospital and inability to fend for one's family during bouts of opportunistic infections (Castro 2005:1219; Hardon et al 2007:660). The access to drugs while away from home is another factor that has been identified that affects adherence among patients on ART (Nachega et al 2004:1053-1056; Garcia et al 2006:1251).

Structural factors have also been described as having influence on adherence to ART. These are issues that are beyond the control of the patients, structural approach to adherence does not see adherence as a simple individual behaviour but as one that occurs within social and environmental context. In other words, it is difficult for some people to adhere to ART because the adherence barriers are not generated at individual

level (Mukherjee et al 2006:S123-124). Some of these are out-of-pocket cost of health services and medication, transportation, homelessness, lack of access to food and water and poor accessibility to health facilities. All these are structural barriers to adherence that have to be addressed at the societal level in order to improve adherence (Hardon et al 2007:664; Mukherjee et al 2006:S124; Weiser et al 2003:284).

Reduction in the structural barriers to healthcare has been shown to improve patient's adherence levels in ART (Mukherjee et al 2006:S124). Adequate knowledge of the medication and understanding the need for strict adherence, self-efficacy, sense of self worth, acceptance of HIV status, making use of reminder tool and social support have been shown to influence adherence to ART in different settings (Garcia et al 2006:1251).

2.7.4.2 Treatment-related factors

ART has been described as a complex treatment due to the pill burden, dietary and fluid restrictions and timing of medication intake. The complexity of drug regimen is one of the causes of non-adherence in patients on chronic medication (Glass et al 2010:200; Cauldbeck et al 2009:7). This has also been reported among HIV patients taking ARV, three times or more daily dosing regimens are associated with non-adherence (Protopopescu et al 2009:602; Frank 2002:S11; Roca, Lapuebula & Vidal-Tregedor 2005:197). The pill burden has been described as a major challenge since combination ART is used and it often contains 2-20 pills that have to be taken in a day together with the other requirements like timing of dosages and food requirements (Protopopescu et al 2009:602).

The numerous and potentially debilitating side-effects have also been shown to contribute to irregular drug use and deliberately stopping of medication intake by some patients (Waters & Nelson 2007:986; Weiser et al 2003:285). Regimens with significant side-effects profile have been associated with poor adherence (Glass et al 2010:200; Cauldbeck et al 2009:7).

Various authors have suggested that the health care providers should consider the circumstances of patients while prescribing ART (Harries, Zachariah, Lawn & Rosen 2010:71); a potent combination therapy may not fit into a patient's daily schedule and

may therefore affect the adherence to such medication. Regimen-based strategies that can improve long term adherence among patients include simplification of ART regimens which will assist in the long term adherence to treatment and maintaining efficacy of treatment (Harries, Zachariah, Lawn & Rosen 2010:72; Protopopescu et al 2009:604; Howard et al 2002:2180; Frank 2002:S12; Cauldbeck et al 2009:7).

2.7.4.3 Provider-based factors

Providers' characteristics and the clinical setting also affect patients' adherence; overall patients' satisfaction with the level of care has been found to correlate with increased adherence (Gauchet, Tarquinio & Fischer 2007:145). The aspects of clinical setting that may positively influence adherence are friendly and supportive environment, non-judgmental health care providers, convenience appointment schedule and confidentiality in service provision (Altice, Mostashari & Friedland 2001:54; Simoni et al 2006:S32). Long waiting time, poor staff attitude, intermittent drug availability and other procedural barriers have been found to decrease adherence to taking medications and keeping clinic appointments (Hawkins & Murphy 2007:1041; Iliyasu et al 2005:92). Continuous access to health care services and medications by patients has also been shown to influence treatment adherence (Hawkins & Murphy 2007:1042). The patient-provider relationship is another factor that has been well researched in terms of adherence to ART; research showed that good patient-provider relationship results in patient's trust and confidence in the provider which in turn influences good adherence (Altice, Mostashari & Friedland 2001:54; Gauchet, Tarquinio & Fischer 2007:145).

The challenge of adherence is not limited to the patient alone but extends to the health care provider; therefore, the relationship between the patient and the health provider is a form of therapeutic alliance where both parties work toward a common goal of improving the health of the patient. That is why frequent change in health care providers has been associated with poor adherence (Glass et al 2010:201). Discussing ART initiation in the context of an informed decision on the part of the patient has been reported to be an effective strategy that enhances patient-provider interaction. It enables an alliance formation which allows patient and provider to define therapy goals, side-effects, medication management and adherence monitoring (Harries, Zachariah, Lawn & Rosen 2010:71).

According to Nachega et al (2006) social support and ability to disclose one's status are important issues to be considered when assessing treatment adherence irrespective of the context. In a study done by Julius, Novitsky and Dubin (2009:34-44) on adherence of patients to chronic medications, the authors recommend that therapeutic alliance between patients and providers should be strengthened, time should be devoted to address adherence among patients, and patients should be well assessed to identify barriers to treatment adherence.

2.7.4.4 Disease characteristics

The clinical outcomes achieved with the use of ART been linked to adherence level. Studies have shown that prior opportunistic infections in an HIV patients before initiating ART has the potential of influencing adherence as the patient may perceive the disease to be severe enough requiring good adherence to treatment in order to achieve the treatment outcome (Cauldbeck et al 2009:7). Although the Swiss HIV Cohort Study revealed that long standing HIV disease was among the predictors of worsening adherence (Glass et al 2010:201).

2.7.5 Monitoring and assessing ART Adherence

Medication adherence is defined as the percentage of prescribed medications taken in any form for a specified period; instructions adherence is defined as the percentage of medications for which the correct special instructions were followed at each prescribed dose. Based on any of the method used, ART adherence is calculated as the percentage of doses taken over those prescribed within a given period. Although adherence is one of the modifiable variables in ART, its monitoring is difficult among patients, as no standard method exists to monitor adherence in ART, multiple approaches are often used (Nachega et al 2009:66; Mills et al 2006:687; Simoni et al 2006:S25). Some of the commonest methods are self-report, electronic device monitoring, pills count, pharmacy refill tracking, biological markers, provider estimation and therapeutic drug monitoring. Adequate monitoring of adherence is vital in preventing treatment failure and development of resistance to antiretroviral drugs (Colebunders et al 2006:56).

2.7.5.1 Self-report of adherence

Self report remains the main measure of adherence in developing countries although other techniques have been used widely; it involves asking patients to report their adherence periodically (Kouanfack et al 2008:217). Studies have found correlation with actual medication intake in research done on self-report as a method of adherence monitoring (Oyugi et al 2004:1101; Ross-Degnan et al 2010:42). In the Ugandan study that used 3-day self report adherence, median adherence correlated with other measures of adherence (Oyugi et al 2004:1101). The major drawback of this method is overestimation of adherence by patients due to recall bias (Mills et al 2006:688). Adherence guidelines advise that accuracy of adherence self-report can be achieved if patients are approached in a non-judgmental way during assessment (Colebunders et al 2006:56).

2.7.5.2 Pill counts method

Pill count as a measure of adherence involves calculating the percentage of the number of pills prescribed and dispensed for the period between hospital appointments with the number of pills returned at the following appointment (San Lio et al 2008:1611). It can be done during patient visits to health facilities or unannounced at patients' home. This technique is cheap and correlate well with adherence measured using viral load (San Lio et al 2008:1614) but its major shortcoming is manipulation of pills by the patient. Pills dumping prior to hospital visit has been documented which will result in overestimation of adherence for the patient. Unannounced pill count is more reliable but this has been shown to affect the trust between the patient and health care provider which may eventually hinder adherence (Bangsberg 2006:939). Pill counts may be a reliable and economical tool for monitoring adherence in resource-limited settings although viral load monitoring has been described as the preferred method (San Lio et al 2008:1615). Bell, Kapitao, Sikwese, Van Oosterhout and Lallo (2007:560-563) assert that though they may overestimate adherence; pill counts and self-report are still the mainstay of measuring adherence in resource-limited setting.

2.7.5.3 Electronic monitoring devices (EMD)

This involves an electronic chip that is implanted on the bottle lid that records the opening and closing of the bottle that contained the prescribed medicines, a computer program is later used to extract information from the lid and the data is then analyzed. This technique assumes that opening of the bottle by the patient coincides with actual intake of the drug. Although this method has shown some correlation with actual drug intake in some studies (Howard et al 2002:2178; Paterson et al 2000:25), others have described it as an expensive and non-reliable device. A study in Malawi to compare methods of adherence monitoring found no correlation between electronic device monitoring, self-reporting and pill counts (Bell et al 2007:562). Electronic devices may underestimate or overestimate adherence since it is difficult to know if a patient opening a drug bottle is actually taking the tablets or just opening the bottle, therefore, actual medication intake by patients is not measured by EMD. (Bova, Fennie, Knafi, Dieckhaus, Watrous & Williams 2005:108). A study of electronic monitoring device used among HIV patients on ART revealed that patients who rely on pill boxes are not likely to use EMD because pill boxes are the tools used by patients with numerous medications (Bova et al 2005:108).

2.7.5.4 Pharmacy based-records

Pharmacy record is a simple and effective tool for monitoring adherence in ART and has been proved to be useful in adherence monitoring in resource-limited setting (Rougemont et al 2009:21; Nachega et al 2006a:82). This method employs pharmacy records to monitor adherence among patients when collecting their medication at the pharmacy. Patients collecting their medication regularly are said to be adherent by the pharmacy. Ross-Degnan et al (2010:42) showed that pharmacy records in resource limited settings are useful in measuring adherence, in their study, adherence measured by pharmacy records correlated with CD4 count and weight gain in patients (Ross-Degnan et al 2010:42). Adequate record keeping is necessary for pharmacy refill tracking information to be useful; the major setback is that the method only assumes that patient are adherent based on their empty pill boxes and the regular collection of their medication, it does not measure actual medication intake. The method also requires patients to be collecting their medication at the same pharmacy for all refills which may not be possible in all cases.

2.7.5.5 Biological markers monitoring

Viral load level and CD4 counts are used as indicators for treatment outcomes and success, viral load is regarded as the main indicator of the risk of therapeutic failure, they can also be used in measuring adherence (San Lio et al 2008:1614; Wilson et al 2009). Low viral load and increase in CD4 count are suggestive of good adherence although some patients may have high viral load despite taking the ART regularly. Research has shown that CD4 is a good measure of adherence and correlated with weight gain, self report and pharmacy records (Ross-Degnan et al 2010:42). Viral load was also found to correlate with pill counts and good clinical outcomes in patients (San Lio et al 2008:1614). The major drawback is cost and availability in resource limited settings (Colebunders et al 2006:53).

2.7.5.6 Provider estimation method

In provider estimation method of measuring adherence, the health care providers estimate patient's adherence based on factors such as socio-demographic and economic factors. In this method there is no correlation with actual medication intake, studies have shown that health care providers overestimate adherence to HIV treatment when factors such as demographic characteristics are used to predict adherence as it is very difficult to predict adherence based on demography (Paterson et al 2000:28). Ross-Degnan et al (2010:42) found that consistent clinic attendance did not correlate with other measures of adherence among patients on ART.

2.7.5.7 Therapeutic drug monitoring

Therapeutic drug monitoring involves measuring the levels of the drug in the blood stream of the HIV patient, this method is not used routinely as most ARVs have short circulating times in the body, couple with the fact that it is very expensive. Presently therapeutic drug monitoring is restricted for research purposes. A study that combined therapeutic drug monitoring (TDM) and viral resistance monitoring to find causes of virologic failure in patients on ART revealed that TDM is necessary in patients who developed adverse reactions while on ritonavir boosting regimen as there is risk of drug toxicity in these patients. The researchers conclude that TDM assists clinicians in choosing the best regimens for their patients and should be used routinely in clinical

practice (Duong et al 2004:222). A prospective cohort study in Cameroon to compare adherence of fixed-dose combination of nevirapine, stavudine and lamivudine using nevirapine plasma level monitoring and self-report by patients found that self reported adherence was significantly higher than adherence measure by nevirapine level monitoring (Kouanfack et al 2008:217). The authors conclude that nevirapine plasma concentration monitoring provides accurate measurement of adherence compared to self-report but caution that it is not feasible in most clinical settings in resource-limited areas (Kouanfack et al 2008:218).

2.7.6 Strategies and tools for enhancing adherence

Adherence is very complex and unpredictable among patients on chronic medications; several methods of enhancing adherence exist in ART and are usually used in combination for effectiveness. The interventions used to enhance adherence among patients are aimed at addressing potential barriers to adherence to achieve successful HIV treatment outcomes.

2.7.6.1 Antiretroviral therapy strategies

This entails simplifying regimen characteristics; simplification of dosing schedules; reduction of pill burden, and adjusting dietary restrictions to match patients' activities of daily living. In addition, identifying previous ART use, pre-existing medical conditions that may affect ART use and ensuring continuous provision of ART have also been reported to enhance adherence to ART (Birbeck et al 2009:672). Studies have demonstrated improved adherence with once or twice daily dosing of ART (Kauf et al 2012:158). Many fixed-dose combinations (FDC) of ARVs are now available and have been shown to improve adherence in patients (Haberer et al 2011:6; Kauf et al 2012:158). The buddy system has been widely used in resource-limited settings where relatives or friends agree to assist the patient in adhering to the medication, buddies remind patients to take their medication, encourage them and assist in keeping hospital appointment, this approach has led to improved ART adherence according to documented evidence (Birbeck et al 2009:672). Social support not only assists the patient in adhering to ART but also provide psychological support to the patient that helps them to cope with the disease (Nachega et al 2006b:131).

2.7.6.2 Education and counselling

This is usually the mainstay of ART programme in any setting in order to empower the patient to be part of the treatment process. Knowledge about the disease, its symptoms, treatment and side-effects of the medications are crucial information to be passed across to the patient (Magadza, Radloff & Srinivas 2009:369). During counselling, potential barriers to adherence may be identified and addressed. Studies have shown that counselling assists the patient in developing positive beliefs and perception towards the disease (Barclay et al 2007:47), it also helps in setting goals and increases the self-efficacy of the patient (Johnson et al 2007:577). A randomized controlled trial in the USA to compare effect of person-to-person contact and support adherence with medication alarms technique revealed improved responses to therapy and good adherence among the group that received interpersonal adherence support (Mannheimer et al 2006). This finding is consistent with the literature where repeated supportive adherence has been described as the most effective intervention since it provides human contact and support (Simoni, Pearson, Pantalone, Marks & Crepaz 2006:S30).

2.7.6.3 Adherence tools for patients

These tools are often combined with other behavioural interventions (Saberi & Johnson 2011:6). Pill boxes are containers used for storing the ARV for regular use as prescribed; it enables the patient to take the medication correctly. Electronic versions of pill boxes with reminders to the patient are also available. The major setback of this strategy is the lack of confidentiality and privacy as patients may want to hide their medication, another one is the responsibility of the patient in filling out the boxes, uneducated patients may not be able to do this correctly. Pill chart involves visual display of the pills in terms of their colour and shape, name and dosage of the medication during counselling. This is very useful especially among the uneducated patients (Saberi & Johnson 2011:6).

Electronic devices such as beepers, alarm and watches that remind patients to take their medication according to the prescribed schedule have been used to enhance adherence (Colebunders et al 2006:56). Electronic pager linked to the internet may also be used to send reminders to patient to take their drugs. Reminder tools have been reported by patients as one of the facilitators of adherence (Skinner, Rivette & Bloomberg

2007:606), although the major disadvantage of this strategy is the lack of privacy associated with it. Telephone calls are also used as reminders for patients to take their medication, the shortcoming of this is the cost required to set up this kind of service and the challenges of the patient having the telephone with them all the time (Skinner et al 2007:606).

Medication diaries are very useful in understanding the pattern of drug use by the patient and the reason for not taking the medication regularly. Diaries are used by the patients to document the time and date of taking the medications and missed doses and the reasons for it. This tool may also be used to identify side-effects or other problems that the patient may encounter in the course of taking ART. Research has shown that some tools appear to be of more benefit to patients when they are combined with patient education or counselling. A large multicenter randomized trial in the USA has revealed that reminder devices alone do not enhance adherence and suggests that they should be combined with counselling as part of comprehensive support for patients on ART (Mannheimer, Morse et al 2006:45).

2.7.6.4 Directly administered antiretroviral therapy (DAART)

This technique has been used successfully in TB by asking patients to take medication under the supervision of adherence counsellors. Directly administered ART can be clinic or home-based, once-daily, twice-weekly, or once-weekly. The challenge in ART is different from TB as timing of medication intake varies across ARVs and the fact that the treatment is for life. Although this approach has shown some benefit in improving adherence, research does not support routine use of directly administered ART; Modified directly observed therapy (mDOT) has been suggested for use in ART and a home-based mDOT strategy has been used to improve adherence rate in resource-limited settings (Farmer et al 2001:1147), although adherence to ART was only seen in early weeks of an (mDOT) study in Kenya (Sarna et al 2008:617). Despite its limited use, the benefits of mDOT in ART seen in early stage of treatment may help patient to develop good understanding of the treatment and develop good treatment taking behaviour; it may also assist the patient in developing trusting relationship with the health care provider (Farmer et al 2001:1149).

2.7.6.5 Health system and service delivery interventions

These include interventions that target barriers to ART adherence at the level of health care delivery of HIV services such as food supplements, transportation to health facilities, staffing and integration of services. Research has demonstrated that ART adherence and retention in care are associated with interventions that offer food supplements, address transportation issues and integrated services. Serrano et al (2010:72) assert that family nutritional support for HIV positive patients on ART improves adherence leading to good clinical outcomes, and that this could be integrated into ART adherence interventions as an effective and comprehensive community-based primary care (Serrano et al 2010:72). In a South African study, nurse-initiated ART services have been shown to produce the same outcomes with ART services run by doctors, which indicate that where human resources are limited, nurses can be used to provide ART care (Sanne et al 2010:38). Another study in the USA showed that addressing issue of transportation to the health facilities among HIV patients and integration of home-based care into ART services lead to improve attendance in clinics appointments (Andersen et al 2007:39).

2.8 CONCLUSION

Adherence to ART has become one of the major challenges facing HIV/AIDS services following the rapid scale-up of ART to provide life-saving treatment to eligible patients. Health behaviour theories needed to be well examined to enhance our understanding of how relevance they are concerning adherence to medication in chronic condition such as HIV/AIDS (Gill, Hamer, Simon, Thea & Sabin 2005:1247; Peltzer et al 2010:111). ART adherence needs to be studied in relation to the patients' self-efficacy and their beliefs about medicines considering the fact that ART is a lifelong therapy and near prefect adherence is required to achieve the desirable positive clinical outcome. This research explored patients' self-efficacy and their beliefs about medicines and how these relate to ART adherence, and further make recommendations for interventions that will target cognitive perspective of health behaviour variables with a view to enhancing ART adherence in South Africa.

The literature review also looked at epidemiology and clinical aspect of HIV/AIDS as a chronic disease, mode of transmission of HIV infection, treatment and prevention mo-

dalities. In addition, factors influencing ART adherence and consequences of non-adherence were discussed; modalities for measuring adherence and strategies of improving adherence were also described. The literature review further focused on the various cognitive-behavioural theories used in modifying health behavioural which involves a number of theories that could be used in interventions that address multiple obstacles to medication adherence among patients on chronic medication.

The literature review of the relevant resources substantiates the assumption that there is relationship among self-efficacy, beliefs about medicines and ART adherence. In the next chapter, the research methodology used for the research will be described.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 INTRODUCTION

The previous chapter dealt with the relevant literature on antiretroviral therapy adherence, relevant health behaviour theories, theoretical framework applied in this study, and factors that influence adherence among patients on chronic medication. This chapter describes the research methodology employed by the researcher that was used to investigate the interrelationship of ART adherence self-efficacy, beliefs about medicines and ART adherence. It includes the aims and objectives of the study, the research design, the description of the sample population and sampling procedures, the data collection tools, process of data collection, contents of the research instruments, validity and reliability of the research instruments, pre-testing of data collection tools and the pilot study. Finally, the data analysis and ethical issues relevant to the current research were also discussed in this chapter.

3.2 AIM AND OBJECTIVES OF THE STUDY

This study aimed to provide a framework for antiretroviral therapy adherence improvement through focused intervention on modifiable factors that are strongly associated with ART adherence.

The specific objectives of this research are to:

1. Explore the cognitive variables of adherence self-efficacy and beliefs about medicines that influence adherence among patients on ART.

2. Determine the inter-relationships among adherence self-efficacy, beliefs about medicines and ART adherence.

3. Describe the modalities of enhancing adherence to ART through focused interventions on the identified factors that are strongly associated with ART adherence.
4. Develop a framework for the improvement of ART adherence based on the factors identified in this study.

3.3 RESEARCH DESIGN

Research design is the overall plan of the study that describes the strategies and approach used in obtaining data about the phenomenon of interest; in addition, it provides the structure that the research follows in terms of data collection and analysis (Tredoux & Smith 2008:161). According to Durrheim and Painter (2008:147-152), in choosing the method to be used in research, there is need to aim at achieving much control over factors that may interfere with the validity and reliability of the study findings.

3.3.1 Quantitative research design

Quantitative research method is often referred to as the traditional scientific approach to research that is grounded in the philosophical paradigm for human inquiry called positivism. It involves the collection of numerical data that can be subjected to statistical analysis that results in quantifiable information (Terre Blanche & Durrheim 2008:7). Research that takes the positivist approach places much emphasis on rationality, objectivity, prediction and control (Baum 1995:463). Quantitative research is often embraced by researchers who support the view that its design is less susceptible to bias based on the belief that the social world lends itself to objective forms of measurement characterized by a set of orderly and disciplined procedure (Sale, Lofeld & Brazil 2002:44). This has resulted in advocates of quantitative approach being referred to as objective scientists who are committed to the discovery of quantifiable information (Baum 1995:460).

Despite the strict application of standardized procedures to minimize systematic bias and avoid making erroneous conclusions in quantitative research, there are some methodological limitations of this approach especially in health research that may limit their applicability in practice (Walker 2005:574). Research with human participants is subject to certain external influences that may affect the findings, ensuring external validity in quantitative research is not sometimes possible due to practical and ethical rea-

sons, to add to this, attaining consistent internal validity may also prove difficult in quantitative methods (Walker 2005:575). The sampling procedure is usually based on specific inclusion and exclusion criteria that require the researcher to select a sample from the study population that is representative of the parent population. Failure to achieve this means the findings cannot be generalized; the practical implication of this is that these criteria may systematically exclude certain proportion of the study population who may have the characteristics that the researcher is investigating. Furthermore, the Hawthorne effect where subjects change their behaviour or respond in a certain manner because of the awareness that they are being observed is another limitation of quantitative method (Leonard & Masatu 2006:2333; McCarney, Warner, Iliffe, Van Haselen, Griffin & Fisher 2007:30).

According to Baum (1995:466), some public health issues need quantification while others are more qualitative in nature; methodologies for health research need to be diverse and chosen to suit the problem being investigated by the researcher. The variables under investigation in this study consist of cognitive mechanisms that are quantifiable; the researcher therefore adopted an objective and detached epistemological stance towards the study variables and followed the positivist approach using quantitative design in undertaking this research.

Quantitative research can be experimental, quasi-experimental or non-experimental and make use of descriptive and inferential statistics. Quantitative study is further divided into cross-sectional in which data are collected a specific point in time or longitudinal which extend over a period of time. This study used a non-experimental cross sectional design as data were collected at a point in time and there was no manipulation of the subjects who participated in the research.

3.3.2 Non-experimental research design

A non-experimental quantitative research methodology was employed using a descriptive correlational design to assess the predictive relationships of ART adherence Self-Efficacy, Beliefs about Medicines and ART adherence in HIV-infected patients on HAART. Correlational research is a measure of the association or co-variation of two or more dependent variables and is used in exploring causal relationships (Walker 2005:573). Correlational design method has some advantages in quantitative research

in that it allows for examination of relationships between variables without introducing any interventions and also allows for generation and testing of hypotheses (Terre Blanche & Durrheim 2008:7). A non-experimental descriptive correlational design was best suited for this research; it enabled the researcher to examine the relationships between the study variables without introduction of any intervention. Data collected by means of quantitative instruments were used to examine the relationships between the independents variables and the dependent variable.

3.4 RESEARCH METHODS

3.4.1 Population

Study population refers to the larger pool from which sample participants are drawn (Durrheim & Painter 2008:133). The study population were male and female, 18 years or older, of all races and socio-economic groups who were on ART at a large clinic within the Tshwane Metropolitan area at the time of conducting this study. This health institution is part of the Comprehensive Care, Management and Treatment program of the Gauteng Department of Health. This area was selected because it is an area where one can find the entire population groups in South Africa representing a heterogeneous population. According to the clinic records, there were 2312 adult patients 18 years or older on ART in the clinic as at the time of this study (Antiretroviral Clinic Statistics 2011). These 2312 adults formed the study population for this research and the study samples were drawn from them.

3.4.2 Power of the study

Power of a study is the ability of the study to demonstrate an association or causal relationship between two variables, given that an association exists. In quantitative research it is necessary to specify the desired study power and to calculate the sample size needed to achieve this power when planning the study to avoid conducting a study with insufficient power. Traditionally, researchers consider a study power of 80% to be the minimum, although higher values are commonly used (Harvey & Lang 2010:736). An exact binomial test with a nominal two-sided significance level will have 87% power to detect the difference between the Null hypothesis proportion π_0 of 0.600 and the Alter-

native proportion π_A of 0.700 when the sample size is 232 (Chernick & Liu 2002:149-155).

3.4.3 Sampling and sample size

Sampling is the process of selecting a portion of the study population that is representative of the entire population (Durrheim & Painter 2008:133). Systematic random sampling method was used in selecting the sample size to ensure all the study population had equal chance of being selected using the inclusion criteria of (a) 18 years and above, (b) Free of severe opportunistic infections (c) No cognitive impairment as determined by the mini-mental state examination (d) Ability to understand English or any of the South African official languages (e) Have been on ART for at least one year. The file numbers of all the 2312 patients were listed in ascending order and every tenth person on the list was selected to participate in the study until the desired sample size of 232 was reached. Where a selected participant declined to participate in the study or ineligible the next person on the list was included.

3.4.4 Data collection

Two research assistants were recruited and trained to assist in the administration of the questionnaires. The assistants included a registered professional nurse who has over five years experience working in HIV/AIDS services; she is involved in HIV counselling and testing, initiation of ART to eligible patients and screening of patients for Tuberculosis and other opportunistic infections associated with HIV/AIDS. She is fluent in Afrikaans, English, Setswana and Sesotho. The other assistant was an enrolled male nurse who has been working as ART adherence counsellor for over two years; his duties include identifying patients who are not adhering to their treatment and developing plan of action to ensure adherence. He is well acquainted with terminologies used in HIV management and speaks English, Setswana and IsiZulu very well. The two assistants were not working at the study setting of this research.

The research assistants were given a short training on protecting human participants in research. In order to ensure consistency, role play was used to ensure standard procedures of obtaining informed consent, in completing the questionnaires, and in handling questions before or in the process of administration of the questionnaires. Simulated

patients were used by each of the assistants to demonstrate how they would explain the research process to potential participants, how they would obtain informed consent, and how they would handle queries related to the research from the participants. The research assistants were informed to resolve difficult issues with the principal investigator before, during and after the administration of the questionnaires. The questionnaires were in English and the two research assistants chosen were able to clarify issues and communicate effectively with study participants.

The patients on ART at the study setting were informed about the study and that they were all potential participants. The risk, benefits, time commitment and eligibility for the study were explained. Informed consent was obtained from selected respondents and appointment fixed for the completion of the questionnaires. The study made use of questionnaires that were completed with the assistance of the researcher and his assistants. Almost all the participants completed the questionnaires on their own with the exception of fifteen people (7%) that had no formal education and were assisted in completion of their questionnaires by either of the research assistants who are fluent in their home language. Completion of the questionnaires was conducted in separate rooms and at the convenient of the selected participants, the average time for completing each questionnaire was 45-60 minutes.

3.4.5 Research instruments

The four quantitative instruments used for data collection in this study were combined together as a single questionnaire (Annexure D) and consists of the following: Demographic Data Questionnaire (developed by the researcher); the HIV Treatment Adherence Self-Efficacy Scales (HIV-ASES); the Beliefs about Medicines Questionnaire (BMQ) and the AIDS Clinical Trial Group (ACTG) Adherence Questionnaire. Permission to use the ACTG and HIV-ASES is granted for HIV research purposes by the Center for AIDS Prevention Studies (CAPS) at University of California, San Francisco (Center for AIDS Prevention Studies 2011). The researcher also obtained permission to use the BMQ questionnaire from the copyright holder (Annexure F).

The independent or predictor variables in this study are demographic characteristics, self-efficacy and beliefs about medicines. The dependent variable is ART medication adherence. The Demographic Data Questionnaire provided information on the demo-

graphic characteristics of the participants and their ART regimens. Participants' ART Adherence self-efficacy was assessed using the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES). The medication beliefs of the study participants were assessed using the Beliefs about Medicines Questionnaire (BMQ) and the medication adherence was assessed with the AIDS Clinical Trial Group (ACTG) Adherence Questionnaire.

3.4.5.1 The demographic data questionnaire

The demographic data questionnaire was developed by the researcher after extensive literature review and was based on the research objectives. The questionnaire was pretested by the researcher by using it to collect information from twenty randomly sampled patients in a clinic that was not included in the final study sample; it was subsequently adjusted, tested again and later finalized before the actual data collection started. The demographic data questionnaire, a 15-item self-report instrument provided information on the demographic characteristics of the participants. Demographic data captured were age, gender, marital status, education, occupation, social habits. Other information included in the demographic data questionnaire is length of time since HIV diagnosis, disclosure of HIV status, possible way of being infected with HIV, length of time on antiretroviral therapy, antiretroviral regimen, number of pills taken daily and available social support in terms of treatment buddy.

3.4.5.2 HIV treatment adherence self-efficacy scale (HIV-ASES)

Self-Efficacy in this research is conceptualized as medication-taking self-efficacy beliefs, or one's belief in his/her ability to plan and perform a desired behaviour (ART adherence). General self-efficacy instruments have little explanatory and predictive value, therefore self-efficacy tools must be tailored to the specific behavioural discipline that is of interest to researchers (Bandura 2004:145). According to Bandura (2004:145) in order to accurately measure medication-taking self-efficacy, the tool must measure the participant's beliefs about their abilities to execute different levels of medication adherence. Self-efficacy in this study was measured using the HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES)**.** The scale developed in the context of HIV treatment to provide a measure of ART adherence self-efficacy in HIV-infected patients on ART, is a 12-item scale (Johnson, Neilands, Dilworth, Morin, Remien & Chesney 2007:359). Psy-

chometric properties of the instrument including content validity, construct validity and internal consistency and stability have been established (Johnson et al 2007:364). Factor analysis supports subscales measuring Adherence Integration (eigenvalue=6.12) and Adherence Perseverance (eigenvalue=1.16) accounting for 61% of the variance in scale items. The instrument demonstrates robust internal consistency (ρs> .90) and test-retest reliability of (*r*s> .70) at 3-month and (*r*s> .40) at 15-month. The authors further state that the concurrent validity analyses showed relationships with ART adherence, clinical status, psychosocial measures and health service utilization (Johnson et al 2007:364).

The HIV-ASES has an 11-point Likert response format with possible range of scores from 0 ("cannot do at all") to 10 ("completely certain can do"). The questions were asked in the form of how confident are that you can do the following? An exemplar question is 'how confident have you been that you can integrate your treatment into your daily routine? High and low categories of ART adherence self-efficacy were defined as above and below the median of the 11 summed items respectively. For this study self-efficacy items score were added and divided by the total number of items to form a composite adherence self-efficacy score.

3.4.5.3 Beliefs about medicines questionnaire (BMQ)

The Beliefs about Medicines Questionnaire (BMQ) is an 18-item scale designed to measure cognitive representations of medication in patients on chronic therapy (Horne, Weinman & Hankins 1999:18). The questionnaire assesses beliefs about specific medications and beliefs about medications in general. The reliability, criterion-related and discriminant validity of the scale has been demonstrated (Horne, Weinman & Hankins, 1999:18; Mårdby, Åkerlind & Hedenrud 2009). It has been validated for use in patients with chronic illnesses and has been shown to predict adherence to treatment (Porteous et al 2010:227; Tordera, Moragon, Fuster, Bayo & Ciscar 2009:220; Aikens, Nease, Nau, Klinkman & Schwenk 2005:27; Russell & Kazantzis 2008). People with strong beliefs in the necessity of taking medication to maintain their health were found to be more adherent to treatment, and those with higher levels of concern about medication, commonly about the dangers of dependence and long-term side-effects, were more likely to be non-adherent (Ireland & Wilsher 2010:40; Chia, Schlenk & Dunbar-Jacob 2006:198; Neame & Hammond 2005:765; Riekert & Drotar 2002:183).

The BMQ is made up of two sections namely, the BMQ-Specific which assesses the representation of medications prescribed for personal use and the BMQ-General which assesses beliefs about medications in general. The BMQ-Specific comprises two 5-item subscales assessing beliefs about the necessity and efficacy of medicines prescribed (*Specific-Necessity*) and concerns about the harmful effects of the prescribed medicines based on belief about the drug and its long-term adverse effects *(Specific-Concerns)*. The BMQ-General has two 4-item subscales; one assesses beliefs about harm associated with medications in general (*General-Harm*) and the other assesses beliefs about the overuse of medicines in general (*General-Overuse*) (Horne, Weinman & Hankins 1999:21).

When the instrument was analyzed for construct validity using principle component analysis, factor analysis on combined items from the BMQ-Specific and BMQ-General factors on pooled data for six illness groups (n=524) showed eigenvalue of 3.38 for Specific-Concerns; 2.92 for Specific-Necessity; 1.60 for General-Harm and 1.44 for General-Overuse (Horne, Weinman & Hankins 1999:12). In a separate study to validate the BMQ conducted by Tordera et al (2009:218-223), data from 126 respondents were analyzed for internal consistency, analysis of the 2 components of the questionnaire revealed excellent internal consistency for the 4 subscales (general overuse, α=0.70; specific necessity, α=0.83; specific concern, α=0.72; and α=0.68 for the general harm subscale (Tordera et al 2009:220).

The exemplar questions for the 4 subscales in relation to HIV/AIDS include:

1. Assessing beliefs about the necessity and efficacy of medicines prescribed for HIV/AIDS (e.g. “Without ARVs I would be quite ill”).

2. Assessing beliefs on concern about the harmful effects of medicines prescribed for HIV/AIDS (e.g. “Having to take ARVs worries me”).

3. Assessing beliefs about the overuse of medicines in general (e.g. “Doctors use too many medications”).

4. Assessing beliefs about harm associated with medications in general (e.g. “medicines do more harm than good”).

The response options for this instrument are rated on a 5-point Likert scale ranging from: Strongly agree, Agree, Uncertain, Disagree to Strongly disagree. Higher score indicates a stronger belief about the corresponding concepts in each sub-scale.

3.4.5.4 AIDS clinical trial group (ACTG) adherence questionnaire

The ACTG Adherence questionnaire is a 5-item tool that assesses adherence to doses, scheduling and dietary instructions, it is less expensive and a much more convenient method for collecting adherence data (Reynolds et al 2007:407). This tool is also a measure of patient's reason for missing medication or dietary requirements. The tool has been used in various studies and found to be a reliable and valid measure of self-reported adherence to ART (Peltzer et al 2010:111; Mathews et al 2002:157; Reynolds et al 2007:408; Chesney et al 2000).

In a series of analyses conducted to estimate the reliability of the 5-item ACTG Adherence Questionnaire by Reynolds and colleagues, Cronbach α coefficients for the standardized scores for the ACTG Adherence Questionnaire items (5 items and 8 variables) were all greater than 0.80, demonstrating good reliability. The authors also confirmed that the measure of adherence using items 1 to 4 of the ACTG Adherence Questionnaire was found to be strongly associated with plasma HIV RNA outcome and was also comparable to adherence measured by medication events monitoring system (Reynolds et al 2007:406).

The questionnaire queries the participants on the number of doses missed of a medication during each of the 4 days before a clinic visit (e.g., ''How many doses did you miss yesterday, the day before yesterday, 3 days ago, and 4 days ago?''). In addition, other adherence behaviour were assessed with 4 questions regarding adherence with the daily schedule as follows; ''Most ARV medications need to be taken on a schedule … How closely did you follow your specific schedule over the last 4 days?'' ''Do any of your medications have special instructions? If so, how often did you follow those instructions over the last 4 days?'' ''When was the last time you missed any of your medications?''
The constructs for the three behavioural questions and the response categories are as follow:

1. How closely was the schedule followed? 0=never, 1=sometime, 2=half of the time, 3=most of the time, 4=all of the time.

2. How closely were instructions followed? 0=never, 1=sometime, 2=half of the time, 3=most of the time, 4=all of the time.

3. When any medication was last skipped? 0=never, 1=>3 months, 2=1 to 3 months, 3=2 to 4 weeks, 4=within past 2 weeks, 5=within past 2 days.

Medication adherence is defined as the percentage of prescribed medications taken in any form for the last 4 days; *instructions adherence* is defined as the percentage of medications for which the correct special instructions were followed at each prescribed dose. Adherence to ART in this study is defined as patients compliant to HIV medication in previous four days. Adherence is calculated as the percentage of doses taken over those prescribed.

3.5 PILOT STUDY

Pilot study assists researchers in identifying possible problems in the proposed study and allows for revision of the methods and instruments before data collection (Terre Blanche, Durrheim & Painter 2008:94). The researcher carried out a pilot study at a separate clinic that was not included in the final study sample. The four instruments were tested among randomly selected 30 participants that had similar characteristics to the sample selected for this study for contents clarity before being administered to the selected sample. The respondents were asked to give constructive feedback with regard to clarity of the questions, comprehension and time necessary to answer all the questions in the questionnaire. The respondents did not experience difficulty in completing the questionnaires and completed the questionnaire between 45-60 minutes, they made some valuable comments described below which were considered during the administration of the questionnaires to the 232 patients selected for this study. The following were the comments made by the 30 participants who participated in the pilot study.

Question 9 on the demographic data questionnaire: What is/are the most likely way(s) that you became infected with HIV? When asked about the modality of acquiring HIV infection, about half of the respondents indicated they did not know. This prompted the researcher to include an option “Don’t know” in the revised questionnaire.

Question 14 on the demographic data questionnaire: What is the number of pills you swallow every day? Participants queried what the number of pills meant; as there were some participants who had co-morbidities e.g. asthma, diabetes, hypertension etc. who were also on ART. They wanted to know if they should add up all the ARVs and other pills. In the revised questionnaire the researcher specified the number of pills to mean ARVs only to avoid confusing the participants.

Furthermore, the participants in the pilot study identified some similarity between questions 4 and 7 in the HIV-ASES questionnaire. Question 4 asked: “How confident are you that you can stick to your treatment schedule even when your daily routine is disrupted?” Question 7 asked: “How confident are you that you can continue with your treatment even if doing so interferes with your daily activities?” The researcher clarified the ambiguity noted here with the participants during the administration of the questionnaires to the 232 selected individuals. Sticking to treatment schedule mentioned in question 4 meant continuing taking medication as prescribed in terms of dosing, scheduling and dietary instructions. To continue with treatment mentioned in question 7 meant continuing taking medication without emphasizing sticking to dosing, scheduling and dietary instructions.

Some participants indicated they did not know the meaning of T-cells in question 8, where participants were asked how confident they were in continuing with their treatment plan prescribed by their physician even if their T-cell drops significantly in the next three months. The researcher changed T-cell to CD4 in the revised questionnaire that was eventually used in this study since all HIV-infected patients on ART know what CD4 means; they are informed of it during the counselling process.

The researcher having revised the questionnaire based on the above feedback from the pilot study informed the research assistants to note them and educated them on how to handle the query that may arise from the perceived similarity between questions 4 and 7 on the HIV-ASES questionnaire.

3.6 DATA ANALYSIS

The Statistical Package for Social Sciences (SPSS) version 19.0 manufactured by IBM was used for data analysis. Descriptive statistics including means, percentages and frequency distribution were used to summarize the demographic data, HIV-ASES, BMQ and ACTG questionnaire. Measures of variability were applied to characterize the differences that exist among the scores and the central tendency of the data. Pearson correlation analysis was used to assess the bivariate associations among the variables, and multivariable logistic regression was used to determine predictors of medication adherence. A p-value of <0.05 was considered to be significant; an alpha level of 0.05 is the probability of a type I error, that is, the probability of rejecting the null hypothesis given that that the null hypothesis is true. The significance of each independent variable as well as the combined significance of the independent variables to the dependent variable was explained by the variance observed in the dependent variable. Variables included in the model are summary scores from the BMQ and HIV-ASES that were significantly associated with adherence as measured by ACTG questionnaire.

3.7 INTERNAL AND EXTERNAL VALIDITY OF THE STUDY

Internal validity is the extent to which causal conclusion can be drawn from a study findings and a study is said to have external validity if the finding can be generalised beyond the confines of the design and the study settings (Van der Riet & Durrheim 2008:90). The use of cross-sectional design to investigate adherence to HIV medication at a point in time, will limits the degree to which causal inferences and generalizations can be made from the research findings, but the use of systematic random sampling ensured the selected samples were representative of the target population, and the use of a fairly large sample size enhanced the external validity of the study.

3.8 CONTENT VALIDITY OF THE RESEARCH INSTRUMENTS

Content validity is based on the extent to which a measurement reflects the specific intended domain of content; it focuses on the adequacy with which the domain of the characteristics is captured by the measure (Vogt, King & King 2004:232). To ensure that all the measures in this study represent the facets of the constructs under investigation, the following steps were taken by the researcher:

- An extensive review of relevant literature on the constructs being investigated; this enabled the researcher to conceptually define the domains of the characteristics i.e. specifying what the variables are and what they are not.
- Ongoing refinement of definitions of the constructs being investigated.
- Consultation with members of the target population to increase the chance that items are content valid for their intended purpose.
- Consultation with subject matter experts in the field of this research for content validity of the instruments.

3.9 RELIABILITY OF RESEARCH INSTRUMENTS

In quantitative research summated scales are often used in survey instruments to probe underlying constructs of interest to the researcher. These are often comprised of indexed responses to dichotomous or multi-point questionnaires which are later added up to arrive at a composite score for individual participant (Kanjee 2008:488). Since these summated scales are an assembly of interrelated items that are designed to measure underlying constructs, it is very crucial to know their reliability. Reliability testing allows the researcher to know whether the same set of items would provide a good assessment that if the questionnaire is re-administered; there is a good chance of getting the same result. According to (Durrheim & Painter 2008:152-154) reliability is best described as the dependability of a measurement instrument; it is the extent to which the instrument yields the same results repeatedly.

3.9.1 Cronbach's Alpha: an index of reliability

One of the common reliability statistics that is used in statistical analysis is Cronbach's alpha; it determines the internal consistency or average correlation of items in a survey instrument to gauge its reliability (Durrheim & Painter 2008:152-154). The value of Cronbach’s coefficient alpha ranges from 0 (no internal consistency) to 1 (maximum internal consistency) and may be used to describe the reliability of factors extracted from dichotomous (that is, questions with two possible answers) and/or multi-point formatted questionnaires or scales (i.e., rating scale: 1=poor, 5=excellent). The higher the score,

the more reliable the generated scale is. In questionnaire type scales, alpha value greater than 0.75 are considered reliable (Durrheim & Painter 2008:154).

Although three of the research instruments used in this study have been validated in many studies as reliable research tools, Cronbach's coefficient alpha was determined for the four combined research instruments in the current study and the results showed the following: Number of items in the scale=49, Average inter-item correlation=0.0719, and Cronbach's coefficient alpha of 0.7915. These results indicate the internal consistency of the research instruments used in this study.

3.10 ETHICAL CONSIDERATIONS

In research ethics refers to a set of standard principles, values and behavioural expectations that guide the research process about accepted conduct towards study participants and other stakeholders in the research community (De Vos et al 2005:57). Important among these principles are justice and respect for human right. In this research, a vulnerable group of people (HIV-infected) were the participants; therefore strict ethical consideration was adhered to throughout the study.

3.11.1 Ethical permission

The researcher obtained ethical clearance from the Higher Degrees Committee of Department of Health Studies, University of South Africa before data collection commenced (Annexure A). Furthermore, permission was sought and obtained from the management of the health institution where the study was carried out (Annexure C).

3.11.2 Informed consent

The researcher informed the participants about the nature and topic of the study, purpose, risk, benefit, type of information to be collected and time commitment (Annexure E). This provided opportunity for the participants to have their concerns and questions addressed. All participants were able to sign the consent form that allowed them to participate in this research; the choice and decision to participate in the study were made voluntarily by the participants through written consent. They were assured that they were free to withdraw at anytime and that they will not be punished for doing so.

3.11.3 Confidentiality

The researcher assured participants that the information collected in the process of this research would be treated with strict confidence. The research assistants for this study received training on the issue of confidentiality and were required to sign a document pledging to keep research data confidential. Further to this, all collected data were stored electronically in a secured location and protected with password. Raw data were also securely stored and access to them restricted.

3.11.4 Anonymity

Identification numbers were used for the questionnaires that bore no link with participants' name or hospital number, and the sample participants were not identified in published or disseminated results.

3.11.5 The principle of justice

Right to fair treatment and privacy

Every participant was accorded fair and equal treatment by the research team. The researcher ensured that the research team handled all participants with courtesy and showed sense of patience and tolerance in their conduct towards the participants. Participants were given the opportunity of arranging time for completion of the questionnaires which was conducted in separate rooms to ensure their right to privacy was not violated.

3.11.6 Principle of beneficence

Freedom from harm

Although no major risk was anticipated in this study, the researcher ensured that participants were fully protected from any harm, research assistants were well trained to handle sensitive issues and interviews were conducted in safe environment. Participants were also told they could report any adverse incidents to the researcher in the course of

data collection. The researcher assured participants that their HIV-positive status would not be exploited for any personal or financial gain by the research team.

Benefit from the research

Participants did not receive any monetary gain for their participation in the study; they however contributed to the existing body of knowledge in the field of HIV/AIDS and would benefit from the outcome of the study through their participation.

3.11.7 Principle of respect for human dignity

The right to self-determination

The participants were be able to consent to participate in the research and were not coerced into taking part. They were also able to exercise the right to refuse answering any questions and could withdraw from the study without any consequences.

The right to full disclosure

All aspect of the study was disclosed to the hospital management where the study was conducted and to the participants. Name and phone numbers of the researcher and his supervisor were provided in the event that any concerns regarding the research arose.

3.11.8 The right of vulnerable subjects

As the participants in this study are vulnerable group in the society who has had to deal with stigma and emotional trauma due to their HIV status, the researcher took necessary steps to ensure that the research process did not subject them to more stigma and psychological trauma. All aspect of the study that involves interaction between participants and the members of the research team were handled with respect and participants were not judged based on their responses. Furthermore, the researcher honoured all agreement of follow-up from study participants and counselling services were made available for participants who developed emotional trauma as a result of their participation in this research.

3.12 CONCLUSION

This chapter described the research methodology used in the current study and justified why such design was chosen. Method of statistical analysis was also described together with the quantitative research instruments, and the pilot study conducted prior to data collection. It concluded with the description of ethical issues related to the research and the measures taken by the researcher to ensure all ethical standards were strictly complied with. The next chapter contains the results of the research.

CHAPTER 4

ANALYSIS, PRESENTATION AND DESCRIPTION OF THE RESEARCH FINDINGS

4.1 INTRODUCTION

The previous chapter dealt with the research methodology adopted for the current study and described the design used together with the ethical considerations related to the study. This chapter presents the results of the participants' responses regarding the implications of self-efficacy and beliefs about medicines on adherence to ART. It contains both the descriptive and analytical statistics of the research.

The specific objectives of this research were to:

1. Explore the cognitive variables of adherence self-efficacy and beliefs about medicines that influence adherence among patients on ART.

2. Determine the inter-relationships among adherence self-efficacy, beliefs about medicines and ART adherence.

3. Describe the modalities of enhancing adherence to ART through focused interventions on the identified factors that are strongly associated with ART adherence.

4. Develop a framework for the improvement of ART adherence based on the factors identified in this study.

4.2 DATA MANAGEMENT AND ANALYSIS

The data collected were captured into Excel spreadsheet and analysed with the Statistical Package for Social Sciences (SPSS) version 19.0 manufactured by IBM. Before data analysis each questionnaire was checked for completion by the researcher to ensure that they were answered correctly and subsequently scrutinized by the researcher

again before the data were eventually entered into Excel spreadsheet using double entry method, checked for errors, cleaned and then exported into the SPSS programme for processing and analysis. The data that differed during double entry were cross-checked against the questionnaires concerned. Before data analysis each variable was examined separately through various SPSS functions for accuracy of data entry, missing values, and fit between their distributions and the assumptions of multivariate analysis. Accuracy of data entry was confirmed by checking univariate descriptive statistics for strange data such as values out of range, means, standard deviations and univariate outliers. ART adherence is the variable that the researcher believes would be influenced by changes in other variables; therefore it was depicted as the dependent variable, and the other variables referred to as independent variables. Descriptive analysis was done for the **dependent variable** (ART adherence) which was measured by the ACTG questionnaire and **independent variables** (Demographic data questionnaire, HIV adherence self-efficacy questionnaire and beliefs about medicines questionnaire), followed by correlation and regression analysis.

Frequencies were run for all variables in the demographic data questionnaire, these include age group, gender, marital status, highest level of education, smoking habits, alcohol consumption, work status, period of HIV diagnosis, mode of HIV infection, disclosure of HIV status, availability of treatment buddy, extent of treatment buddy assistance, period of ART use, amount of pills consumed daily and history of ART adverse reactions.

The HIV adherence self-efficacy section consisted of twelve questions, all expressing confidence on a scale of 0–10, high and low scores were defined as above and below the median of the 11 summed possible score (0–10). For each of the 12 items on the HIV-ASES scale, participants that scored 5 and above were categorized as high score and those that scored 4 and below were categorized as low score. In addition, composite adherence self-efficacy score (SES) for each participant was calculated; to arrive at composite score for each participant, the twelve scores were averaged to produce a composite score out of 10 as an index of overall confidence in complying with the treatment schedule.

The beliefs about medicines-specific section consisted of ten questions rated on a 1–5 scale of strongly agree, agree, uncertain, disagree, and strongly disagree. The 10 ques-

tions were in the direction that an optimal score was 5. The frequencies of responses on the Beliefs about Medicines questionnaire were calculated after categorizing the Likert scale responses into three (Agree, uncertain and disagree). To calculate composite score for each participant on the BMQ-specific scale, these ten scores were averaged to produce a composite score out of 5 as an index of positive beliefs about medicines – specific. Higher scores indicated a stronger belief in necessity and concerns about specific medicines prescribed for use in antiretroviral therapy.

The Beliefs about medicines-general section consisted of eight questions rated on a 1–5 scale of strongly agree, agree, uncertain, disagree, and strongly disagree. The 8 questions were in the direction that an optimal score was 5. The frequencies of responses were calculated after categorizing the Likert scale responses into three (Agree, uncertain and disagree). To calculate composite score for each participant the eight scores were averaged to produce a composite score out of 5 as an index of positive beliefs about medicines – general. Higher scores indicated a stronger belief in overuse and harm associated with medicines prescribed for use in medical conditions.

Adherence to ART using the ACTG questionnaire was calculated as total number of doses taken divided by total number of doses prescribed over four days and expressed as a percentage. Proportion of doses missed in last 4 days was calculated for each participant together with the extent to which they complied with prescribed dosing scheduled of ART and the extent of their compliance with special dietary instructions.

Correlation analysis was performed on the variables to establish the relationships among HIV adherence self-efficacy, Beliefs about medicines and ART adherence. Correlation coefficients among the predictor variables HIV-ASES BMQ-S, BMQ-G and the outcome variable (ART adherence) were examined. Finally, multiple regression analysis was conducted to examine the relationships among the independent variables and ART adherence.

4.3 DESCRIPTIVE ANALYSIS OF THE STUDY POPULATION

The socio-demographic characteristics of the study population are presented in Table 4.1 below. Two hundred and thirty-two patients took part in this study, 69 (30%) were male and 163 (70%) were female. The majority 208 (90%) fell largely in the 25-55 years

age group, and clustered at 100 (43%) in the 35-44 years age group. There were 6 (2.6%) in the 18-24 years age group, and 18 (7.8%) over 55 years of age.

Table 4.1 Socio-demographic characteristics of study population

Characteristics	Frequency (N=232)	%
Age		
18-24	6	2.6
25-34	50	21.6
35-44	100	43
45-55	58	25
>55	18	7.8
Sex		
Male	69	30
Female	163	70
Marital status		
Never married	141	61
Married	60	26
Cohabiting	2	1
Widowed	12	5
Separated	12	5
Divorced	5	2
Highest level of education		
No schooling	15	7
Primary education	54	23
Secondary education	140	60
Tertiary education	23	10
Employment status		
Employed	82	35.3
Unemployed	131	56.5
Student	2	1
Social grant	16	6.9
Retired	1	0.4
Frequency of alcohol consumption		
More than once daily	4	1.7
Once daily	2	0.9
A few times per week	10	4.3
About once a week	30	12.9
Seldom	41	17.7
Never	145	62.5
No of cigarette smoked daily		
None	204	87.9
1-4 sticks	13	5.6
5-9 sticks	10	4.4
10-14 sticks	4	1.7
15 and more	1	0.4

A large proportion, 141 (61%), had never been married, and a further 60 (26%) were married. The remainder were split between 2 (1%) cohabiting, 12 (5%) separated, 12

(5%) widowed and 5 (2%) divorced. In terms of education, most patients – 140 (60%) had a secondary education, and a fair number – 54 (23%) had a primary education.

There were 15 (7%) with no schooling, and 23 (10%) with tertiary education. The work status in the previous three months was that the majority – 131 (56.5%) were unemployed and 62 (35.3%) had employment. There were 16 (7%) social grant recipients, 2 (1%) students, and a retired person.

When looking at smoking and drinking habits, it was noted that most of the participants – 204 (88%) did not smoke cigarettes at all. 13 (6%) smoked 1-4 cigarettes per day, 10 (4%) smoked 5-9 cigarettes per day, 4 (2%) smoked 10-14 cigarettes per day, only one person smoke more than 15 cigarettes per day. There was a similar pattern with alcohol consumption, where the majority – 145 (63%) never drank, 41 (18%) seldom drank, 30 (13%) drank about once a week, 10 (4%) drank a few times a week, 2 (1%) drank once daily, and only one patient drank more than once daily.

4.3.1 Duration of HIV diagnosis

The duration of HIV diagnosis among study participants is described in Figure 4.1 below. Majority, 129 (55.6%) of the participants have been living with HIV/AIDS for more than 36 months. About one-fifth 44 (19%) were diagnosed with HIV in less than 24 months and 59 (25%) have been diagnosed between 24–36 months.

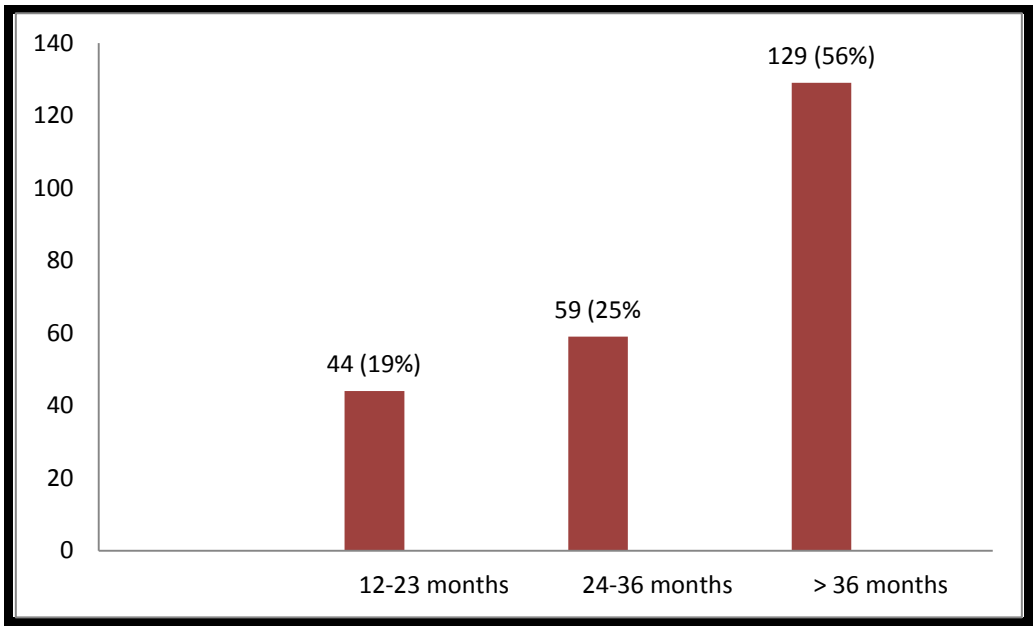

Figure 4.1 Duration of HIV diagnosis (N=232)

4.3.2 Modality of acquiring HIV infection

The majority – 146 (63%) believe that they had become infected with HIV by having sex with an HIV-positive person. Another 75 (32%) did not know how they had become infected. The remainder were spread between 5 (2.2%) cases of sexual assault, 3 (1.3%) with occupational exposure to blood or body fluid, and one each of shared needles with an HIV-positive person, mother-to-child transmission, and blood transfusion or medical procedure.

Table 4.2 Modality of acquiring HIV infection

	Frequency (N=232)	%
Sex with HIV+ person	146	63
Shared needles with HIV+ person	1	0.4
Mother-to-child transmission	1	0.4
Occupational exposure to blood/body fluids	3	1.3
Sexual assault	5	2.2
Blood transfusion or medical procedure	1	0.4
Don't know	75	32
TOTAL	**232**	**100**

4.3.3 Disclosure of HIV status

As shown in Figure 4.2 below almost 227 (98%) all the participants have already disclosed their HIV status to their family members and only 5 (2%) had not.

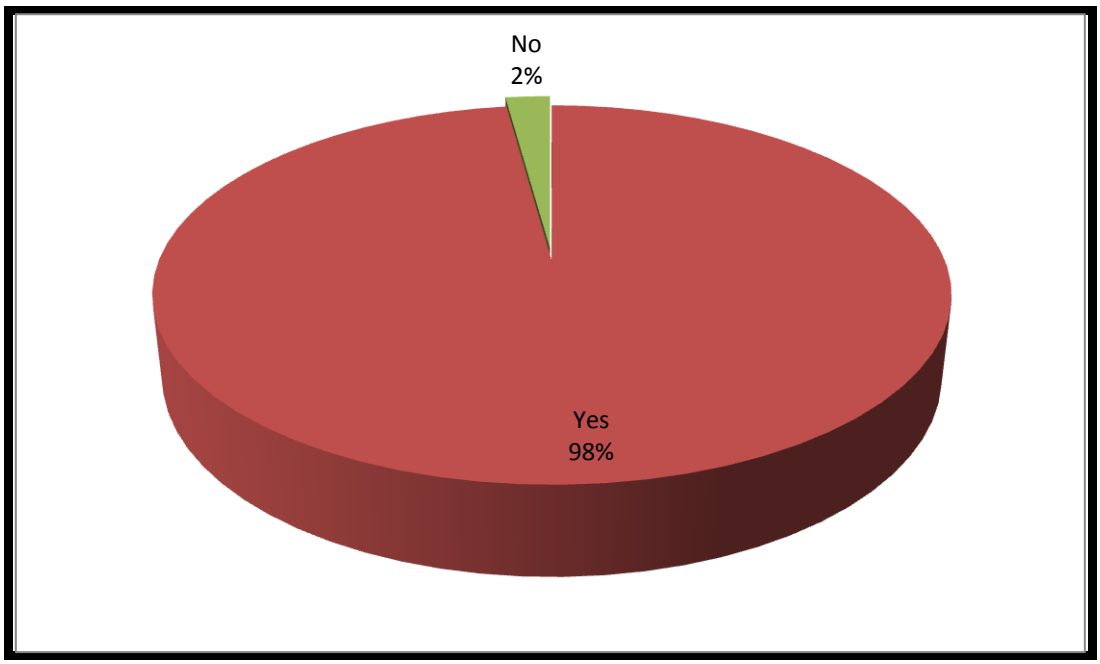

Figure 4.2 Disclosure of HIV status (N=232)

4.3.4 Proportion of participants with treatment buddies

Majority 217 (94%) of the participants in the study reported having treatment buddies as depicted in Figure 4.3 below. Out of the 217 respondents who have treatment buddies, about two-thirds 134 (62%) said their buddies help them a lot in adhering to their medications with just 1% who described their treatment buddies as not helpful at all in adhering to their antiretroviral therapy (Figure 4.4).

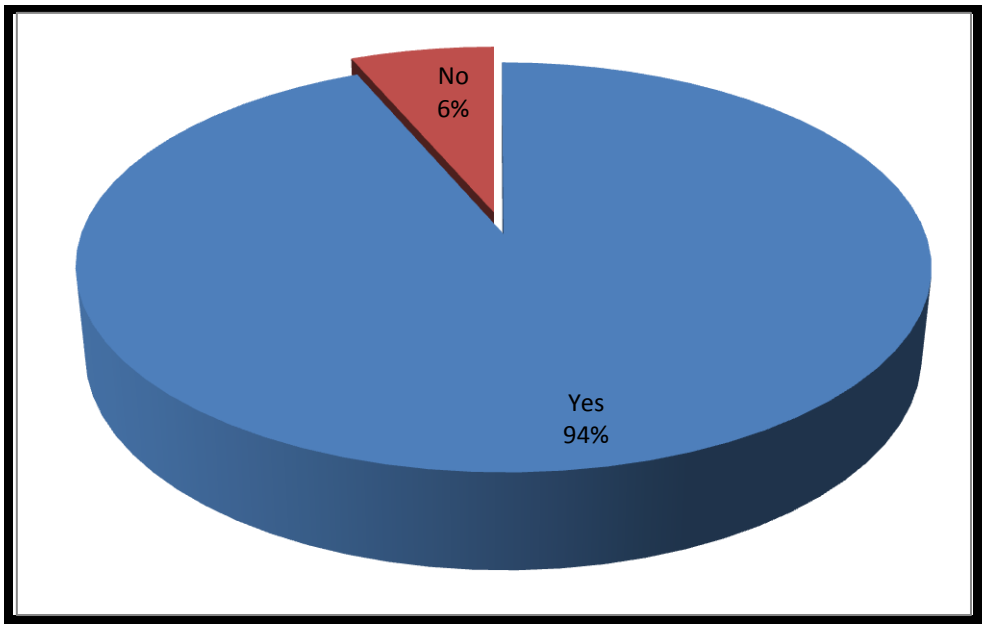

Figure 4.3 Proportion of participants with treatment buddies (N=232)

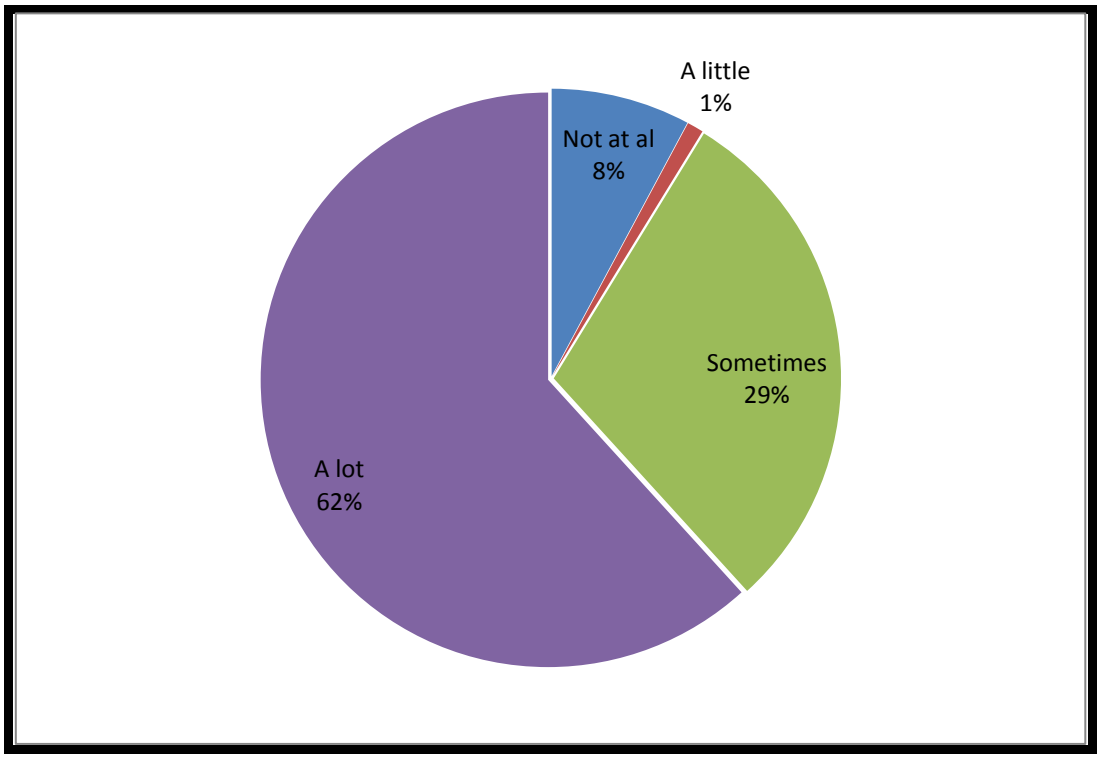

Figure 4.4 Extent of treatment buddies' assistance (N=232)

4.3.5 Duration of ART use

Figure 4.5 shows the duration of ART use among the participants. Over half 128 (55%) have been on treatment for more than 36 months, followed by 74 (32%) who have been on ART for between 2–3 years.

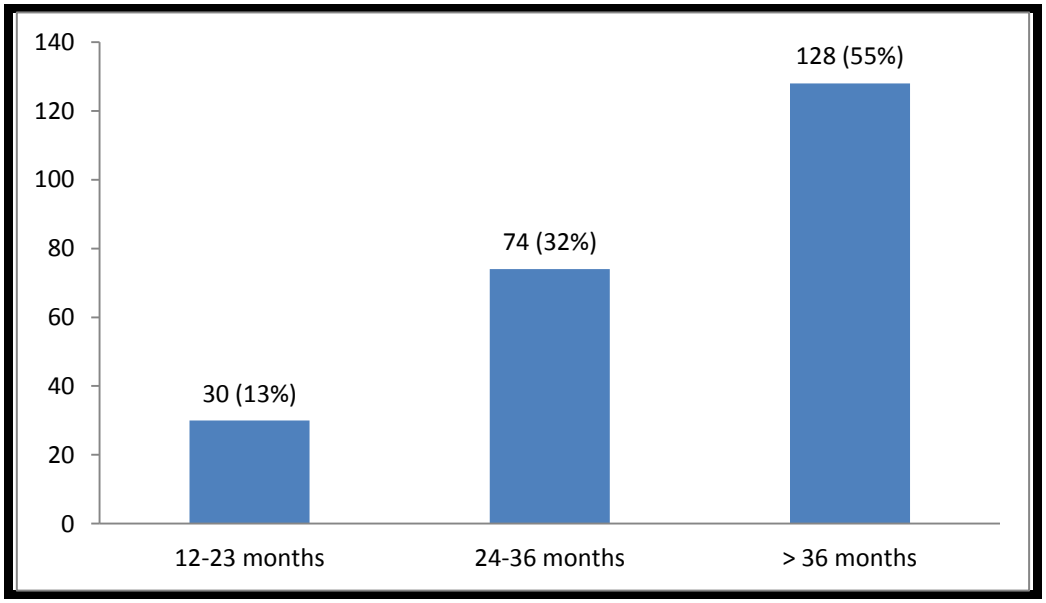

Figure 4.5 Duration of antiretroviral use (N=232)

4.3.6 Amount of pills consumed daily

The number of pills ingested by the participants is represented in Figure 4.6 below. Majority 190 (82%) take between 2-3 pills daily, followed by 41 (18%) who consumed between 6-10 pills daily. Only one participant reported having to take more than 10 pills daily which represent less than 1% of the study population.

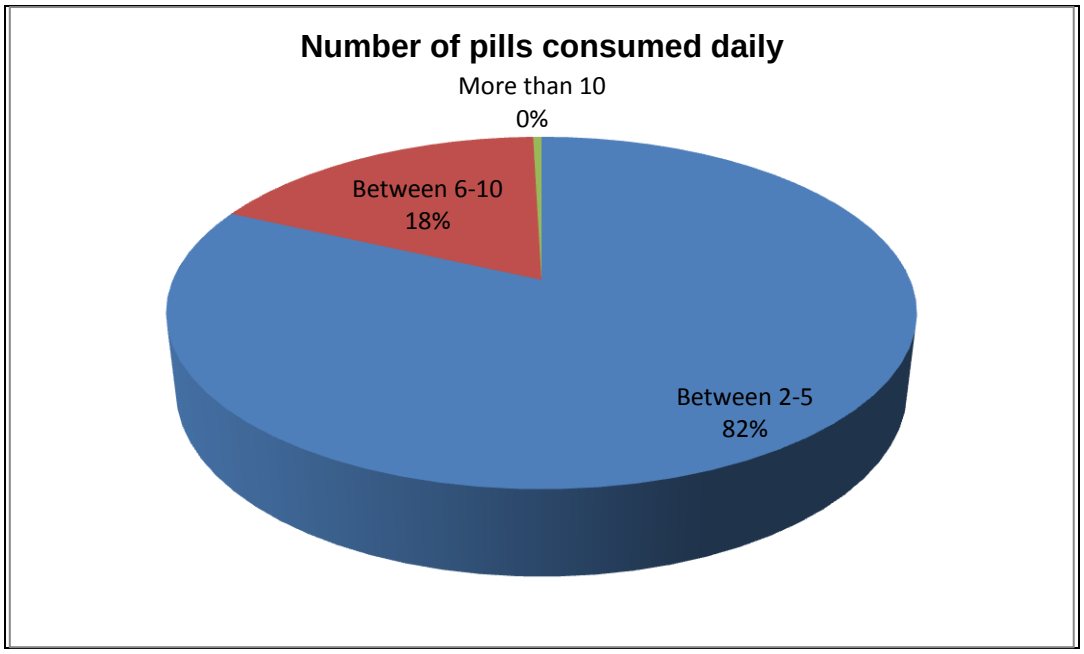

Figure 4.6 Number of pills consumed daily (N=232)

4.3.7 History of adverse reactions to ART

Participants were asked if they have ever experienced adverse reactions to ART that would require them to stop the medications (Figure 4.7). Most of them 201 (87%) reported never having such reactions.

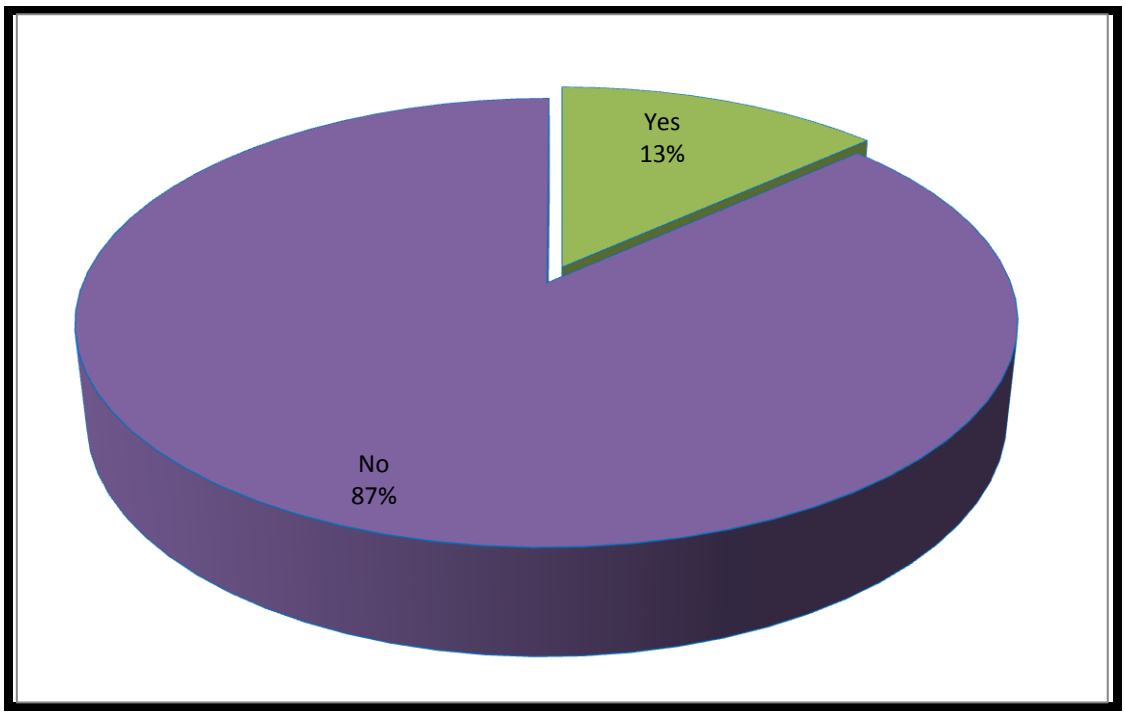

Figure 4.7 History of adverse reactions to ART (N=232)

4.3.8 HIV treatment adherence self- efficacy

Self-efficacy in this research was conceptualized as medication-taking self-efficacy beliefs, or one's belief in his/her ability to plan and perform desired behaviour that would result in adhering to ART. The HIV adherence self-efficacy section consisted of twelve questions, all expressing confidence on a scale of 0–10. High and low categories of ART adherence self-efficacy were defined as above and below the median of the 11 summed possible score (0–10). For each of the 12 items on the HIV-ASES scale, participants that score 5 and above were categorized as high score and those that score 4 and below were categorized as low score. The summary of both high and low scores are shown in Table 4.3 below.

The participants demonstrated high level of confidence on all the 12 items tested in the HIV-ASES scale. When asked how confident they were integrating HIV treatment plans into daily activities, about 169 (73%) of the participants obtained high score in that category. When asked how confident they were about sticking to treatment schedule when they don't feel well, 172 (74%) of the study participants scored high. The item where the participants seem to score the least is item 9; when they were asked how confident they were in continuing with the HIV treatment even when they are feeling discouraged about their health; the participants that got high score in this item were 162 (69.8%).

A composite adherence self-efficacy score (SES) for each participant was calculated; for each participant, the twelve scores were averaged to produce a composite score out of 10 as an index of overall confidence in complying with the treatment schedule. The mean score on the HIV-ASES was 6.45 (SD= 2.47). The score ranged from 0.17 to 10 with a higher score indicating greater self-efficacy. Only one participant scored a perfect score of 10. The summary score of HIV-ASES may be seen in Table 4.3 below.

Table 4.3 Summary scores of HIV-ASES high and low score categories (N=232)

	High score		Low score	
	Freq	%	Freq	%
1. Stick to your treatment plan even when side effects begin to interfere with your daily activities?	**169**	**72.8**	**63**	**27.2**
2. Integrate your treatment into your daily routine?	**171**	**73.7**	**61**	**26.3**
3. Integrate your treatment into daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV+	**170**	**73.3**	**62**	**26.7**
4. Stick to your treatment schedule even when your daily routine is disrupted?	**171**	**73.7**	**61**	**26.3**
5. Stick to your treatment schedule when you aren't feeling well?	**172**	**74.1**	**60**	**25.9**
6. Stick to your treatment schedule when it means changing your eating habits?	**170**	**73.3**	**62**	**26.7**
7. Continue with your treatment even if doing so interferes with your daily activities?	**165**	**71.1**	**67**	**28.9**
8. Continue with the treatment plan your physician prescribed even if your CD4 count drop significantly in the next three months?	**174**	**75**	**58**	**25**
9. Continue with your treatment even when you are feeling discouraged about your health?	**162**	**69.8**	**70**	**30.2**
10. Continue with your treatment even when getting to your clinic appointments is difficult?	**166**	**71.6**	**66**	**28.4**
11. Continue with your treatment even when people close to you tell you that they don't think that it is doing any good?	**175**	**75.4**	**57**	**24.6**
12. Get something positive out of your participation in treatment, even if the medication you are taking does not improve your health?	**172**	**74.1**	**60**	**25.9**

4.3.9 Beliefs about medicines-specific

The BMQ-S measurements reflected participants' beliefs about the perceived necessity and concerns about use of ARVs in treating HIV/AIDS, it consisted of ten questions rated on a 1–5 scale of strongly agree, agree, uncertain, disagree, and strongly disagree. The first 5 items on the scale related to the beliefs about the necessity of the ARVs medicines for maintaining health (Specific-Necessity) and items 6-10 dealt with concerns about ARVs (Specific-Concerns).

Table 4.4 Frequency of responses on the Beliefs about Medicines-Specific scale (N=232)

	Agree		Uncertain		Disagree	
	Freq	%	Freq	%	Freq	%
1. My health, at present, depends on my ARVs	225	97.4	3	1.3	3	1.3
2. My life would be impossible without my ARVs	218	94	8	3.5	6	2.5
3. Without my ARVs I would become very ill	222	95.6	9	3.8	2	0.8
4. My health in the future will depend on my ARVs	217	93.5	12	5.2	3	1.3
5. My ARVs protect me from becoming worse	216	93	8	3.5	8	3.5
6. Having to take ARVs worries me	36	15.5	14	6.1	182	78.4
7. I sometimes worry about long-term effects of my ARVs	71	30.6	27	11.6	134	57.8
8. I don't know how my ARVs work	50	21.6	24	10.3	158	68.1
9. My ARVs disrupt my life	26	11.2	35	15.1	171	73.7
10. I sometimes worry about becoming too dependent on my ARVs	42	18.1	41	17.7	149	62.2

To calculate frequencies of participants' responses on the BMQ-Specific scale, the 5 Likert scale responses were categorised into three (agree, uncertain and disagree). These may be seen in Table 4.4 above. Most participants 225 (97.4%) for the first variable (at present) and 217 (93.5%) for the second variable (future) believed that their

health depends on antiretroviral medication. Only 36 (15.5%) of the participants reported that having to take ARVs worries them, few 50 (21.6%) claimed not to know how their ARVs work and 26 (11.2%) confirmed that ARVs cause disruption in their lives. Most 222 (95.6%) of the sample reported that their medications kept their health from deteriorating. Majority 134 (58%) of the participants were not worried about the long-term effects of ARVs including dependency 149 (62.2%).

To calculate the composite score for each participant, the scores on the 10 items were averaged to produce a composite score out of 5 as an index of positive beliefs about medicines – specific. The participants' score on the BMQ-S ranged from 2.9 to 4.9, with a mean of 4.05 (SD=0.42). Higher scores indicated a stronger belief in specific medicine prescribed in antiretroviral therapy, in this case antiretroviral drugs.

4.3.10 Beliefs about medicines-general

The BMQ-G measurements reflected participants' beliefs about the harm and overuse associated with use of medicines in general, it consisted of eight questions rated on a 1–5 scale of strongly agree, agree, uncertain, disagree, and strongly disagree. The 8 questions were in the direction that an optimal score was 5. To calculate frequencies of participants' responses on the BMQ-General scale; the 5 Likert scale responses were categorised into three (agree, uncertain and disagree). These may be seen in Table 4.5 below. Items 1–4 on the BMQ-general dealt with nature of medicines (General-Harm) and the remaining four items dealt with views about how they are used by doctors (General-Overuse).

One hundred and nineteen participants (51%) believed that doctors overused medications in general, placed too much trust on medicines 193 (83.2%) and spent little time with patients thereby prescribing many medications 127 (54.7%). Almost half 106 (45.7%) of the participants believed that medicines are addictive. Few 12 (5.2%) endorsed the belief that natural remedies are safer than medicine, all medicines are poisons 29 (12.5%) and that people on chronic medicines should stop taking them very often 24 (10.3%).

To calculate the composite score for each participant, the eight scores were averaged to produce a composite score out of 5 as an index of positive beliefs about medicines

– general, the mean score was 3.18 (SD=0.5), with scores ranging from 1.87 to 4.62. Higher scores indicated stronger beliefs about the harm and overuse associated with the use of medicines in general in the management of disease conditions.

Table 4.5 Frequency of responses on the Beliefs about Medicines-General scale (N=232)

	Agree		Uncertain		Disagree	
	Freq	%	Freq	%	Freq	%
1. Doctors use too many medicines	119	51	30	13	83	36
2. People who take medications should stop their treatment for a while every now and again	24	10.3	22	9.5	186	80.2
3. Most medicines are addictive	106	45.7	42	18.1	84	36.2
4. Natural remedies are safer than medicines	12	5.2	20	8.6	200	86.2
5. Medicines do more harm than good	70	30.2	45	19.4	117	50.4
6. All medicines are poisons	29	12.5	28	12.1	175	75.4
7. Doctors place too much trust on medicines.	193	83.2	16	6.8	23	10
8. If doctors had more time with patients they would prescribe fewer medicines	127	54.7	58	25	47	20.3

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4.3.11 Antiretroviral therapy adherence

Medication Adherence was calculated as the proportion of medication taken out of the amount prescribed over the last four days and expressed as percentages. Mean adherence for the total population (232) was 95% (SD=13.2). For the purpose of this study, a participant is said to be adherent at above 95%, therefore 189 (81.5%) participants were adherent. Thirteen (5.6%) were 80%-95% adherent, 29 (12.5%) were 50%-79% adherent, and only one patient (0.4%) was assessed at <50%.

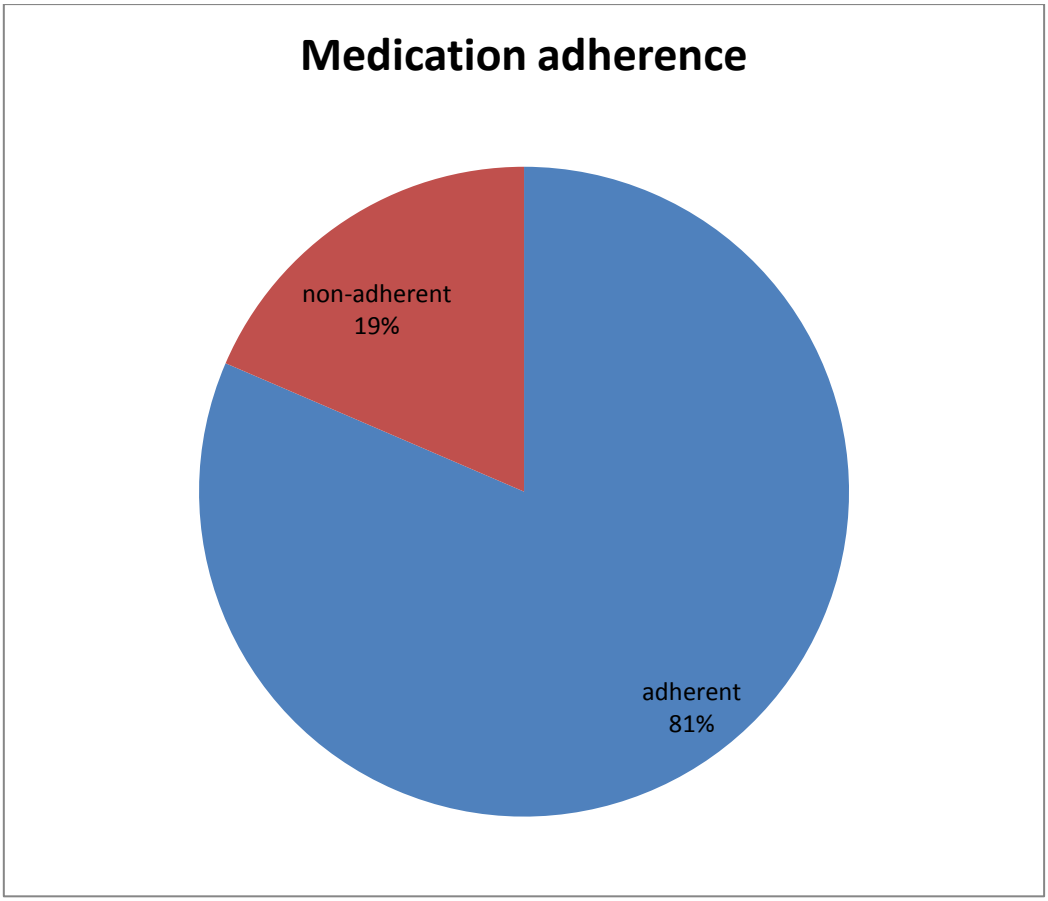


Figure 4.8 Medication adherences over previous 4days (N=232)

When adherence was further broken down, as shown in Table 4.6 below, it was found that in the previous four days 208 (89.7%) patients reported never missing any doses, 18 (7.8%) reported missing a dose on one day, and 16 (2.6%) reported missing a dose on two days.

Table 4.6 During the past 4 days, on how many days have you missed taking all your doses? (N=232)

Responses	Frequency	Percentage	Cumulative %
None	208	89.7	89.7
1 day	18	7.8	97.5
2 days	6	2.6	100
Total	**232**	**100**	

The ACTG questionnaire has a section where the following statement was made*; most anti-HIV medications need to be taken on a schedule, such as "2 times a day" or "3 times a day" or "every 8 hours". How closely did you follow your specific schedule over the last 4 days?* The results are shown in Table 4.7 below.

Table 4.7 How closely did you follow your medication's specific schedule over the last 4 days? (N=232)

Responses	Frequency	Percentage	Cumulative %
All of the time	110	47.4	47.4
Never	57	24.6	72
Most of the time	39	16.8	88.8
Some of the time	18	7.8	96.6
About half of the time	8	3.5	100
Total	**232**	**100**	

In terms of following the specific dosage schedule, 110 (47%) patients said they did so all of the time, 39 (17%) said most of the time, 8 (3%) said about half of the time, 18 (8%) said some of the time, and 57 (25%) said never.

The ACTG questionnaire has a section where the following question was asked; *Does any of your anti-HIV medications have special instructions, such as "take with food" or "on an empty stomach" or "with plenty of fluids?" If yes, how often did you follow those special instructions over the last four days?* The results are shown below in figure 4.8

Regarding medication with specific instructions which is depicted in Figure 4.8, 146 (63%) said their medications did have specific instructions, while 86(37%) said they did not. Of those with the specific instructions, (Table 4.8), 63 (43%) followed them all of the time, 51 (35%) followed them most of the time, 2 (1%) followed them about half the time, 14 (10%) followed them some of the time, and 16 (11%) never followed them.

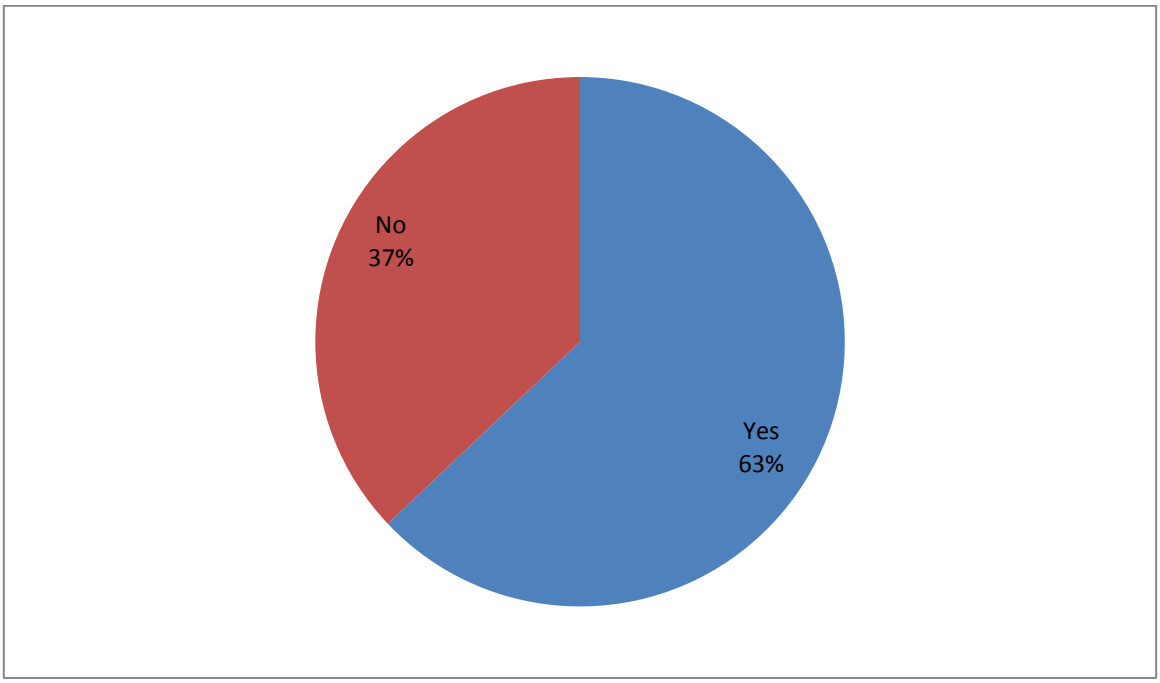


Figure 4.9 Does any of your HIV medications have special dietary instructions? (N= 232)

Table 4.8 How often did you follow your medication's special dietary instructions over the last 4 days? (N=146)

Responses	Frequency	Percentage	Cumulative %
All of the time	63	43	43
Most of the time	51	35	78
Never	16	11	89
Some of the time	14	10	99
About half of the time	2	1	100
Total	**146**	**100**	

Table 4.9 Summary of Scale Scores

	HIV-ASES	BMQ-S	BMQ-G	ACTG
Number	232	232	232	232
Mean	6.45	4.05	3.18	95
Median	7.08	4.05	3.18	-
Standard deviation	2.47	0.42	0.5	13.2
Range	0.17-10	2.9-4.9	1.87-4.62	10-100

4.4 CORRELATIONS ANALYSES

All of the patients' scores for HIV-ASES, BMQ-S, BMQ-G and ACTG were tested for significant relationships using Pearson correlation analysis. The correlation matrix is shown in Table 4.10 below. These results effectively showed no correlation between HIV-ASES and BMQ-S, HIV-ASES and BMQ-G, HIV-ASES and ACTG, and BMQ-S and ACTG. There was a weak positive correlation between BMQ-G and ACTG (r=0.2). There was a moderate positive correlation between BMQ-S and BMQ-G (r=0.4). These results may therefore be taken to indicate that two of the cognitive or attitudinal variables under investigation, HIV-ASES and BMQ-S, had no any link with adherence among the study participants, as measured in this research. The link between BMQ-G and adherence was weak, but statistically significant. There was a moderate link between the two independent variables, BMQ-S and BMQ-G.

Table 4.10 Correlation matrix for HIV-ASES, BMQ-S, BMQ-G and ACTG

	BMQ-S	BMQ-G	ADHERENCE
HIV-ASES	**r=0.171**	**r=0.037**	**r=0.036**
	t=2.626	t=0.564	t=0.539
	p=0.009	p=0.573	p=0.590
BMQ-S	-	**r=0.419**	**r=0.040**
		t=7.004	t=0.606
		p < 0.001	p=0.545
BMQ-G		-	**r=0.219**
			t=3.403
			p=0.001
No. of valid cases=232 r=Pearson Product Moment Correlation t=t-statistic p=p-value (level of significance) at <0.05			

The interpretation of these findings is that perceived beliefs about the general harm and overuse of medicines influence adherence behaviour among the participants. An individual with strong beliefs about the general harm and overuse of medicines is likely to adhere to antiretroviral therapy. Conversely, the correlation between the two independent variables BMQ-G and BMQ-S indicates that specific necessity and concerns about

ARVs and perceived beliefs about the general harm and overuse of medicines have influence on each other. A patient with strong beliefs about the general harm and overuse of medicines will likely have strong beliefs about specific necessity and concerns about ARVs.

4.4.1 Correlations in non-adherence

There were 43 patients who indicated adherence of 95% or less. These scores were isolated and independently correlated with the HIV-ASES, BMQ-S and BMQ-G measures. The correlation matrix may be seen in Table 4.11 below. These results showed no correlation between BMQ-S and ACTG, and between BMQ-G and ACTG. There was a weak positive correlation between HIV-ASES and ACTG. Amongst the independent variables, there was a weak positive correlation between HIV-ASES and BMQ-G, a moderate positive correlation between BMQ-S and BMQ-G, and a strong positive correlation between HIV-ASES and BMQ-S. Taken together these results may indicate a small link between HIV-ASES and adherence in the case of non-adherent patients.

Table 4.11 Correlation matrix for HIV-ASES, BMQ-S, BMQ-G and ACTG for adherence <95%

	BMQ-S	BMQ-G	ADHERENCE (ACTG)
HIV-ASES	**r=0.711**	**r=0.373**	**r=0.313**
	t=6.483	t=2.575	t=2.107
	p=0.000	p=0.014	p=0.041
BMQ-S	-	**r=0.459**	**r=0.130**
		t=3.304	t=0.838
		p=0.002	p=0.407
BMQ-G		-	**r=0.145**
			t=0.937
			p=0.354
No. of valid cases=43 r=Pearson Product Moment Correlation t=t-statistic p=p-value (level of significance) at <0.05			

The interpretation of these findings is that HIV adherence self-efficacy influence adherence behaviour among the participants who were non-adherent to their treatment. Therefore a patient with low self-efficacy is likely to be non-adherent to ART. The correlation between the two independent variables HIV-ASES and BMQ-G indicates that HIV adherence self-efficacy have influence on perceived beliefs about the general harm and overuse of medicines. An individual with high self-efficacy is likely to have strong beliefs in the general harm and overuse of medicines. Furthermore, the correlation between the two independent variables BMQ-G and BMQ-S indicates that specific necessity and concerns about ARVs and perceived beliefs about the general harm and overuse of medicines have influence on each other. A patient with strong beliefs about the general harm and overuse of medicines will likely have strong beliefs about the specific concerns and necessity of ARVs. In addition, the strong positive correlation between HIV-ASES and BMQ-S means that HIV adherence self-efficacy have influence on specific necessity and concerns about ARVs. An individual with high self-efficacy is likely to have strong beliefs about the specific necessity and concerns of ARVs.

4.5 REGRESSION ANALYSIS

Multiple regression analysis in advanced statistical analysis is used to examine the separate and collective contributions of multiple independent variables to the variation of the dependent variable (Tredoux, Pretorius & Steele 2008:255). The multiple correlation coefficient ***(R)*** is the correlation between the dependent variable and the best linear combination of the predictors i.e. a strength-of-relationship index that indicates the correlation between predicted scores and the dependent variable score. In this study ***R*** and R_2 (which refers to the percentage of accountable variation) were used to assess how well the linear combination of explanatory variables in the regression model predicted the dependent variable (Tredoux, Pretorius & Steele 2008:255).

All predictors were initially entered into the model and then eliminated one by one in the backward method (backward deletion) based on how insignificant they were (level of significance alpha=0.05). A backward stepwise regression of scores from all patients indicated significance for BMQ-G on ACTG (F(1;231)=11,583;p<0,001) with BMQ-G explaining 4,8% of the variance. When a regression analysis was run on only those patients who were 95% or less adherent, there was significance for HIV-ASES on ACTG (F(1;41)=4.440;p<0.041), with HIV-ASES explaining 9,8% of the variance. These results

would indicate that in perceived general harmful effects and overuse of medications was a very weak predictor of adherence, and when patients with less than 95% adherence were isolated HIV adherence self-efficacy was a weak predictor of their adherence behaviour.

4.6 OVERVIEW OF RESEARCH FINDINGS

Findings from the study indicated that majority of the participants were females 163 (70%), age group 35-44 years constitute the highest percentage among the participants, most are not married 60 (61%), unemployed 131 (56.5%), do not smoke 204 (88%) or consume alcohol 145 (63%) and very few had no formal education 15 (7%). Majority (55.6%) have been living with HIV/AIDS for more than 3 years, sex with HIV infected appeared to be the modality of acquiring HIV 146 (63%). Almost all 227 (98%) have disclosed their HIV status to family members and a high proportion 217 (94%) have treatment buddies, over half 128 (55%) have been on ART for more than 3 years, most of the participants 190 (82%) consume between 2-3 pills daily and never experienced 201 (87%) adverse reaction that require them to stop taking ARVs.

The participants demonstrated high level of confidence on all the 12 items tested in the HIV-ASES scale. After calculating composite scores for each participant, the mean score on the HIV-ASES was 6.45 (SD=2.47), with a high score indicating greater self-efficacy. Only one participant scored a perfect score of 10. The participants score on the BMQ-Specific ranged from 2.9 to 4.9, with a mean of 4.05 (SD=0.42). Higher scores indicated a stronger belief in specific medicine prescribed in antiretroviral therapy in this case antiretroviral drugs. The mean score on BMQ-general was 3.18 (SD=0.5), with scores ranging from 1.87 to 4.62. Higher scores indicated a stronger beliefs in general medicines prescribed in the management of disease conditions

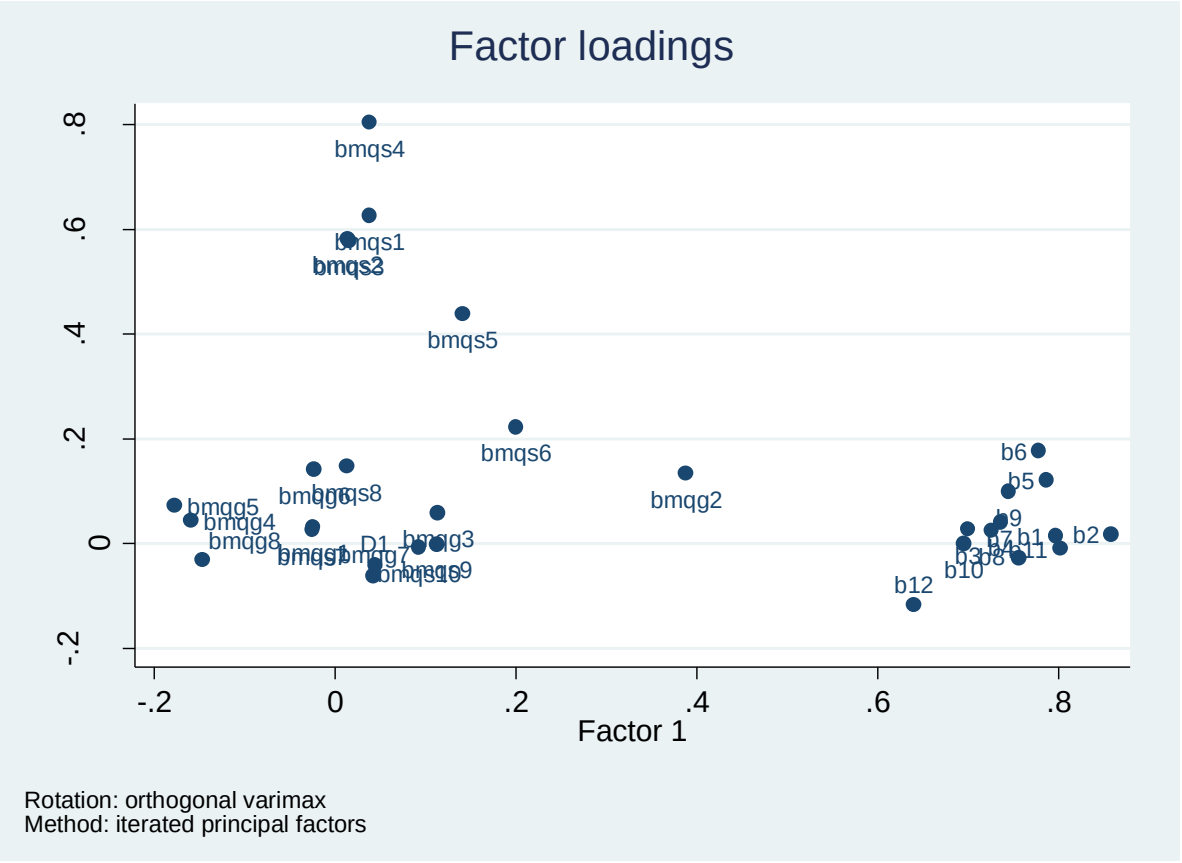
Mean adherence for the total 232 participants was 95% (SD=13.2), 189 (81%) participants were adherent, 208 (89.7%) patients reported never missing any doses, 110 (47%) were adherent to specific dosage schedule. Out of the 146 participants whose ARVs have specific dietary instructions, only 63 (43%) followed them all the time.

Correlation analysis showed a weak link between perceived general harmful effects and overuse of medications and adherence, and moderate link between the two independ-

ent variables, BMQ-S and BMQ-G. Among non-adherent participants a strong positive correlation was found between HIV adherence self-efficacy and BMQ-S. Regression analysis revealed that HIV adherence self-efficacy is a weak predictor of adherence to ART, and perceived general harmful effects and overuse of medications is a weak predictor of adherence among non-adherent participants.

4.7 FACTOR ANALYSIS

This is a statistical method used in identifying a relatively small number of factors in order to represent the relationship among sets of interrelated variables (Tredoux, Pretorius & Steele 2008:248). Factor analysis is often done in order for the researcher to know if a wide range of variables could be more meaningfully represented by a smaller number of underlying dimensions. This is useful in future research and in the planning of interventions than the wide range of variables (Tredoux, Pretorius & Steele 2008:248). The researcher carried out factor analysis on the variables in the research instruments; from Figure 4.10 above, it can be observed how the variables cluster according to the factor loadings. Factor 1 essentially marks the importance of the B1–B12 (HIV adherence self-efficacy) performance and that explains about 53% of the variability. The second factor is more on the bmqs1, bmqs2, bmqs3, bmqs4 and bmqs5 (perceived necessity and concerns about medicines) which explains about 15.7% and the third factor relates mostly to bmqs7, bmqs9, bmqs10, bmqg3 & bmqg5 (items on the perceived harm and overuse of medicines and perceived necessity and concerns about medicines). It can also be observed that D1 which measure of medication adherence in terms of proportion of medication missed out of the quantity prescribed is also a factor to be reckoned with (factor 5). The scree chart shown in Figure 4.11 below indicates that only 4 factors (factors 1, 2, 3 and 4) will be needed to explain the relevant variability in the current research.



Rotation: orthogonal varimax
Method: iterated principal factors

Figure 4.10 Factor loadings

Table 4.12 Rotated factor loadings (pattern matrix) and unique variances

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Uniqueness
b1	0.7968						0.3191
b2	0.8579						0.2559
b3	0.6997						0.5022
b4	0.7360						0.4171
b5	0.7864						0.3372
b6	0.7783						0.3421
b7	0.7560						0.4116
b8	0.7255						0.4434
b9	0.7447						0.3815
b10	0.6948						0.4678
b11	0.8015						0.3389
b12	0.6393						0.5372
bmqs1		0.6268					0.5836
bmqs2		0.5820					0.5941
bmqs3		0.5780					0.6419
bmqs4		0.8039					0.2634
bmqs5		0.4391				0.3833	0.5837
bmqs6						0.3397	0.7325
bmqs7			0.3555				0.7813
bmqs8				0.3408			0.8149
bmqs9			0.4223				0.7743
bmqs10			0.4601	0.3265			0.6656
bmqg1						0.3902	0.7349
bmqg2	0.3874			0.3595			0.6492
bmqg3			0.5527				0.6306
bmqg4							0.8788
bmqg5			0.3637		0.4782		0.4859
bmqg6				0.5737			0.5933
bmqg7							0.9206
bmqg8						0.3350	0.7941
D1					0.5285		0.7084

(blanks represent abs(loading)<.3)

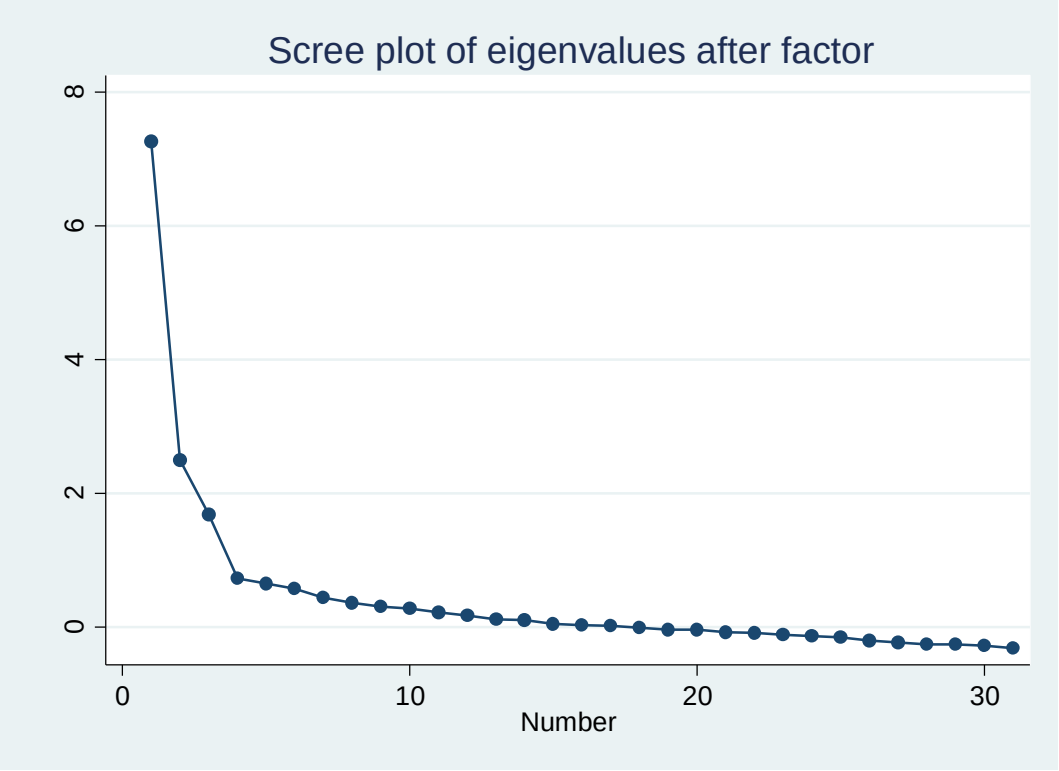


Figure 4.11 Scree plot of eigen values after factor loading

4.8 CONCLUSION

This chapter described the analysis and presentation of the research findings. Demographic characteristics of the study population were described; frequencies of responses on the HIV-ASES, BMQ and adherence were also shown in this chapter. Correlation and multiple regression analyses were performed on the variables to identified relationships among them. Finally, factor analysis of the wide range of variables in the research instruments were done and indicated that only four factors explain the variability of the current study. In the next chapter the results of the research would be discussed in the context of existing literature, conclusions of the study findings would be elaborated and appropriate recommendations made on modalities of enhancing adherence.

CHAPTER 5

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

The purpose of this study was to identify modifiable cognitive factors that are strongly associated with ART adherence with a view to providing a framework for antiretroviral therapy adherence among patients in South Africa. With the rapid roll-out of ART that has resulted in over a million people on treatment, few studies have examined cognitive factors that influence adherence to ART in South Africa. This study addresses the gap in knowledge by examining the predictive relationships of HIV adherence self-efficacy and Beliefs about medicines on adherence to ART in persons with HIV infections who are taking antiretroviral therapy. The significance of the predictor variables with the dependent variable was also examined; understanding the factors influencing adherence to ART is very crucial in enhancing interventions that could improve adherence among patients which would results in good clinical outcomes and good quality of life.

In this chapter, the interpretation of the research findings will be discussed, the implications for ART adherence will also be highlighted, study limitations and suggestions for further research will be mentioned. Finally, a framework for enhancing antiretroviral therapy adherence among patients on life-long treatment will be described.

5.2 DISCUSSIONS OF THE RESEARCH FINDINGS

5.2.1 Demographic characteristics of the study participants

Participants for this study were drawn from a large clinic within the Tshwane Metropolitan area which is part of the Comprehensive Care, Management and Treatment program of the Gauteng Department of Health. The research findings in the current study are consistent with the national trends of HIV/AIDS distribution pattern in South Africa (NDOH 2010c). HIV infection in South Africa affects mostly people in the age group 15-49 years, a report released by the National Department of Health in 2010 revealed that while the national prevalence of HIV was 10.5%, the prevalence among people within

15-49 age group was 15% (NDOH 2010c:20). This is reflected in this study as 156 (67%) of the participants fell into 18-44 years age group. Furthermore, HIV prevalence remains disproportionately high for females in comparison to males in South Africa. It is highest among women within 25-29 years age group, where one in three women are found to be HIV positive (NDOH 2010c:20). It is therefore not surprising that majority 163 (70%) of the participants in this study were women as they are the worst affected by the HIV epidemic in South Africa. This also indicates that there are more females on ART than males. This assertion is supported by earlier studies that show that more women are accessing HIV treatment than men (Johnson 2012:24). The percentage of HIV infected patients, aged 55 years and above was 18 (7.8%) in this study which is similar to the national average of around 6% reported for people aged 50 and above (NDOH 2010c:24).

The majority 141 (61%), had never been married, 140 (60%) had only secondary education, only 62 (35%) of the participants were employed, the rest were either unemployed or relied on social grants. The fact that most of these participants were unemployed and lacked tertiary education may have influence on their psychosocial well-being; unstable housing, depression, decreased quality of life, work and family responsibility have been described as potential barriers in adhering to antiretroviral therapy (Glass et al 2010:200; Protopopescu et al 2009:603; Mills et al 2006:687). In their study conducted among patients on ART in Zimbabwe, Skovdal et al (2011:309) reveal how poverty and sources of economic and materialistic support influence patients' ability to adhere to ART. The authors found adherence to be highly influenced by lack of food and difficulties in meeting the costs associated with treatment.

Most of the participants did not smoke 204 (88%) or consume alcohol 145 (63%). Alcohol consumption and substance abuse have been associated with poor compliance with medication which often results in poor clinical outcomes in the management of HIV infection (Glass et al 2010:200). Psychosocial factors like drugs and alcohol use have been linked with non-adherence. Studies have found that these serve as barriers to adherence among HIV-infected patients on life-long treatment (Glass et al 2010:200; Protopopescu et al 2009:603; Mills et al 2006:687). In terms of psychosocial response of patients to ART, Skovdal et al (2011:309) found that men in particular consume excessive alcohol to avoid their perceived reality of having lost their manhood to AIDS as they are constantly reminded of this reality when they take their ARVs every day.

There have been some studies which suggest that socio-demographic characteristics do not often predict adherence to ART. The authors contend that it is not quite simple to use socio-demographics characteristics to predict adherence to ART among patients as studies have found mixed results between demographic characteristics and patient adherence level (Rougemont et al 2009:21; Cauldbeck et al 2009:7). This has made it difficult for adherence counsellors to use socio-demographics as a strong predictor of adherence to antiretroviral therapy. What research has found is that socio-demographic factors can be used to identify particular populations that may benefit more extensively from targeted interventions that address specific barriers (Gordillo et al 1999:1766; Cauldbeck et al 2009:7). The importance of these findings in ART initiation is that denying an individual the benefit of ART based on the assumption that the person will not adhere due to his or her demographic characteristics is a futile exercise as no scientific data are available to substantiate such action (Ickovics & Meade 2002:S99).

Furthermore, various studies have found that socio-economic factors could be part of barriers to adherence to ART in multiple settings in sub-Saharan Africa. These include the cost of ART, availability and accessibility to medications (Weiser et al 2003:284; Hawkins & Murphy 2007:1041; Iliyasu et al 2005:92; Mukhtar-Yola, Adeleke, Gwarzo & Ladan 2006:142; Hardon et al 2007:661; Tuller et al 2009). In addition to this, there are indirect costs associated with ART which influence adherence; these are the time taken off work, the time spent in hospital and inability to fend for one's family during bouts of opportunistic infections (Castro 2005:e338; Hardon et al 2007:660). Therefore, high adherence to ART demonstrated by the participants in this study needs to be interpreted with caution as they all received free ART services as part of the government's ART roll-out to ensure wide access to treatment in South Africa.

Due to the conflicting findings on the role of socio-demographics in influencing adherence to ART, Campbell & Cornish (2010:1577) have advocated for a health enabling social environment model in the context of HIV/AIDS management. According to Skovdal et al (2011:314), such an environment allows for attention to be paid to contextual and psychosocial dimensions that influence adherence to prescribed ART.

5.2.2 Modality of acquiring HIV infection

HIV transmission in South Africa has been shown to be predominantly through heterosexual transmission between couples, followed by mother-to-child transmission (NDOH 2010c:20). This is also reflected in the current study as majority 146 (63%) of the study participants were infected through sexual intercourse with an HIV-positive person. This is further supported by available literature which shows that HIV transmission in sub-Saharan Africa is largely transmitted heterosexually (UNAIDS 2010), and the identified drivers of the HIV epidemic in South Africa include intergenerational sex, multiple concurrent partners, low condom use, excessive use of alcohol and low rates of male circumcision (NDOH 2010c:20).

The mode of HIV transmission differs in developed countries. However, it appears to be mainly through homosexual transmission as reported by Gauchet, Tarquinio & Fischer (2007:143) in the study among 127 HIV-infected persons in a Hospital in France where 44% of the participants contracted HIV through homosexual transmission. Nevertheless, another study among women in the USA reported that over 70% of the women acquired HIV infection heterosexually (Jones, Owens, Lydston, Tobin, Brondolo & Weiss et al 2010:1503).

Sexual assault is another mode of contracting HIV that has been documented in South Africa although very few 5 (2.2%) of the participants in this study reported being infected through sexual assault. Occupational exposure to blood or body fluid; sharing needles with an HIV-positive person; mother-to-child transmission; and blood transfusion or medical procedure account for very little as the modality of HIV transmission in the study. These findings differ sharply from the study referred to above where 12% of the participants were infected through needle sharing (Gauchet, Tarquinio & Fischer 2007:143). An explanation for this may be due to the high number of injection drug users in developed countries compared to South Africa.

The continuous trend in heterosexual transmission of HIV in South Africa has informed policy around increased campaign about consistent use of condom and awareness of uptake of medical male circumcision among sexually active males. Studies have reported reduced risk of about 60% in sexually HIV transmission among circumcised men

(Auvert et al 2005:11; Bailey, Moses, Parker et al 2007:651; Gray, Kigozi, Serwadda et al 2007:664).

5.2.3 Duration of HIV diagnosis and ART use

Majority 129 (55.6%) of the participants have been living with HIV/AIDS for more than 36 months and a large proportion of the participants have disclosed their HIV status to their family members 227 (98%) which is an indication of having come to terms with the disease. Disclosure is very vital in HIV management as research has shown that people who disclosed their status are likely to adhere to treatment as well as receive support from their families (Glass et al 2010:200; Protopopescu et al 2009:603; Mills et al 2006:687), which is why social support and ability to disclose one's status have been described as important issues to be considered when assessing treatment adherence (Nachega et al 2006b:131). The stigma and discrimination associated with HIV/AIDS within the society unlike any other chronic illnesses constitute one of the greatest challenges facing people on ART (Elliott, Utyasheva & Zack 2009:29). Due to this stigma, some patients would prefer to take their ARVs in secrecy which might invariably may affect their compliance to the treatment (Hardon et al 2007:662; Weiser et al 2003:285).

A large proportion of the participants in this research were people who have been using antiretroviral for quite a long period as 202 (87%) of them have been on treatment for more than 2 years. This percentage is similar to the 75-82% reported nationally (NDOH 2010c:25). Survival on ART has been associated with good clinical outcomes which resulted from halting the proliferation of the viral replication, improvement in immune response and reduction in the viral load (Reddi, Leeper, Grobler et al 2007:13; Wool-Kaloustian et al 2006:43). The clinical outcomes achieved with the use of ART been linked to adherence level, research has shown that prior opportunistic infections in an HIV patients before initiating ART has the potential of influencing adherence as the patient may perceive the disease to be severe enough requiring good adherence to treatment in order to achieve the treatment outcome (Cauldbeck et al 2009:7). Duration of treatment with ART and time since HIV diagnosis were found to influence adherence in the study conducted by Gauchet, Tarquinio and Fischer (2007:145), although this finding differs from the Swiss HIV Cohort Study revealed that long standing HIV disease was among the predictors of worsening adherence (Glass et al 2010:201).

The majority, 190 (82%) take between 2-3 pills daily, followed by 41 (18%) who consumed between 6-10 pills daily. Only one participant reported having to take more than 10 pills daily which represent less than 1% of the study population. The amount of pills that patients on chronic medication take every day influences adherence; pill burden has been described as a major challenge in ART as patients have to take a combination of ARVs (Protopopescu et al 2009:602). The pill burden is a major challenge for patients taking ART as some of them may also have co-morbidities like asthma, diabetes, hypertension and arthritis. These may require them to take multiple doses of tablets including prophylaxes against opportunistic infections, multi vitamins and even tuberculosis drugs. The pill burden therefore becomes enormous and constitutes a major challenge in the administration of ART (Frank 2002:S10).

5.2.4 History of adverse reactions to ART

Adverse reactions to ARVs have been associated with non-adherence in ART in various research carried out among HIV-infected populations who were on antiretroviral therapy (Waters & Nelson 2007:986; Weiser et al 2003:285). Most of the participants 201 (87%) in this study reported never having adverse reactions to ART that would require them to stop the medications. This might have resulted in the high level (95%) of adherence reported among them. According to previous research, ART regimens with significant side-effects have been shown to result in poor adherence among patients on antiretroviral therapy which subsequently results in increased HIV-related morbidity and mortality (Glass et al 2010:200; Cauldbeck et al 2009:7). This is why it has been proposed that health care providers need to consider the individual patient's circumstance while initiating them on ART (Harries, Zachariah, Lawn & Rosen 2010:71). Regimen-based strategies such as reduced pill burden and simplification of ART regimens that fit perfectly into the patient's daily schedule, have been shown to assist in the long term adherence to treatment and maintaining efficacy of treatment (Harries, Zachariah, Lawn & Rosen 2010:72; Protopopescu et al 2009:604; Howard et al 2002:2180; Frank 2002:S12; Cauldbeck et al 2009:7).

5.2.5 HIV treatment adherence self- efficacy

According to Bandura, although SCT acknowledges that knowledge of health risk and benefit of treatment are necessary to perform health behaviour, this in itself is not enough, additional self-influences are necessary to achieve necessary changes that will result in the desired health behaviour, this concept is called self-efficacy (Bandura 2004:145). Self-efficacy is a known predictor of a wide range of health behaviour of patients on chronic medication including medication adherence, and has been shown to influence adherence to ART (Johnson et al 2007:367; Rudy et al 2009:188), although a study in the USA has found that adherence self-efficacy is not associated with adherence to ART among older patients (Barclay et al 2007:46). According to Clark and Dodge (1999:84), individuals with health promoting behaviour possess self-beliefs, enabling them to exercise control over their thoughts, feelings, and actions. People who engage in self-management of health habits reduce major health risks and live healthier and more productive lives (Clark & Dodge 1999:86).

With a mean score of 6.45 out of possible 10, the participants demonstrated high level of confidence on all the 12 items tested in the HIV-ASES scale. This compares well with the findings of Berg et al (2009:245), where the mean of adherence self-efficacy was a moderate 1.81 on a scale of zero to three in a study that seek to find if self-efficacy and depression mediate in the relationship between pain and adherence to antiretroviral therapy. The participants in the current study showed high ability in integrating HIV treatments plans into their daily activity, including sticking to their daily treatment schedule when feeling sick, and continuing HIV treatment even when they are feeling discouraged about their health. In addition, the participants demonstrated that they were confident with continuing with their treatment even when they felt discouraged about their health, when taking the treatment interferes with their daily activities, and when experiencing side effects of ARVs. This high level of belief regarding their capabilities to carry out these tasks is hinged on the belief that doing so will result in better and living quality life despite being HIV-infected. In the context of adherence self-efficacy in ART, patients who demonstrated stronger confidence have been shown to adhere well to treatment and those with low confidence in carrying out tasks that would result in adherence have been shown to be non-adherent to treatment (Johnson et al 2007:367; Rudy et al 2009:188).

5.2.6 Beliefs about medicines-specific

Beliefs about medicines questionnaire is a measure of cognitive representation of medication among patients on chronic treatment. The BMQ-S measurements reflected participants' beliefs about the necessity and concerns about the use of specific medicines, in this study antiretroviral drug. The use of medication is strongly influenced by patient's perception on the benefits of taking such medication (Munro et al 2007:104) and positive or negative medication beliefs would influence medication use behaviour. According to the self-regulatory theory, patients' treatment perceptions and illness representations also influence medication adherence. Furthermore, patients on chronic treatment often undertake a cost–benefit analysis, considering whether their beliefs about the necessity of medications for maintaining health outweigh their concerns about the potential adverse effects of taking them (Reynolds 2003:117-124).

Beliefs about the importance of antiretroviral therapy in the management of HIV infection was generally positive among the respondents, the mean score of 4.05 out of 5 indicates strong belief in the use of antiretroviral therapy. Over 97% (n=225) agreed that their current health is dependent on the antiretroviral medication and 94% (217) also agreed that their future health would depend on the medication. Most of the sample reported that their medications kept their health from deteriorating 222 (95.6%), and more than half 134 (58%), were not worried about the long-term effects of ARVs.

The strong belief about the necessity of medication use and concerns about medication use shown among the participants are in line with findings from the literature. Research suggests that patients who are highly adherent are those who have positive beliefs about the use of medications for chronic medical conditions (Neame & Hammond 2005:764; Porteous, Francis, Bond & Hannaford 2010:228; Ireland & Wilsher 2010:39).

5.2.7 Beliefs about medicines-general

The BMQ-G measurements reflected participants' beliefs about the harm and overuse associated with the use of medicines in general. Medication use behaviour of patients has been shown to be influenced by the direct experience of medication adverse effects; medication use behaviour of such patient is therefore influenced by belief of potential adverse effects of the medications (Munro et al 2007:104). A patient with prior

adverse drug reactions to medication which is an indication of personal negative experience with medications may logically strengthen such belief to attribute adverse event easily to ARVs. Mean score of participants on this scale was 3.18 out of a possible 5, although this is less than the average score on BMQ-Specific, the participants still demonstrated they have strong belief about the overuse and harm that medications in general can cause. This was revealed among the participants as 51% (n=119) believed that doctors overused medications in general, 83.2% (193) agreed that doctors placed too much trust on medicines and 55% (127) believed doctor spent little time with patients thereby prescribing many medications. Almost half 45.7% (106) of the participants believed that medicines were addictive. Concerning harm associated with use of medicines generally, few 12 (5.2%) endorsed the belief that natural remedies are safer than medicine, all medicines are poisons 29 (12.5%) and that people on chronic medicines should stop taking them very often 24 (10.3%).

In their study, Porteous et al (2010:228) found that perceived general harm and overuse of medicines appear to remain stable over time, irrespective of changes in health status. The implication of this in patients on chronic medication is that the general beliefs about medicines remained a useful variable for intervention in enhancing adherence. The authors further state that it is advisable to asses these beliefs in patients being prescribed medication given the association between beliefs about medicines and adherence to medication regimes, but the writers caution on the assumption of easily changing these beliefs as such beliefs are often difficult to change (Porteous et al 2010:228).

5.2.8 Antiretroviral therapy adherence

The Adherence questionnaire used in this study measured compliance with prescribed medication over the previous 4 days. Medication adherence was calculated as the proportion of the ARVs taken out of the amount prescribed. Although adherence is one of the modifiable variables in ART, its monitoring is difficult among patients as no standard method exists to monitor adherence in ART, various authors have advised multiple approaches in adherence monitoring (Nachega et al 2009:66; Mills et al 2006:687; Simoni et al 2006:S25). This study only employed self-report in measuring adherence. Participants in this study appeared to be highly adherent to antiretroviral therapy with 81% being 100% adherent; this is higher than the self-report adherence rate of 55-77% reported among patients on ART by Mills et al (2006:687) and Malangu (2008:49) who report-

ed only 50% of his study participants being adherent to prescribed ARVs. Several explanatory factors for this finding can be offered. First, the study participants received free ART services; this might influence their level of adherence. Secondly, the institution where these patients receive ART provides adherence counselling and support on an on-going basis for the participants in this study and this also might have influenced their adherence level.

Previous studies indicate that adherence at 95% and above is necessary to achieve good clinical outcomes in ART (Bangsberg et al 2003:1930; Paterson et al 2000:26; Bangsberg 2006:940; Nachega et al 2007:569) and patients who fall below this level are at risk of developing resistance to ARVs and have increased chances of morbidity and mortality associated with the HIV disease (Graham et al 2010:1541). Research has shown that non-adherence is common among patients on ART, and it is estimated that non-adherence is between 30-50% among patients and more than 10% of patients usually miss one or more of their daily doses of antiretroviral drugs (Chesney 2000:S172).

Instructions adherence is defined as the percentage of medications for which the correct special instructions were followed at each prescribed dose. The percentage of the participants who strictly followed the specific dosage schedule was only 110 (47%); while the remaining 122 (53%) did not do so or partially followed schedule instructions. In fact, a quarter 57 (25%) of the participants never followed these instructions. Of the 146 participants with specific instructions on how to take their ARVs (e.g. take with food, on an empty stomach or with plenty of fluids), only 63 (43%) followed them all of the time, out of the remaining 83 (57%) who did not comply, 16 (11%) never followed these instructions. This implies that though the participants in this study were highly adherent to their medications, majority did not follow the necessary instructions that require them to take medication at certain intervals. Since non-adherence is not limited to non-intake of medication but includes other acts like not following instructions regarding the schedule, dietary or fluid restrictions and not taking medication at the prescribed time; participants in this study appeared to have been adherent to taking the prescribed medication only. They were non-adherent to instructions regarding dietary or fluid restrictions and did not take medication at the prescribed time. Non compliant with prescribed medicines in ART has been linked to recurrent opportunistic infections and poor clinical outcomes among patients (Graham et al 2010:1541; Moore et al 2005:290; Nachega et al 2006a:83).

5.3 RELATIONSHIPS AMONG STUDY VARIABLES

Correlation analyses showed that there was a weak positive correlation between BMQ-G and ACTG that is statistically significant and a moderate positive correlation between BMQ-S and BMQ-G. These results may therefore be taken to indicate that two of the cognitive or attitudinal variables under investigation, HIV-ASES and BMQ-S, had no link with adherence among the sample participants as measured in this research. This study revealed that participants' general beliefs about medicines and adherence to ART were correlated; and two independent variables, BMQ-S and BMQ-G correlated. These findings are consistent with previous studies (Neame & Hammond, 2005:764; Porteous, Francis, Bond & Hannaford 2010:228; Ireland & Wilsher 2010:39). This demonstrates that the stronger the beliefs about the harm and overuse associated with prescribed medications for chronic medical conditions, the stronger the adherence to ART. When Beliefs about medications subscales were related to each other, BMQ-S and BMQ-G correlated with each other. This implies that the stronger the beliefs about the necessity and concerns about ARVs prescribed for HIV/AIDS, the stronger the beliefs about the overuse and harm that medications in general can cause.

When the scores of the 43 (18.5%) patients with adherence of 95% or less were isolated and independently correlated with the HIV-ASES, BMQ-S and BMQ-G measures, there was a weak positive correlation between HIV-ASES and ACTG. Amongst the independent variables, there was a weak positive correlation between HIV-ASES and BMQ-G, a moderate positive correlation between BMQ-S and BMQ-G, and a strong positive correlation between HIV-ASES and BMQ-S. HIV-ASES and ACTG were found to correlate with each other. This can be interpreted to mean that the stronger the confidence in the patient's ability to carry out tasks that would results in adherence, the higher the adherence to ART.

In addition, positive correlation between HIV-ASES and BMQ-G means that the stronger the confidence in the patient's ability to carry out tasks that would results in adherence, the stronger the beliefs about the overuse and harm that medications in general can cause. When Beliefs about medications subscales were related to each other, BMQ-S and BMQ-G correlated with each other, meaning that the stronger the beliefs about the necessity and concerns about ARVs prescribed for HIV/AIDS, the stronger the beliefs about the overuse and harm that medications in general can cause. This finding is simi-

lar to that of Ireland & Wilsher (2010:40) who reported positive correlation between the two subscales among patients on chronic treatment. Finally, among non-adherent participants a strong positive correlation between HIV-ASES and BMQ-G was found, indicating that the stronger the confidence in the patient's ability to carry out tasks that would result in adherence, the stronger the beliefs about the overuse and harm that medications in general can cause.

The findings of this study are similar to that of Gauchet, Tarquinio and Fischer (2007:147); where the authors found patients' beliefs about medicines to be related to adherence as the researcher found in the current study. The authors showed further that the influence of beliefs about medicines on medication adherence is also mediated by patient-provider relationship and by HIV illness/medication representation on the part of the patients. Their finding is therefore consistent with self-regulatory model described by Reynolds (2003:117-124) which postulates that the association between the patient-provider relationship and medication adherence is mediated by HIV illness/medication representation. According to Gauchet, Tarquinio and Fischer (2007:147), "the relationship between confidence in physician and adherence is in part positively mediated by patients' beliefs about the necessity of antiretroviral treatment and negatively mediated by patients' beliefs about the harmfulness of medication in general". Although the current study did not find the above associations, it is possible that some factors influencing adherence which were not investigated in the current study might be responsible. Further studies on patient-provider relationship and beliefs about medicines could provide a better understanding of these in the future.

5.3.1 HIV adherence self-efficacy as predictor of non-adherence to ART

The current research findings are consistent with previous findings that sought to evaluate the relationship of self-efficacy and adherence to ART (Johnson et al 2007:367; Rudy et al 2009:188). HIV adherence self-efficacy or individual's personal belief regarding their capabilities to carry out prescribed instructions in adhering to ART was a significant variable in the regression analysis predicting adherence to ART among patients who were non-adherent. Previous studies have shown that self-efficacy is a known predictor of adherence in antiretroviral therapy (Johnson et al 2007:367; Rudy et al 2009:188). There was significance for HIV-SES on ACTG ($F(1;41)=4.440;p<0.041$), with

HIV-SES explaining 9.8% of the variance, indicating self-efficacy had a weak predictive value. One can therefore conclude that HIV-SES is a weak predictor of ART adherence among patients who are non-adherent to therapy.

5.3.2 Perceived general harm and overuse of medicines as predictor of ART adherence

In this study, general beliefs about medicines, a measure to gauge patients' beliefs about the general harm and overuse of medicines was the significant variable in the regression analysis that was conducted. It predicted adherence among patients on antiretroviral therapy, as the regression analysis showed significance for BMQ-G on ACTG ($F(1;231)=11,583$; $p<0,001$) with BMQ-G explaining 4,8% of the variance. This indicates that BMQ-G had a weak predictive value. Therefore, among patients on ART, general BMQ-G is a very weak predictor of adherence. The findings above are in keeping with findings of various studies where low rates of adherence among patients on chronic medications have been found to be consistently related to doubts about personal need for medications (Neame & Hammond 2005:764; Porteous, Francis, Bond & Hannaford 2010:228; Ireland & Wilsher 2010:39).

This study failed to confirm the necessity-concerns framework (BMQ-specific) as a predictor of adherence to medication, perceived necessity and concerns beliefs has been used to predict medication use behaviour in other chronic illnesses such as asthma, diabetes, hypertension (Neame & Hammond, 2005:764; Porteous, Francis, Bond & Hannaford 2010:228; Ireland & Wilsher 2010:39).

5.4 ENHANCING ADHERENCE TO ART THROUGH FOCUSED INTERVENTIONS BASED ON SELF-EFFICACY AND BELIEFS ABOUT MEDICINES MODEL

This study identified HIV adherence self-efficacy and perceived harm and overuse of medicines as a predictor of adherence. Self-efficacy is an individual's personal belief regarding their capabilities to carry out a specific task to achieve a desired outcome. However, such behaviour is likely to be carried out by the patient if he/she believes that such action can be performed.

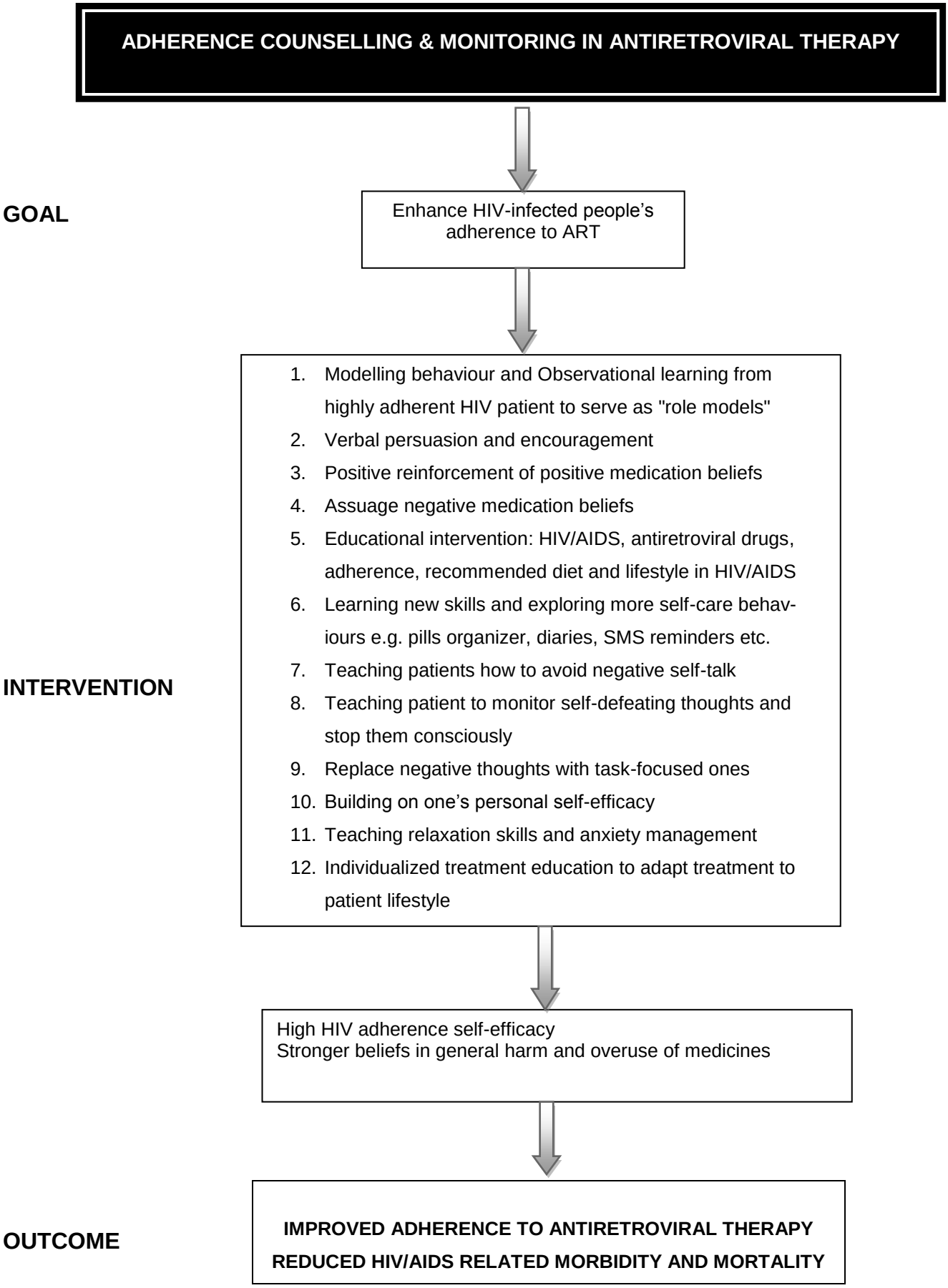


Figure 5.1 Modality of enhancing adherence to ART focusing on self-efficacy and beliefs about medicines

Figure 5.1 represents a modality of enhancing adherence to ART focusing on self-efficacy and beliefs about medicines. It shows the goals, intervention and outcome of the intervention that aim to improve patients' adherence self-efficacy and stronger beliefs about general harm and overuse of medicines.

A strategy such as **vicarious experiences** or modelling behaviour by other patients who are HIV positive and reinforcing mastery of the patient's self-care behaviours are approaches that can be used by adherence counsellors in enhancing ART adherence. Vicarious experience occurs from observing others complete a task successfully contributing as a source of modeling self-efficacy in performing that task (Bandura 1988:284).

Patients' beliefs about medicines are dynamic, and these beliefs are often due to patients' misunderstanding of the role of medications in chronic illnesses. Educational intervention in adherence serves as an opportunity for patients on chronic medications to improve their knowledge about the disease condition, gain better understanding of the role of medications and have any misconceptions harbored about their medications clarified (Magadza et al 2009:369). Patients' beliefs can be modified positively through educational interventions which will result in a change of behaviour. Addressing the risks and benefits of therapy could reinforce positive medication beliefs (such as perceived need for medication) and assuage negative ones (such as general harm and overuse of medicines) through appropriate information and counselling. Increase in knowledge is expected to lead to a change in the participants' beliefs about medicines and improved adherence.

Observational learning or modelling describes how a person acquires skills and information through the actions of other people (Redding et al 2000:185). Counsellors can provide observational learning by finding a highly adherent HIV patient to serve as "role models". Through observation, a person can learn from other people's actions and go further to develop an understanding of and be prepared for the consequences of such actions. The support groups that are formed among HIV-infected patients may serve as a good model where people learn how to do certain things by observing others within the group (Skovdal et al 2011:309). This would improve the individual's self-care behaviour leading to improved adherence to antiretroviral therapy

Verbal persuasion, which is the most often used source of self-efficacy by health care professionals, is used to convince persons that they can succeed at a task. Verbal or social persuasion serves to reinforce feelings of efficacy when facing the minor failures mentioned above (Bandura 1988:285). Adherence counsellors should utilize verbal persuasion and encouragement, and seek to strengthen patients' adherence self-efficacy beliefs by expressing confidence in their capabilities. This form of support results in learning new skills and exploring more self-care behaviours. In addition to this, health workers need to be persistent with encouragement as self-efficacy develops over time, therefore continuous positive reinforcement is needed to enhance adherence among patients on antiretroviral therapy.

Performance mastery refers to the knowledge and skill gained through experience and perseverance (Bandura 1988:285). Adherence counsellors should teach patients how to avoid negative self-talk, monitor these self-defeating thoughts, and stop them consciously. The patients need to be thought how to replace negative thoughts with task-focused ones, so hopelessness associated with adhering to antiretroviral therapy can be avoided. Another strategy is building on one's personal self-efficacy, if a person infected with HIV has the personal belief regarding his/her capabilities to carry out specific tasks to achieve good adherence to ART and believe that by doing so he/she will have improved health and lead quality life, then such individual is more likely to perform the behaviours.

Cognitive technique in counselling by health care workers assist the patient to learn relevant information about HIV/AIDS and the courses of action to make in taking decision about their disease and solving problems (Skovdal et al 2011:309). The support groups in HIV/AIDS can use cognitive and behavioural strategies to empower patients to handle problem and establish supportive relationships. Issues around disclosure of HIV status, relaxation skills, anxiety management and treatment education are skill taught in these groups that may result in better adherence to treatment (Skovdal et al 2011:309).

5.5 DEVELOPMENT OF A FRAMEWORK TO ENHANCE ART ADHERENCE

There is much information from various studies that explain several factors that serve as barriers and facilitators of ART adherence. Some of these studies, like the current research, were guided by health behaviour theories focussing on the individual level of

analysis, with behaviour viewed as the outcome of conscious rational choice. Research has shown that patients' medication beliefs can be altered through focused intervention (Magadza et al 2009:369). The framework described here is based on the findings of the current research and focuses on the individual behaviour assuming that it is shaped by cognitions such as attitudes, beliefs, motivations and self-efficacy. HIV-infected patients need to have confidence in their ability to perform the required self-management activities (self-efficacy) and hold positive beliefs about their medications. They must believe that exhibiting self-care behaviour and holding the right beliefs about their medications lead to good clinical outcomes which translate to quality health.

Developing a framework to enhance adherence to antiretroviral therapy is necessary in assisting these patients to attain competence in self-efficacy and to develop positive beliefs about medications that would result in good adherence and a subsequent better clinical outcomes on ART. This study revealed cognitive factors, such as self-efficacy and perceived general harm and overuse of medicines, as part of the factors influencing adherence to ART. The researcher proposed that attention should be given to these cognitive-behavioural variables that can influence successful compliance to treatment.

5.5.1 Structure of the framework

The framework for enhancing ART adherence among HIV-infected patients comprises of the following:

- Purpose of the framework
- Assumptions of the framework
- Participants within the framework

5.5.1.1 Purpose of the framework

The purpose of the framework is to provide modalities for adherence counsellors and other health care providers involved in HIV management on how to enhance adherence of patients on antiretroviral therapy using the identified cognitive factors in this study. The major aim of the framework is to improve adherence to ART among patients thereby reducing the morbidity and mortality associated with HIV/AIDS.

The research findings revealed that HIV adherence self-efficacy is a predictor of adherence to ART among patients who are non-adherent to antiretroviral therapy and general beliefs about medicines is a predictor of ART adherence among HIV-infected patients on ART. In addition, there is inter-relationship between adherence self-efficacy and general beliefs about medicines; and between specific beliefs about medicines and general beliefs about medicines.

5.5.1.2 Assumptions of the framework

The guidelines for the initiation of ART in South Africa stipulate the minimum counselling sessions for a potential HIV-infected patient to be initiated on treatment. Since ART is a life time commitment, it is very important to counsel a patient adequately before initiation of treatment. The assumptions of this framework are based on the following in cognizance of ART guidelines:

- Adequate counselling will precede initiation of ART initiation.
- The adherence counsellors will identify the potential barriers and facilitators of adherence before initiation of ART.
- Where necessary, treatment buddies will be involved in counselling sessions with the patient.
- Adherence monitoring and counselling is a continuum and will not be treated as once-off event in antiretroviral therapy.

5.5.1.3 Participants within the framework

This is a framework for enhancing ART adherence among patients on antiretroviral treatment. However, other stakeholders will be involved to achieve the desired outcome of this framework. Participants in the framework will include:

- HIV-infected patients on ART
- Health care providers
- Treatment buddies and family members of patients

It is important to include people with whom patients on ART would collaborate in the framework. As such, the health care providers, treatment buddies and family members are the population that forms the core of the framework. All these stakeholders work in an interactive fashion to enhance adherence by assisting the patient to change the unrealistic expectations or behaviour through education that helps to learn how to do things in a new or different ways. According to Bandura (2004:144), patients can control or influence the events that affect their lives by integrating cognitive, social, and behavioural sub-skills related to beliefs of personal efficacy in performing these skills.

5.5.2 Overview and structural description of the framework

The researcher therefore proposes a framework that encompasses HIV-ASES and BMQ-G, BMQ-S and ACTG questionnaires to be used by adherence counsellors in enhancing adherence among HIV-infected patients on ART. Figure 5.2 is a structural representation of the framework for enhancing ART adherence among HIV-infected patients. The oval structures on the left side represent the potential facilitators and barriers to ART adherence namely:

- Socio-demographic characteristics, accessibility to health services, social support.
- HIV adherence self-efficacy.
- Perceived general harmful effects and overuse of medications.
- Specific necessity and concerns about ARVs.

The solid pillar-shaped column on the right side represents adherence to ART which is the desired outcome of antiretroviral therapy use. The arrows pointing to the right indicate direction of the activity and end results of intervention. The up-down arrows indicate interrelationship between certain cognitive variable and the down-arrow callout (marked blue) depicts the intervention carried out after potential barriers to adherence have been identified. The enhancement of adherence is effected through the intervention targeted at the identified barrier or facilitator of adherence.

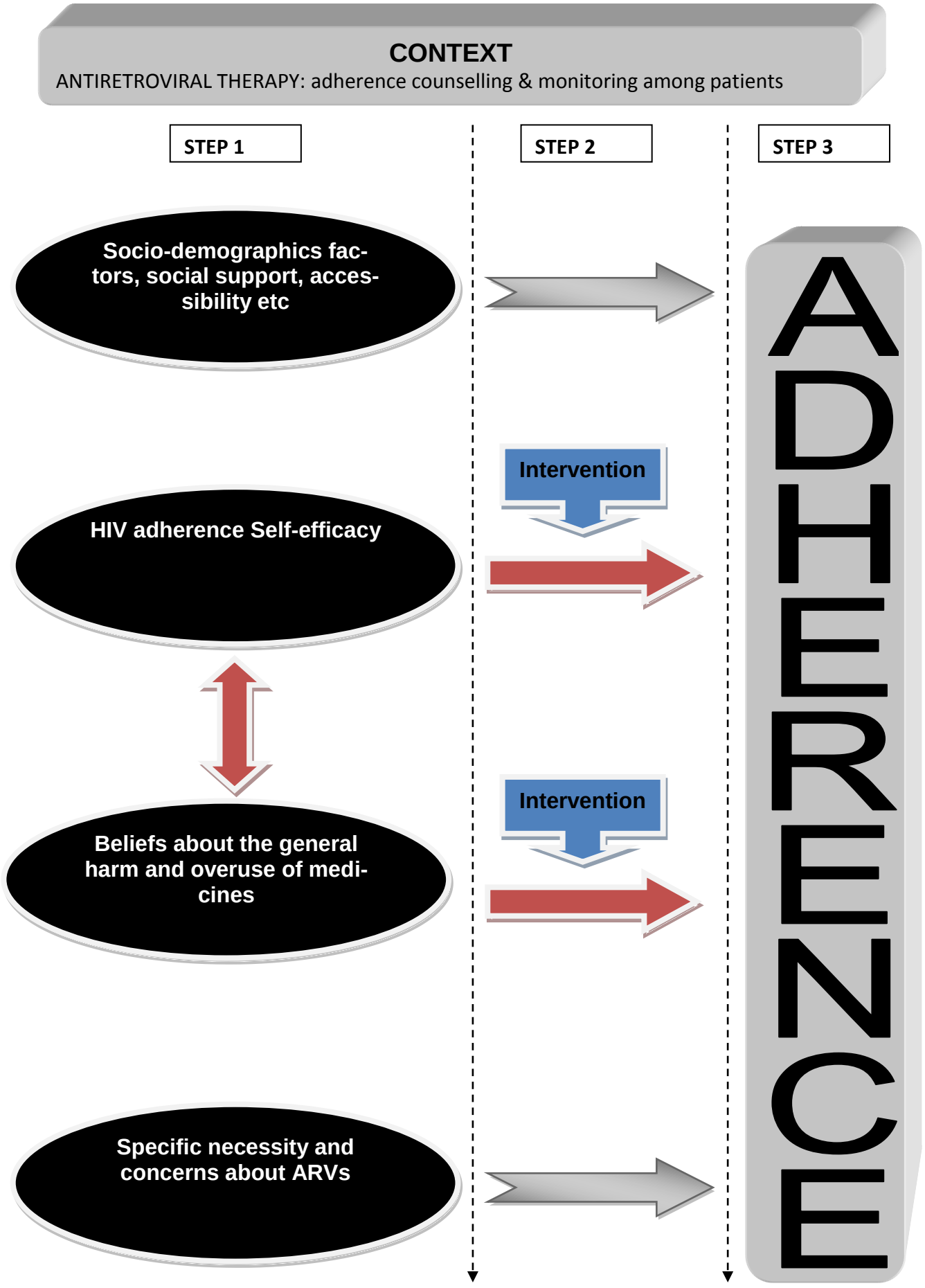


Figure 5.2 Analytical diagram of the framework for enhancing ART adherence

5.5.2.1 STEP 1: Baseline screening for adherence facilitators and barriers

The activity in the framework begins when patients are being counselled and empowered with the necessary information about the ART treatment process. The oval structures in Figure 5.3 represent the factors influencing ART adherence. The framework for enhancing ART adherence among HIV patients focuses on empowering the patients with the necessary skills. This will assist them to attain competence in self-efficacy and poses stronger beliefs about medications that will result in better adherence to ART which will subsequently result in good clinical outcomes and reduced morbidity associated with HIV/AIDS.

The goal at this stage is to identify the cognitive-behavioural factors that will influence the individual in adhering to ART. Adherence counsellors and other health care providers involved in counselling will use the screening tools to identify these factors. At this stage two instruments are used to assess the HIV adherence self-efficacy and about the general harm and overuse of medicines. BMQ-G (Table 5. 1) is used to screen for beliefs about the general harm and overuse of medicines. The patient's average score is recorded and optimal score is 8points. Any patient that scores below 4points is identified and prioritized for further intervention based on the responses on the BMQ-G scale.

Table 5.1 Beliefs about Medicines Questionnaire-General (BMQ-G)

	Strongly agree	**Agree**	**Uncertain**	**Disagree**	**Strongly disagree**
Doctors use too many medicines	1	2	3	4	5
People who take medications should stop their treatment for a while every now and again	1	2	3	4	5
Most medicines are addictive	1	2	3	4	5
Natural remedies are safer than medicines	1	2	3	4	5
Medicines do more harm than good	1	2	3	4	5
All medicines are poisons	1	2	3	4	5
Doctors place too much trust on medicines	1	2	3	4	5
If doctors had more time with patients they would prescribe fewer medicines	1	2	3	4	5

At this stage also, the HIV-ASES is used to assess the confidence of the patients in their ability to carry out the tasks outlined in Table 5.2 below. The performance of these tasks results in the desired outcome which is adherence to ART. The patients are asked the 12 questions on the HIV-ASES and each item is scored between 0-10, the average

score is then calculated, the optimal score is 10. A score below 5 is identified and prioritized for intervention based on the patient's responses on the HIV-ASES scale.

Table 5.2 HIV adherence self-efficacy scale (HIV-ASES)

	Score 0-10
1. Stick to your treatment plan even when side effects begin to interfere with your daily activities?	
2. Integrate your treatment into your daily routine?	
3. Integrate your treatment into daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV+	
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 CD4 count 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 difficult?	
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?	
Total	

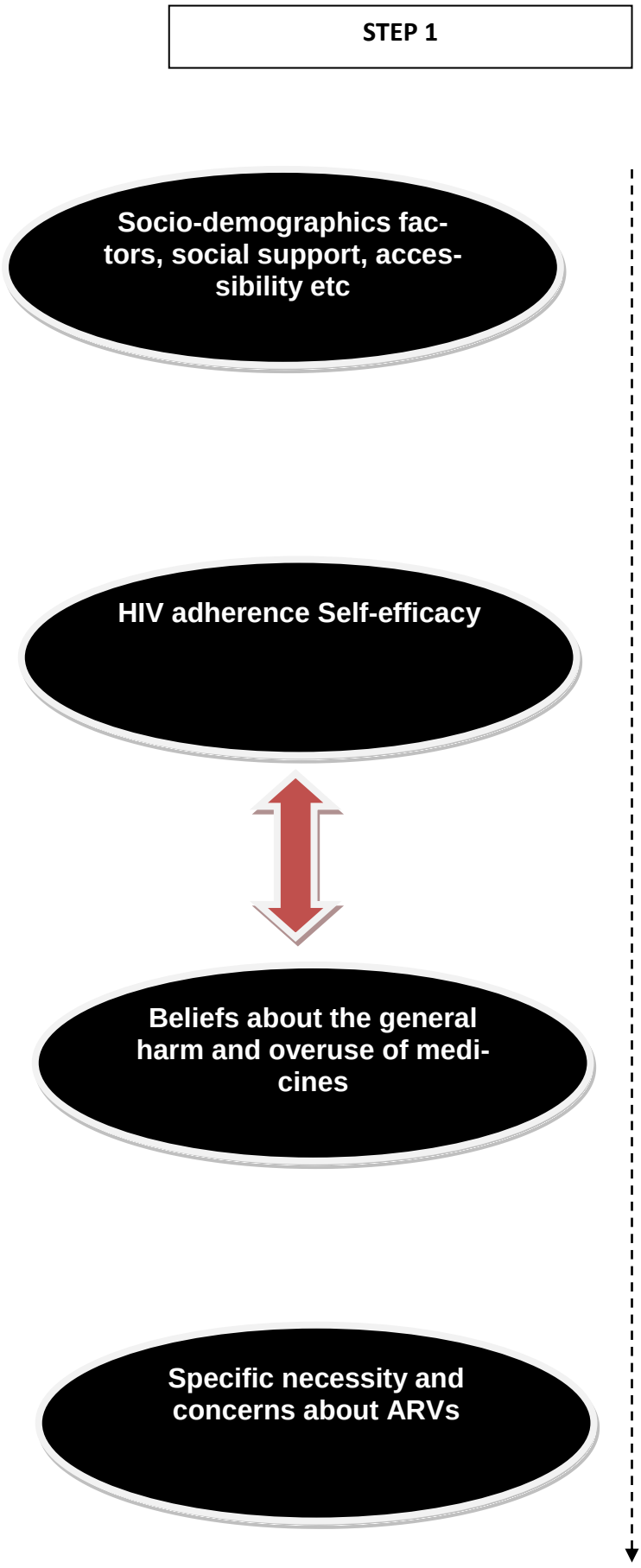


Figure 5.3 Baseline screening for adherence facilitators and barriers

5.5.2.2 STEP 2: Focused interventions on identified barriers of art adherence

The main objective at this stage is to address the identified factors in step 1 that could serve as barriers to ART adherence. The researcher proposes minimum score on the BMQ-G as 4, and minimum score on the HIV-ASES as 5. Patients that score below these cut-off marks are categorized as possessing cognitive-behavioural factors that serve as barriers to ART adherence. The adherence counsellors will define and communicate to the patients the factors that have been identified for intervention. He will then set goals and strategies for the intervention according to the identified psychological and physical needs of the patient.

Figure 5.4 shows a schematic diagram of the identified cognitive variables. The arrows pointing to the right indicate the desired outcome for the patient and the down-arrow callout (marked blue) marks the point of intervention outlined for a specific patient. The activities that could be used at this stage include but not limited to the following:

1. Address the identified cognitive variables in the scales where the individual scores low points by education, counselling, skills development and provide practical assistance where necessary. This may involve discussion with other members of the health team on the need to review ART regimen, schedule etc.

2. Review the individual perception of health goal, HIV disease, purpose of antiretroviral therapy, benefits of adherence and consequences of non-adherence to ART.

3. Educate the individual further on the facts about ART adherence, factors influencing adherence and consequences of non-adherence.

4. Assist the patient to assume a participatory role in decision made about his/her health especially in the timing of medications intake, regimens that suit his/her daily routine etc.

5. Assist the individual to develop a greater sense of self-care behaviour, setting personal goals and implementing strategies to achieve the set goals.

6. Developing skills to incorporate treatment needs into their lifestyle.

7. Assist the patient in terms of self-management training for taking daily medications, motivational interview and social support, if necessary.

8. Reminder devices such as pillboxes, pill chart, medication diaries, beepers and alarms etc may be provided for certain individuals, depending on their circumstances.

Learning occurs through information acquisition and is often interactive. This stage emphasizes the need for learning through feedback and internalization of the processes that lead to behavioural change. Patients need to demonstrate self-reinforcement and self-enhancement through feedback to the adherence counsellors and ability to develop an action plan to achieve improved adherence to ART. The development of cognitive-behavioural competency skills, such as adherence self-efficacy and beliefs about medicines in HIV management, at this stage will result in better adherence.

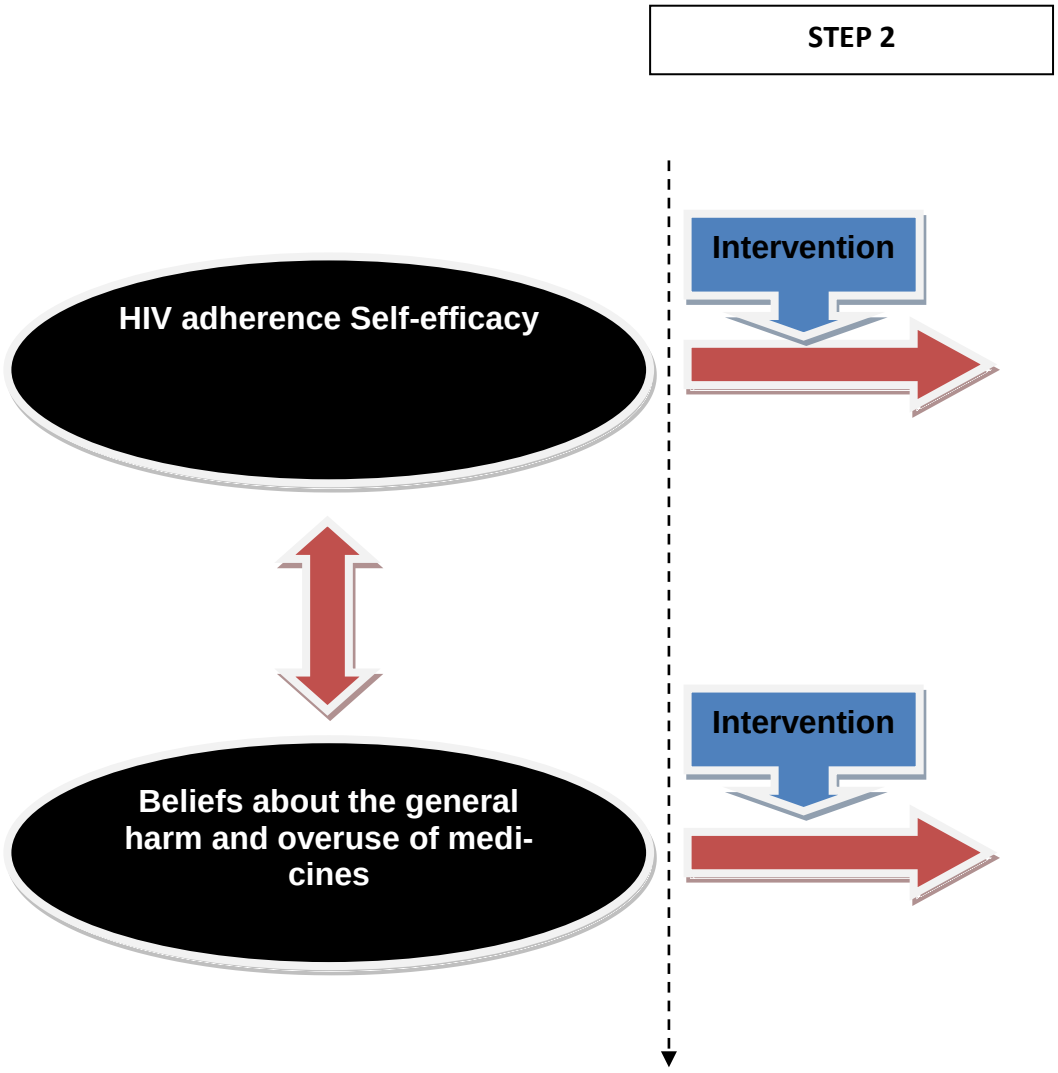


Figure 5.4 Focused interventions on identified barriers to ART adherence

5.5.2.3 STEP 3: Outcome of focused intervention – ART adherence

Figure 5.5 depicts the diagrammatic picture of what occurs in step 3. The solid column on the far right represents adherence to ART that is achieved by cognitive-behavioural intervention carried out in stage 2. The aim of this step is to emphasize the importance of adherence to ART following development of competency in self-efficacy and possession of stronger beliefs in the use of medicines. The achievement of this competency will result in sustained adherence to antiretroviral therapy which will be evident in reduced HIV/AIDS morbidity and mortality. According to Bandura (2004:145), competent individuals are more self-directed and goal oriented which lead to self actualization. The competent patient has the ability to cope with encountered situations and maintain self-care management skills at all time.

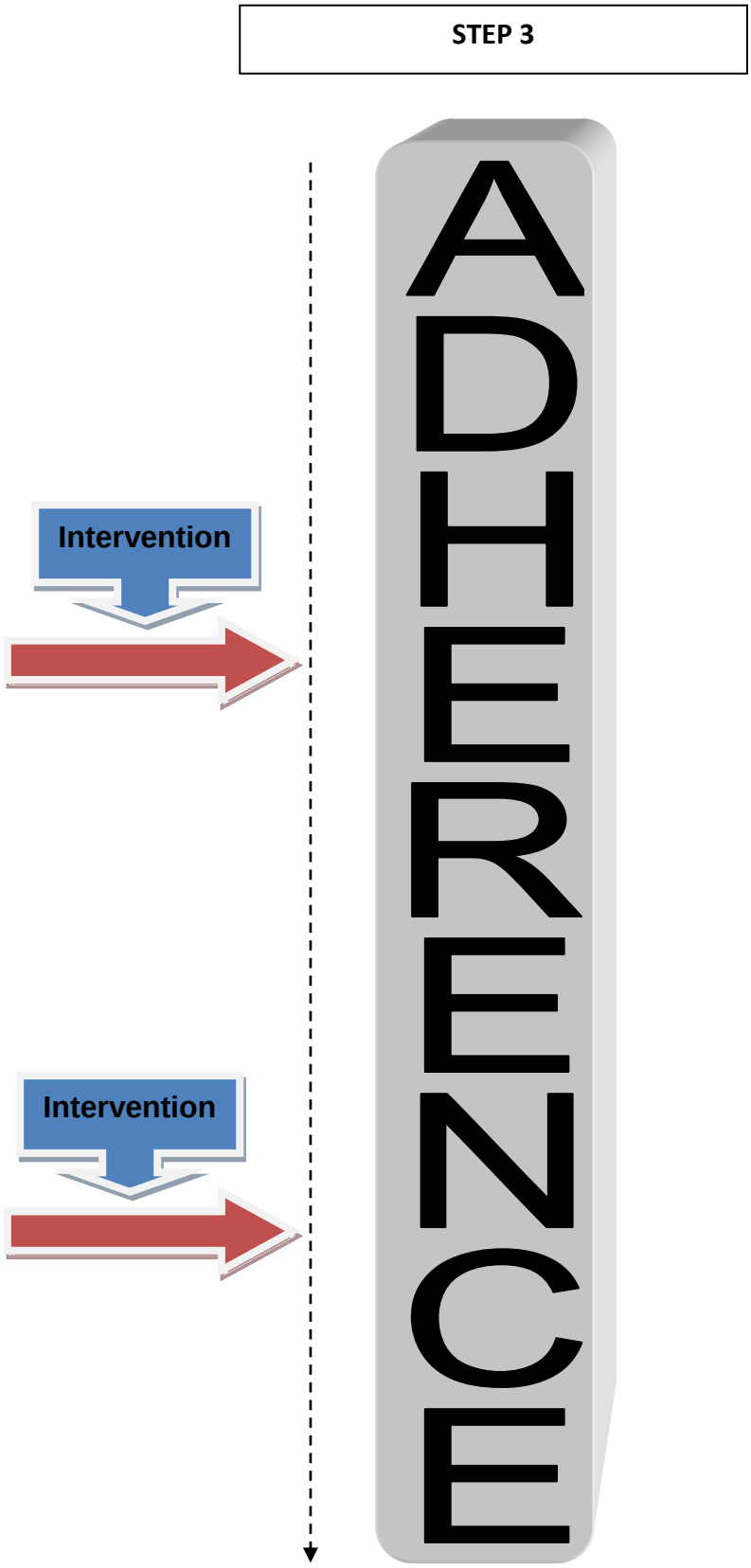


Figure 5.5 Outcome of focused intervention- ART adherence

The ACTG questionnaire is used at this stage and it determines the medication adherence to prescribed ARVs in the previous four days, the compliance of the patient with dosing schedule and the extent to which the patient has followed dietary instructions for ARV use.

The framework described above can be summarized as follows:

Step 1: an HIV-infected patient is screened for cognitive-behavioural factors that could serve as barriers to ART adherence using two instruments (BMQ-Q & HIV-ASES). Based on the score on the instruments, a patient is identified for further intervention.

Step 2: focused intervention on identified barriers is done at this stage with emphasis on interactive learning and feedback.

Step 3: the final stage involves the outcome of the intervention at the previous stage and indicates how successful the intervention was.

5.6 CONCLUSIONS

The purpose of this study was to determine the influence of adherence self-efficacy and beliefs about medicines on ART adherence among patients on lifelong treatment and subsequently use the information obtained to provide a framework for enhancing adherence to antiretroviral therapy. This section looks at the extent to which the objectives of the study have been met.

5.6.1 Objective 1: Explore the cognitive variables of adherence self-efficacy and beliefs about medicines that influence adherence among patients on ART

This objective was achieved through conducting a study using correlation design. Data were collected from participants who are HIV-infected on antiretroviral therapy using quantitative instruments that include HIV adherence self-efficacy scale, the Beliefs about Medicines questionnaire and the ACTG questionnaire. Findings revealed that the participants were highly adherent to ART (average adherence was 95%), had strong confidence in their ability to carry out tasks would enable them to adhere to ART, had high positive beliefs in the necessity that prescribed medications were necessary for

HIV/AIDS and strong beliefs about the overuse and harm that medications in general can cause.

5.6.2 Objective 2: Determine the inter-relationships among adherence self-efficacy, beliefs about medicines and ART adherence

This objective was met through the performance of correlation and regression analyses on the collected data. The predictive relationship of HIV adherence self-efficacy, beliefs about medicines and ART adherence was demonstrated. Multivariate regression was illustrated with ART adherence predicted by HIV adherence self-efficacy among non-adherent patients and predicted by beliefs about the overuse and harm that medications in general can cause among the general population.

5.6.3 Objective 3: Describe the modalities of enhancing adherence to ART through focused interventions on the identified factors that are strongly associated with ART adherence

This objective was met by the researcher through the description of various modalities to enhance ART adherence by focusing on cognitive variables that serve as barrier to adherence. The study revealed that interventions could be manipulated to address the identified cognitive factors of self-efficacy and Belief about medicines that would serve as barriers to adherence to antiretroviral therapy. An HIV-infected person with strong self-efficacy and high belief in medicines has personal belief regarding his capabilities to carry out specific tasks to achieve good adherence to ART and beliefs that prescribed medications were necessary for HIV/AIDS. Therefore, such individual is likely to adhere to prescribed antiretroviral medicines.

5.6.4 Objective 4: To develop a framework for the improvement of ART adherence based on the factors identified in this study

This objective was met through the design and description of a framework that would enhance adherence to ART among patients. The findings of this study suggest that health care workers that are involved with patients on ART should target personal self-efficacy beliefs and beliefs about medicines that would enhance adherence among HIV-infected patients on antiretroviral therapy. The researcher went further by describing a

3-step approach framework that include (1) Baseline screening for adherence self-efficacy and perceived general harm and overuse of medicines (2) Focused interventions on identified barriers of ART adherence and (3) Outcome of focused Intervention: ART adherence.

The researcher concludes by stating that all the objectives of this study have been met.

5.7 CONTRIBUTIONS OF THE STUDY

This study examined a theoretical framework encompassing health beliefs/attitudes, ART self-efficacy and demographic characteristics in relationship to antiretroviral therapy adherence. The researcher examined the relationships between two individual factors (self-efficacy and beliefs about medicines) and health behaviour (HIV medication adherence) in an attempt to identify the potential area for focused interventions that could be used in enhancing ART adherence. It was anticipated that relationship exists among the study variables using the Cognitive perspective of health behaviour as theoretical framework. The study established the predictive relationships between HIV adherence self-efficacy and adherence to ART; secondly it also described the predictive relationship between perceived harm and overuse of medicines and adherence. Finally, the current research also identified the relationships that existed among the independent variables.

This study has significant implications for HIV/AIDS clinical care and research in that it provides a framework that would assist health providers in identifying patients at high risk for medication non-adherence and also the modalities of enhancing their adherence to antiretroviral therapy. The early identification of patients who are likely to be non-adherent in the course of taking ART would assist in reducing the morbidity and mortality associated with HIV/AIDS among non-compliant patients. Secondly, the cost associated with HIV/AIDS management would be reduced if more patients are adhering to their treatment. Furthermore, the development of resistance that results from non-adherence to ART would also be minimized if potential non-adherent patients are identified early and intervention put in place to ensure their good adherence to ART.

5.8 LIMITATIONS OF THE STUDY

The use of cross-sectional design to investigate adherence to HIV medication at a point in time limits the degree to which causal inferences and generalizations can be made from the research findings. A longitudinal study design, which involves taking multiple measures over a defined length of time, could possibly give more information about changes that occur over time in terms of adherence to antiretroviral therapy.

This study was conducted in a public health facility that provides free ART services and psycho-social support to patients on ART, certain socio-economic factors that have been described as barriers to adherence may not have affected the participants in this study. This might have influence on the responses of the participants and the high level of adherence reported in this study.

The proportion of non-adherent patients in this sample appear to be small to make concrete conclusion on non-adherent patients, subsequent studies could focus mainly on non-adherent patient; outcome of such research could shed more light on barriers to ART adherence that are unique among such group of patients.

There are several potential predictors of medication adherence that were not assessed as part of this study e.g. transportation costs, accessibility to health institutions and social support. Their inclusion might have given a different outcome. Another limitation is the self-report questionnaire that was used; self-report could be affected by participant motivation, poor recall and social desirability in responding. Adherence to ART may be over-estimated by participants and non-adherence may be underreported, it is possible that other measures of adherence such as a medication event monitoring system (MEMS), pill count, pharmacy records and laboratory blood monitoring could have yielded different results. As there is no gold standard for measuring adherence to ART (Johnson et al 2005:201), the researcher is of the opinion that ACTG adherence questionnaire, a validated measure of adherence that has demonstrated meaningful relationships with important outcomes such as CD4 count and viral load in other studies employed in this study is an adequate measure of adherence.

5.9 RECOMMENDATIONS

The following recommendations are suggested for future efforts in enhancing ART adherence among patients.

1. Baseline data on adherence should be obtained for all patients before initiation of ART using the tools described in this study irrespective of their socio-economic and demographic characteristics. This would assist in identifying patients that need further cognitive intervention before commencement of ART.

2. In future, studies may utilize multiple measures of adherence, such as medication event monitoring system (MEMS), pill count, CD4 count, viral loads to validate the accuracy of self-reported measures. This would enhance the accuracy of self-reported measure like the ACTG questionnaire.

3. Future research may seek to include different healthcare providers, such as private, public and faith-based organisations. This could bring to light differences in the strategies used by these providers to foster and sustain adherence to ART among their patients, and secondly provide better understanding of potential barriers to ART adherence among patients who are not receiving free ART services.

4. The current study did not investigate how patient-provider relationship influence patients' adherence to antiretroviral therapy. Further studies on patient-provider relationship and beliefs about medicines could provide better understanding of these in the future.

5. A strategy such as vicarious experiences or modelling behaviour by other patients who are HIV positive and reinforcing mastery of the patient's self-care behaviours (Bandura) are approaches that could be used by adherence counsellors in enhancing ART adherence. This would improve the individual's self-care behaviour leading to improved adherence to antiretroviral therapy.

6. Another strategy is building on one's personal self-efficacy, which has been shown to be highly influential in adherence. If persons infected with HIV have the belief regarding their capabilities to carry out specific tasks to achieve good ad-

herence to ART and that believe that by doing so they will have improved health and lead quality life, then they may be more likely to perform the behaviours.

7. Health workers need to be persistent with encouragement as self-efficacy develops over time, therefore continuous positive reinforcement is needed to enhance adherence among patients on chronic medications.

5.10 SUMMARY

HIV is a chronic disease that is managed with medications; successful clinical outcome depends on patient's self-efficacy in adhering to ART and positive beliefs about medications. As health-related knowledge and patients beliefs alone are insufficient to achieve behaviour change especially in chronic condition like HIV/AIDS, there is need for better understanding of other factors that predict patients' behavioural changes that would result in adherence to prescribed medication. The framework described in this study can make a meaningful contribution to adherence monitoring and enhancement among patients on antiretroviral therapy thereby resulting in good clinical outcomes and reduction in morbidity and mortality associated with HIV/AIDS. In conclusion, further study is encouraged in this field of adherence in HIV/AIDS management to assist patients in maintaining quality life as they live with this chronic disease.

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ANNEXURE A: Ethical clearance certificate from UNISA

UNISA university of south africa

UNIVERSITY OF SOUTH AFRICA
Health Studies Higher Degrees Committee
College of Human Sciences
ETHICAL CLEARANCE CERTIFICATE

HSHDC 62/2011

Date of meeting: 6 December 2011 Student No: 4753-803-1

Project Title: Self-efficacy and beliefs about medicines: implications for antiretroviral therapy adherence.

Researcher: Dr Adefolalu Adegoke Olusegun

Degree: D Litt et Phil Code: DPCHS04

Supervisor: Prof ZZA Nkosi
Qualification: D Litt et Phil
Joint Supervisor:

DECISION OF COMMITTEE

Approved [√] **Conditionally Approved** [ ]

Prof E Potgieter
CHAIRPERSON: HEALTH STUDIES HIGHER DEGREES COMMITTEE

Prof MC Bezuidenhout
ACADEMIC CHAIRPERSON: DEPARTMENT OF HEALTH STUDIES

PLEASE QUOTE THE PROJECT NUMBER IN ALL ENQUIRES

ANNEXURE B: Letter requesting permission to do research at study setting

P.O Box 2195
Faerie Glen
Pretoria, 0043

February 8, 2012

The Project Director
Hope for Life Clinics
Pretoria

REQUEST FOR PERMISSION TO CONDUCT RESEARCH IN YOUR INSTITUTION

I am Dr AO Adefolalu, a doctoral student at the Department of Health Studies, University of South Africa. I am requesting permission to conduct research in your hospital for my doctoral thesis titled '***Self-efficacy and beliefs about medicines: implication for antiretroviral therapy adherence***'. The objectives of the study are to:

1. Explore the cognitive variables of adherence self-efficacy and beliefs about medicines that influence adherence among patients on ART.
2. Determine the inter-relationships among adherence self-efficacy, beliefs about medicines and ART adherence.
3. Describe the modalities of enhancing adherence to ART through focused interventions on the identified factors that are strongly associated with ART adherence.
4. To develop a framework for the improvement of ART adherence based on the factors identified in this study.

232 HIV patients attending your hospital will be randomly sampled to participate in this study and will be subjected to interview after giving informed consent.

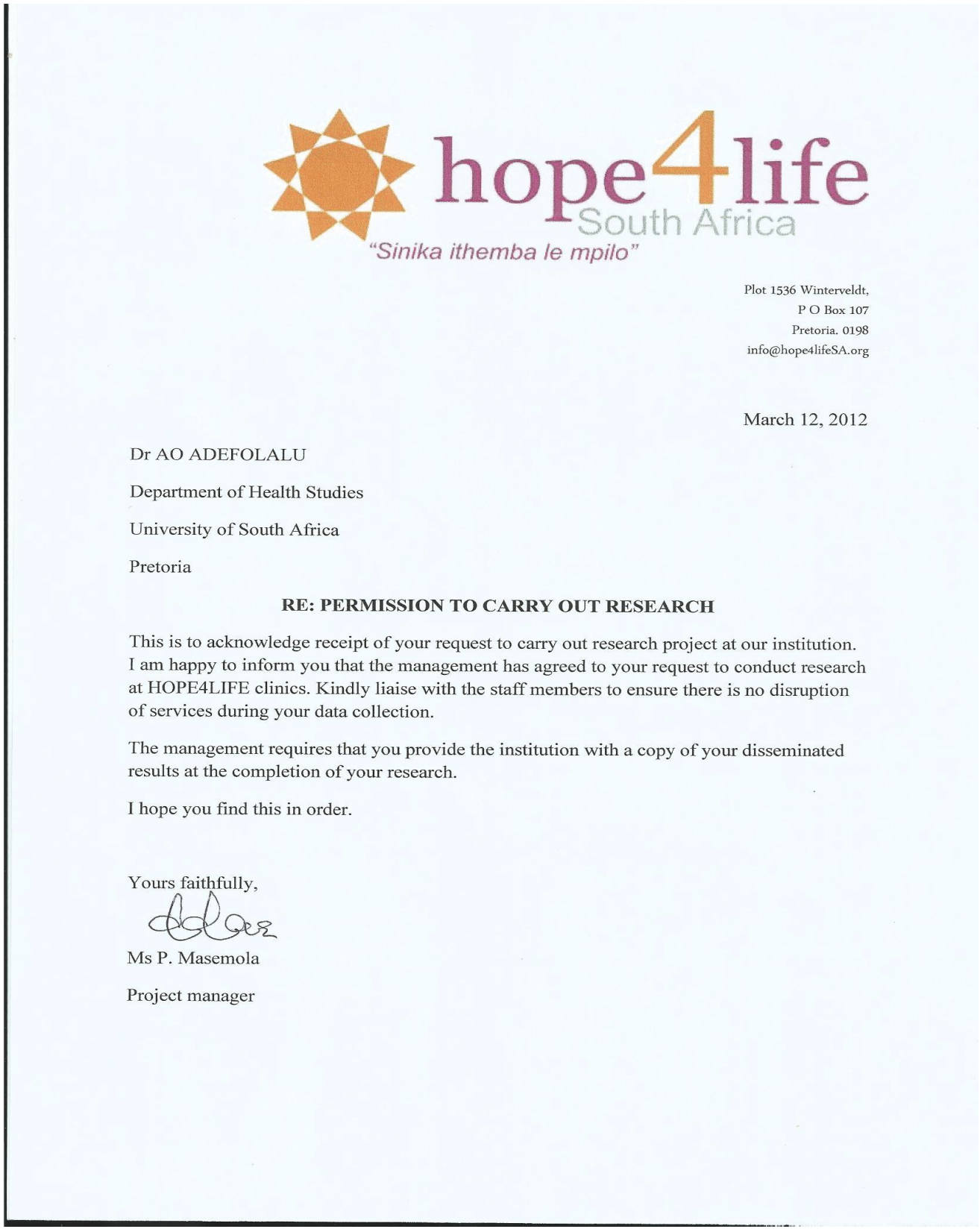
Attached to this request is a copy of my research proposal and ethics clearance certificate from the university Higher Degree Committee.

Kindly inform me should you require more information to support this request.

Yours faithfully,

Dr Adefolalu AO

ANNEXURE C: Letter of approval to conduct research



hope4life South Africa

"Sinika ithemba le mpilo"

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March 12, 2012

Dr AO ADEFOLALU

Department of Health Studies

University of South Africa

Pretoria

RE: PERMISSION TO CARRY OUT RESEARCH

This is to acknowledge receipt of your request to carry out research project at our institution. I am happy to inform you that the management has agreed to your request to conduct research at HOPE4LIFE clinics. Kindly liaise with the staff members to ensure there is no disruption of services during your data collection.

The management requires that you provide the institution with a copy of your disseminated results at the completion of your research.

I hope you find this in order.

Yours faithfully,

Ms P. Masemola

Project manager

ANNEXURE D: Research instruments

QUESTIONNAIRE ***Serial no _____***

SELF-EFFICACY AND BELIEFS ABOUT MEDICINES: IMPLICATIONS FOR ANTIRETROVIRAL THERAPY ADHERENCE

SECTION A: DEMOGRAPHIC DATA

1. How old are you? For office use

18-24 years	1		
25-34 years	2		
35-44 years	3		
45-55 years	4		
>55 years	5	1	

2. What is your gender?

Male	1		
Female	2	2	

3. Marital status

Never married	1		
Married	2		
Cohabiting	3		
Widowed	4		
Separated	5		
Divorced.	6	3	

4. Highest level of education completed

No schooling	1		
Primary education	2		
Secondary education	3		
Tertiary education	4	4	

5. How many cigarettes do you smoke per day?

None	1		
1-4	2		
5-9	3		
10-14	4		
15 and more	5	5	

6. How often do you consume alcohol?

More than once daily	1		
Once daily	2		
A few times per week	3		
About once a week	4		
Seldom	5		
Never	6	6	

7. Work status in the last 3 months?

Employed	1		
Unemployed	2		
Student	3		
Social grant	4		
Retired	5	7	

8. When was the first time you were told about your HIV status?

Between 12 - 23 months	1		
Between 24 – 36 months	2		
More than 36 months	3	8	

9. What is/are the most likely way(s) that you became infected with HIV?

Sex with HIV+ person	1		
Shared needles with HIV+ person	2		
Mother-to-child transmission	3		
Occupation exposure to blood/body fluid	4		
Sexual assault	5		
Blood transfusion or medical procedure	6		
Don't know	7		
Other	8	9	

10. Have you disclosed your status to any of your family members?

Yes	1		
No	2	10	

11. Do you have a treatment buddy presently?

Yes	1		
No	2	11	

12. If yes, to what extent does your treatment buddy helps you to remember taking your medication?

Not at all	1		
A little	2		
Sometimes	3		
A lot	4	12	

13. How long have you been on ART? Would you say

Between 12 - 23 months	1		
Between 24 - 36 months	2		
More than 36 months	3	13	

14. What is the number of pills you swallow every day?

2-5	1		
6-10	2		
More than 10	3	14	

15. Have you experienced any adverse reactions of ART that required you to stop the medications?

Yes	1		
No	2	16	

SECTION B: HIV TREATMENT ADHERENCE SELF-EFFICACY SCALE (HIV-ASES)

I am going to ask you about situations that could occur during your treatment for HIV. Treatment can involve different things for different people. Sometimes, this might refer to taking medications, and other times it could refer to other things that you do to deal with HIV such as diet and exercise or taking vitamins. So, in these questions, when I ask you about your "treatment" or your "treatment plan," I am talking not only about any medications that you might be taking for HIV, but also other things that make up your self-care.

For the following questions, I will ask you to tell me in **the past month, including today**, how confident you have been that you can do the following things. Use these responses scale ranging from 0 ("cannot do at all") to 10 ("completely certain can do").

Cannot do at all	00
	01
	02
	03
	04
Moderately Certain Can Do →	05
	06
	07
	08
	09
Completely Certain Can Do	10

How confident you have been that you can do the following things in the past month, including today?

	00	01	02	03	04	05	06	07	08	09	10
1. Stick to your treatment plan even when side effects begin to interfere with your daily activities?											
2. Integrate your treatment into your daily routine?											
3. Integrate your treatment into daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV+											
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 CD4 count 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 difficult?											
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?											

SECTION C: BELIEFS ABOUT MEDICINES QUESTIONNAIRE (BMQ)

I would like to ask your personal views about ARVs prescribed for you and your personal views about medicines in general. These are statements others people have made about their medications. Please indicate the extent to which you agree or disagree with them by circling the appropriate box. There is no right or wrong answers; I am only interested in your personal views**.**

BMQ-Specific: Your views about ARVs prescribed for you

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
My health, at present, depends on my ARVs	**5**	**4**	**3**	**2**	**1**
My life would be impossible without my ARVs	**5**	**4**	**3**	**2**	**1**
Without my ARVs I would become very ill	**5**	**4**	**3**	**2**	**1**
My health in the future will depend on my ARVs	**5**	**4**	**3**	**2**	**1**
My ARVs protect me from becoming worse	**5**	**4**	**3**	**2**	**1**
Having to take ARVs worries me	**1**	**2**	**3**	**4**	**5**
I sometimes worry about long-term effects of my ARVs	**1**	**2**	**3**	**4**	**5**
I don't know how my ARVs work	**1**	**2**	**3**	**4**	**5**
My ARVs disrupt my life	**1**	**2**	**3**	**4**	**5**
I sometimes worry about becoming too dependent on my ARVs	**1**	**2**	**3**	**4**	**5**

BMQ-General: Your views about Medicines in general

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
Doctors use too many medicines	**1**	**2**	**3**	**4**	**5**
People who take medications should stop their treatment for a while every now and again	**1**	**2**	**3**	**4**	**5**
Most medicines are addictive	**1**	**2**	**3**	**4**	**5**
Natural remedies are safer than medicines	**1**	**2**	**3**	**4**	**5**
Medicines do more harm than good	**1**	**2**	**3**	**4**	**5**
All medicines are poisons	**1**	**2**	**3**	**4**	**5**
Doctors place too much trust on medicines.	**1**	**2**	**3**	**4**	**5**
If doctors had more time with patients they would prescribe fewer medicines	**1**	**2**	**3**	**4**	**5**

SECTION D: ANTIRETROVIRAL THERAPY ADHERENCE QUESTIONNAIRE

You are currently taking the following drugs at the frequency and doses listed.

DRUG NAME/DOSE	Number of Pills each time (Pills Each Dose)	Number of times per day (Doses Per Day)

1. If you took only a portion of a dose on 1 or more of these days, report the dose(s) as being missed.

Step 1 Names of your ARVs	HOW MANY DOSES DID YOU **MISS** . . .			
	Step 2 Yesterday	**Step 3** 2 days ago	**Step 4** 3 days ago	**Step 5** 4 days ago
	-----doses	-----doses	-----doses	-----doses
	-----doses	-----doses	-----doses	-----doses
	-----doses	-----doses	-----doses	-----doses
	-----doses	-----doses	-----doses	-----doses

2. During the **past 4 days**, on how many days have you missed taking all your doses?

None	**1 day**	**2 days**	**3 days**	**4 days**
☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

3. Most anti-HIV medications need to be taken on a schedule, such as **"2 times a day"** or **"3 times a day"** or **"every 8 hours".** How closely did you follow your specific schedule over the **last 4 days**?

Never	**Some of the time**	**About half of the time**	**Most of the time**	**All of the time**
☐ **1**	☐ **2**	☐ **3**	☐ **4**	☐ **5**

4. Does any of your anti-HIV medications have special instructions, such as **"take with food"** or "**on an empty stomach"** or **"with plenty of fluids?"**

● **1** Yes ● **2** No

5. **If Yes**, how often did you follow those special instructions over the last **four** days?

Never	**Some of the time**	**About half of the time**	**Most of the time**	**All of the time**
1	**2**	**3**	**4**	**5**

ANNEXURE E: AUTHORIZATION TO PARTICIPATE IN RESEARCH

AUTHORIZATION TO PARTICIPATE IN RESEARCH

Title of Study: Self-Efficacy and Beliefs about Medicines: Implications for Antiretroviral Therapy Adherence

Introduction

I am **Dr Adefolalu Adegoke**, the researcher responsible for this study and currently registered for DLitt et Phil degree at the Department of Health Studies at UNISA. This research seeks to explain and explore some cognitive correlates of adherence to antiretroviral therapy among HIV-infected patients on treatment in South Africa. The purpose of this doctoral research is to understand what assists or maintains HIV treatment adherence among men and women living with HIV in South Africa. The study specifically, aims at establishing whether an individual's level of confidence in performing role in taking medication and beliefs about medication have relationships with his or her ability to take HIV medication as needed.

Procedure

If you agree to participate in this study, you will be subjected to an interview which involves answering questions about your demographic information, ART adherence self-efficacy, beliefs about medicines and ART adherence. Please answer all questions honestly; you will not be judged based on your responses as there is no right or wrong answer. If you have any questions feel free to ask the research assistant or the researcher.

Voluntary nature and right to decline

Please be advised that your participation is voluntary. If you decide to participate, but prefer not to answer certain questions, you are free to do so and for any reason. You have the right to decline to answer any questions that make you feel uncomfortable, or stop the interview at any time. There are no negative consequences if you decline to participate or refuse to answer any question.

Confidentiality and anonymity

The researcher undertakes to maintain at all time strict confidentiality of you as participant and the data collected during the research. All collected data will be stored electronically in a secured location, protected with password and only the researcher will have access to it. No personal identifiers such as names, birth-date, addresses, and email or telephone numbers will be attached to your responses on the questionnaires. Results of the research will be presented and published in such a manner that participants will not be identifiable.

Risk and Benefits

No major risk is anticipated to you as a participant; however counselling services will be readily available to you should you develop emotional trauma as a result of participating in the study. As a participant you will not receive any monetary benefit for your participation in the study and will not be coerced into participation; however you will contribute to the existing body of knowledge in the field of HIV/AIDS and may benefit from the outcome of the study through your participation.

You will be given a signed copy of this informed consent. Your consent to participate is indicated by completing the four questionnaires. If you have any questions or concerns

about the study, please contact the Researcher: Dr AO Adefolalu on **073 095 9319, 47538031@mylife.unisa.ac.za** or Prof ZZ Nkosi; **012 4296758, nkosizz@unisa.ac.za**

CONSENT TO PARTICIPATE IN THE STUDY

I…….understand that I have been asked to participate in the above named research which aims to find out the influence of self-efficacy and beliefs about medication on adherence among HIV-infected patients on ART.

I confirm that the purpose and details of the research have been fully explained to me and I declare that I fully understand the content of this consent form. I have been given the opportunity to ask questions and I am satisfied with the answers provided. In addition, I have been told that if I decline to participate this will not affect the quality of care given to me in any way whatsoever.

I confirm that I have not been forced or put under any pressure to participate. Furthermore, I have not been offered any reward, in cash or kind for my participation; and I confirm that my consent is voluntary.

I authorize the researcher to use at his discretion the data collected in the course of the study for the purpose of writing the report of this research.

I will be provided with a signed copy of this consent form and the researcher will keep the original copy in a safe place.

I have read this information and hereby volunteer to participate in this study.

Signed at…….. (Place) on …….(Date)

…… ……..

Participant's signature **Witness' signature**

ANNEXURE F: Permission from copyright holder to use BMQ

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Routledge Taylor & Francis Group

Title: The beliefs about medicines questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication

Author: Robert Horne, John Weinman, Maittew Hankins

Publication: Psychology & Health

Publisher: Taylor & Francis

Date: Jan 1, 1999

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ANNEXURE G: Factor Analysis Results for All Variables

Factor Analysis

```
Factor analysis/correlation                       Number of obs    =       232
    Method: iterated principal factors            Retained factors =         6
    Rotation: (unrotated)                         Number of params =       171

    --------------------------------------------------------------------------
         Factor  |   Eigenvalue   Difference        Proportion   Cumulative
    -------------+------------------------------------------------------------
        Factor1  |      7.25954      4.75481            0.5412       0.5412
        Factor2  |      2.50473      0.81602            0.1867       0.7279
        Factor3  |      1.68871      0.96215            0.1259       0.8538
        Factor4  |      0.72656      0.07034            0.0542       0.9079
        Factor5  |      0.65622      0.07715            0.0489       0.9568
        Factor6  |      0.57907      0.13574            0.0432       1.0000
        Factor7  |      0.44333      0.07869            0.0330       1.0331
        Factor8  |      0.36464      0.05396            0.0272       1.0602
        Factor9  |      0.31068      0.02933            0.0232       1.0834
       Factor10  |      0.28135      0.05324            0.0210       1.1044
       Factor11  |      0.22812      0.05342            0.0170       1.1214
       Factor12  |      0.17470      0.05585            0.0130       1.1344
       Factor13  |      0.11886      0.01443            0.0089       1.1433
       Factor14  |      0.10443      0.05441            0.0078       1.1510
       Factor15  |      0.05002      0.01907            0.0037       1.1548
       Factor16  |      0.03095      0.00519            0.0023       1.1571
       Factor17  |      0.02576      0.02763            0.0019       1.1590
       Factor18  |     -0.00187      0.02914           -0.0001       1.1589
       Factor19  |     -0.03101      0.00511           -0.0023       1.1565
       Factor20  |     -0.03612      0.03418           -0.0027       1.1539
       Factor21  |     -0.07030      0.01220           -0.0052       1.1486
       Factor22  |     -0.08251      0.02886           -0.0062       1.1425
       Factor23  |     -0.11137      0.02154           -0.0083       1.1342
       Factor24  |     -0.13291      0.01804           -0.0099       1.1242
       Factor25  |     -0.15096      0.04384           -0.0113       1.1130
       Factor26  |     -0.19480      0.03511           -0.0145       1.0985
       Factor27  |     -0.22991      0.02476           -0.0171       1.0813
       Factor28  |     -0.25466      0.00138           -0.0190       1.0624
       Factor29  |     -0.25605      0.01316           -0.0191       1.0433
       Factor30  |     -0.26921      0.04198           -0.0201       1.0232
       Factor31  |     -0.31119            .           -0.0232       1.0000
    --------------------------------------------------------------------------
    LR test: independent vs. saturated: chi2(465) = 2836.23 Prob>chi2 = 0.0000
```

Factor loadings (pattern matrix) and unique variances

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Uniqueness
b1	0.7901	-0.1221	-0.0856	-0.0673	-0.1711	-0.0244	0.3191
b2	0.8460	-0.1044	-0.0337	0.0863	-0.0885	-0.0346	0.2559
b3	0.6942	-0.1028	-0.0441	0.0124	-0.0147	-0.0542	0.5022
b4	0.7382	-0.0138	0.0739	0.1154	0.0866	-0.1070	0.4171
b5	0.8040	0.0371	-0.0352	-0.0883	-0.0435	0.0647	0.3372
b6	0.7894	0.0307	-0.0901	0.0800	0.0419	-0.1325	0.3421
b7	0.7545	-0.1012	0.0627	-0.0411	0.0347	0.0450	0.4116
b8	0.7194	-0.1136	-0.0649	-0.0392	-0.0352	0.1383	0.4434
b9	0.7566	0.0382	0.0551	0.0622	0.1519	0.1209	0.3815
b10	0.7021	-0.0310	0.1214	-0.0100	0.1395	0.0629	0.4678
b11	0.7891	-0.0630	0.0487	0.1577	-0.0724	-0.0433	0.3389
b12	0.6353	-0.1464	0.1249	-0.1289	0.0155	0.0731	0.5372
bmqs1	0.1050	0.4844	-0.3917	0.0280	0.0450	-0.1202	0.5836
bmqs2	0.0801	0.4957	-0.3651	-0.0527	-0.0672	0.1146	0.5941
bmqs3	0.0711	0.4539	-0.3754	0.0754	0.0102	0.0178	0.6419
bmqs4	0.1390	0.5369	-0.4852	-0.1907	0.3656	-0.1531	0.2634
bmqs5	0.1729	0.4244	-0.2159	0.2908	-0.0500	0.2695	0.5837
bmqs6	0.2400	0.3133	-0.0366	-0.1051	-0.1782	0.2601	0.7325
bmqs7	0.0197	0.3042	0.2913	-0.1435	0.0138	0.1419	0.7813
bmqs8	0.0527	0.3597	0.1332	0.0278	-0.1342	-0.1282	0.8149
bmqs9	0.1543	0.1910	0.2837	-0.1761	0.1149	-0.2018	0.7743
bmqs10	0.1489	0.3078	0.3500	-0.2805	-0.0729	-0.1050	0.6656
bmqg1	0.0088	0.3561	0.2946	0.0436	-0.0930	0.2020	0.7349
bmqg2	0.4161	0.2649	0.1115	0.0992	-0.1426	-0.2548	0.6492
bmqg3	0.1692	0.2708	0.3300	-0.2083	0.3105	0.1367	0.6306
bmqg4	-0.1502	0.2018	0.0781	0.1449	-0.1533	-0.0853	0.8788
bmqg5	-0.1325	0.4930	0.4319	0.2319	0.0850	-0.0773	0.4859
bmqg6	0.0317	0.4380	0.1371	-0.1814	-0.3884	-0.1066	0.5933
bmqg7	0.0597	0.0793	0.2268	-0.0713	0.1074	-0.0381	0.9206
bmqg8	-0.1357	0.1999	0.2572	0.1528	0.0837	0.2259	0.7941
D1	0.0366	0.1285	0.2565	0.4180	0.1430	-0.1130	0.7084

. rotate, varimax horst

Factor analysis/correlation — **Number of obs = 232**
Method: iterated principal factors — **Retained factors = 6**
Rotation: orthogonal varimax (Kaiser on) — **Number of params = 171**

Factor	Variance	Difference	Proportion	Cumulative
Factor1	**7.14395**	**5.03620**	**0.5325**	**0.5325**
Factor2	**2.10775**	**0.73673**	**0.1571**	**0.6897**
Factor3	**1.37103**	**0.31844**	**0.1022**	**0.7919**
Factor4	**1.05259**	**0.17107**	**0.0785**	**0.8703**
Factor5	**0.88152**	**0.02352**	**0.0657**	**0.9360**
Factor6	**0.85800**	**.**	**0.0640**	**1.0000**

LR test: independent vs. saturated: chi2(465) = 2836.23 Prob>chi2 = 0.0000

Rotated factor loadings (pattern matrix) and unique variances

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Uniqueness
b1	0.7968	0.0151	-0.0650	0.1007	-0.1687	-0.0543	0.3191
b2	0.8579	0.0173	-0.0599	0.0552	0.0056	-0.0338	0.2559
b3	0.6997	0.0272	-0.0059	0.0012	-0.0298	-0.0807	0.5022
b4	0.7360	0.0412	0.1038	0.0049	0.1540	-0.0705	0.4171
b5	0.7864	0.1221	0.0878	0.0485	-0.1257	0.0609	0.3372
b6	0.7783	0.1772	0.0275	0.0349	0.0740	-0.1153	0.3421
b7	0.7560	-0.0277	0.1037	-0.0464	-0.0540	0.0149	0.4116
b8	0.7255	0.0249	-0.0246	-0.0631	-0.1390	0.0750	0.4434
b9	0.7447	0.0995	0.1467	-0.1126	0.0721	0.1208	0.3815
b10	0.6948	0.0008	0.1919	-0.0945	0.0314	0.0529	0.4678
b11	0.8015	-0.0100	-0.0281	0.0777	0.1082	0.0006	0.3389
b12	0.6393	-0.1179	0.1445	-0.0482	-0.1274	0.0275	0.5372
bmqs1	0.0383	0.6268	-0.0193	0.1344	0.0390	-0.0447	0.5836
bmqs2	0.0139	0.5820	-0.0390	0.1453	-0.1117	0.1786	0.5941
bmqs3	0.0152	0.5780	-0.0799	0.0960	0.0324	0.0846	0.6419
bmqs4	0.0381	0.8039	0.2129	-0.0920	-0.0642	-0.1760	0.2634
bmqs5	0.1413	0.4391	-0.1511	0.0646	0.1723	0.3833	0.5837
bmqs6	0.2000	0.2233	0.0617	0.1793	-0.1622	0.3397	0.7325
bmqs7	-0.0247	0.0256	0.3555	0.1390	-0.0014	0.2679	0.7813
bmqs8	0.0128	0.1474	0.1587	0.3408	0.1316	0.0679	0.8149
bmqs9	0.1122	-0.0009	0.4223	0.1472	0.0624	-0.0958	0.7743
bmqs10	0.0932	-0.0070	0.4601	0.3265	-0.0603	0.0609	0.6656
bmqg1	-0.0245	0.0318	0.2246	0.2147	0.1212	0.3902	0.7349
bmqg2	0.3874	0.1345	0.1184	0.3595	0.1885	-0.0625	0.6492
bmqg3	0.1131	0.0593	0.5527	-0.0888	0.0328	0.1965	0.6306
bmqg4	-0.1592	0.0438	-0.0269	0.2466	0.1688	0.0621	0.8788
bmqg5	-0.1772	0.0723	0.3637	0.2606	0.4782	0.2204	0.4859
bmqg6	-0.0234	0.1418	0.1733	0.5737	-0.1057	0.1255	0.5933
bmqg7	0.0419	-0.0607	0.2621	0.0214	0.0671	0.0158	0.9206
bmqg8	-0.1463	-0.0315	0.1536	-0.0181	0.2176	0.3350	0.7941
D1	0.0447	-0.0404	0.0732	0.0297	0.5285	0.0494	0.7084

Factor rotation matrix

	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6
Factor1	0.9889	0.1046	0.0962	0.0344	-0.0226	0.0090
Factor2	-0.1257	0.7102	0.3808	0.4331	0.2004	0.3272
Factor3	0.0086	-0.6580	0.5974	0.2267	0.3162	0.2424
Factor4	0.0691	-0.0067	-0.5070	-0.0406	0.8413	0.1695
Factor5	-0.0339	0.2247	0.4688	-0.7816	0.2872	-0.1877
Factor6	0.0137	-0.0348	-0.1098	-0.3838	-0.2629	0.8775

.

LR test: independent vs. saturated: chi2(1225)= 6140.04 Prob>chi2 = 0.0000

. rotate, varimax horst blanks(0.3)

```
Factor analysis/correlation                         Number of obs    =        232
    Method: iterated principal factors              Retained factors =          6
    Rotation: orthogonal varimax (Kaiser on)        Number of params =        171

    --------------------------------------------------------------------------
         Factor  |     Variance   Difference        Proportion   Cumulative
    -------------+------------------------------------------------------------
        Factor1  |      7.14395      5.03620            0.5325       0.5325
        Factor2  |      2.10775      0.73673            0.1571       0.6897
        Factor3  |      1.37103      0.31844            0.1022       0.7919
        Factor4  |      1.05259      0.17107            0.0785       0.8703
        Factor5  |      0.88152      0.02352            0.0657       0.9360
        Factor6  |      0.85800            .            0.0640       1.0000
    --------------------------------------------------------------------------
    LR test: independent vs. saturated: chi2(465) = 2836.23 Prob>chi2 = 0.0000

Rotated factor loadings (pattern matrix) and unique variances

    ------------------------------------------------------------------------------------
        Variable |  Factor1   Factor2   Factor3   Factor4   Factor5   Factor6 |  Uniqueness
    -------------+----------------------------------------------------------+-----------
              b1 |   0.7968                                                 |      0.3191
              b2 |   0.8579                                                 |      0.2559
              b3 |   0.6997                                                 |      0.5022
              b4 |   0.7360                                                 |      0.4171
              b5 |   0.7864                                                 |      0.3372
              b6 |   0.7783                                                 |      0.3421
              b7 |   0.7560                                                 |      0.4116
              b8 |   0.7255                                                 |      0.4434
              b9 |   0.7447                                                 |      0.3815
             b10 |   0.6948                                                 |      0.4678
             b11 |   0.8015                                                 |      0.3389
             b12 |   0.6393                                                 |      0.5372
           bmqs1 |            0.6268                                        |      0.5836
           bmqs2 |            0.5820                                        |      0.5941
           bmqs3 |            0.5780                                        |      0.6419
           bmqs4 |            0.8039                                        |      0.2634
           bmqs5 |            0.4391                              0.3833    |      0.5837
           bmqs6 |                                                0.3397    |      0.7325
           bmqs7 |                     0.3555                             |      0.7813
           bmqs8 |                                0.3408                  |      0.8149
           bmqs9 |                     0.4223                             |      0.7743
          bmqs10 |                     0.4601     0.3265                  |      0.6656
           bmqg1 |                                                0.3902    |      0.7349
           bmqg2 |   0.3874                     0.3595                     |      0.6492
           bmqg3 |                     0.5527                             |      0.6306
           bmqg4 |                                                        |      0.8788
           bmqg5 |                     0.3637              0.4782         |      0.4859
           bmqg6 |                                0.5737                  |      0.5933
           bmqg7 |                                                        |      0.9206
           bmqg8 |                                                0.3350    |      0.7941
              D1 |                                          0.5285        |      0.7084
    ------------------------------------------------------------------------------------
    (blanks represent abs(loading)<.3)

Factor rotation matrix

    ------------------------------------------------------------------
                 | Factor1  Factor2  Factor3  Factor4  Factor5  Factor6
    -------------+----------------------------------------------------
         Factor1 |  0.9889   0.1046   0.0962   0.0344  -0.0226   0.0090
         Factor2 | -0.1257   0.7102   0.3808   0.4331   0.2004   0.3272
         Factor3 |  0.0086  -0.6580   0.5974   0.2267   0.3162   0.2424
         Factor4 |  0.0691  -0.0067  -0.5070  -0.0406   0.8413   0.1695
         Factor5 | -0.0339   0.2247   0.4688  -0.7816   0.2872  -0.1877
         Factor6 |  0.0137  -0.0348  -0.1098  -0.3838  -0.2629   0.8775
    ------------------------------------------------------------------

. estat rotatecompare
```

Rotation matrix -- orthogonal varimax (Kaiser on)

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6
Factor1	0.9889	0.1046	0.0962	0.0344	-0.0226	0.0090
Factor2	-0.1257	0.7102	0.3808	0.4331	0.2004	0.3272
Factor3	0.0086	-0.6580	0.5974	0.2267	0.3162	0.2424
Factor4	0.0691	-0.0067	-0.5070	-0.0406	0.8413	0.1695
Factor5	-0.0339	0.2247	0.4688	-0.7816	0.2872	-0.1877
Factor6	0.0137	-0.0348	-0.1098	-0.3838	-0.2629	0.8775

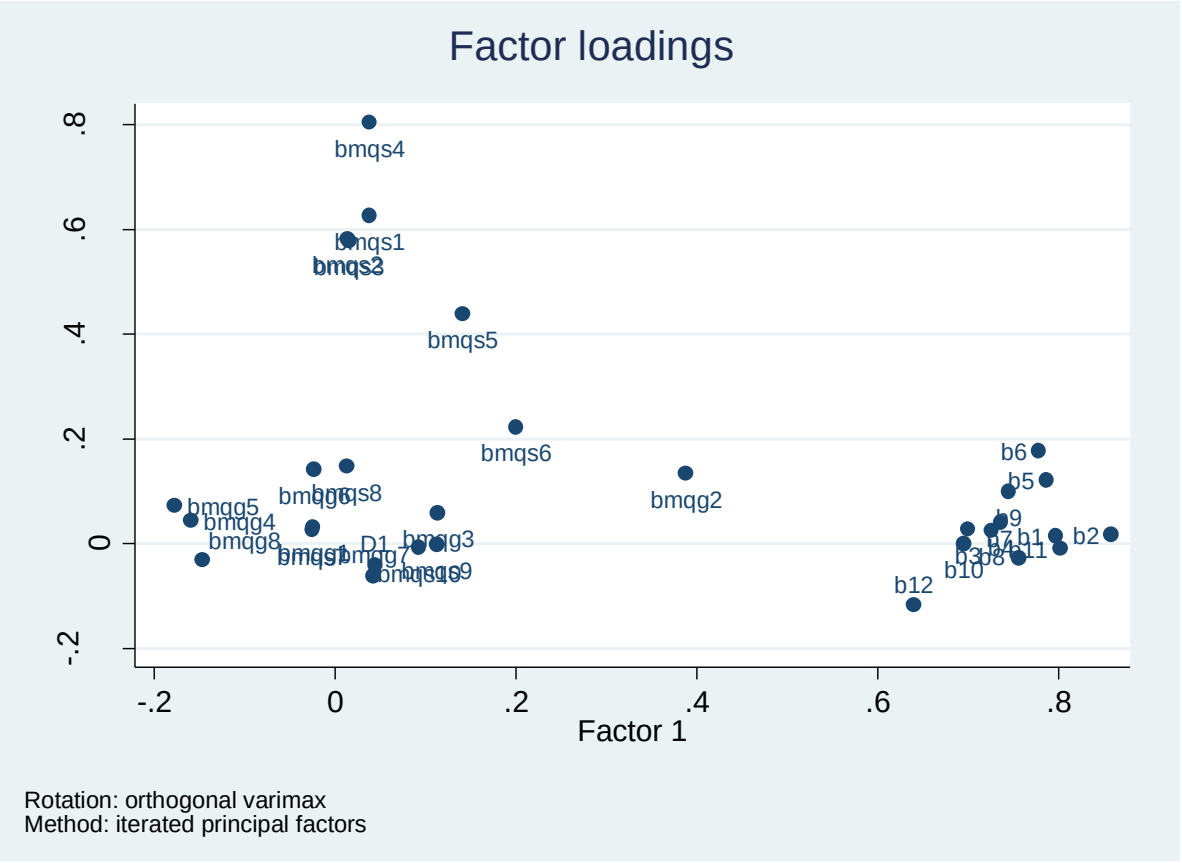
Rotated factor loadings

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6
b1	0.7968	0.0151	-0.0650	0.1007	-0.1687	-0.0543
b2	0.8579	0.0173	-0.0599	0.0552	0.0056	-0.0338
b3	0.6997	0.0272	-0.0059	0.0012	-0.0298	-0.0807
b4	0.7360	0.0412	0.1038	0.0049	0.1540	-0.0705
b5	0.7864	0.1221	0.0878	0.0485	-0.1257	0.0609
b6	0.7783	0.1772	0.0275	0.0349	0.0740	-0.1153
b7	0.7560	-0.0277	0.1037	-0.0464	-0.0540	0.0149
b8	0.7255	0.0249	-0.0246	-0.0631	-0.1390	0.0750
b9	0.7447	0.0995	0.1467	-0.1126	0.0721	0.1208
b10	0.6948	0.0008	0.1919	-0.0945	0.0314	0.0529
b11	0.8015	-0.0100	-0.0281	0.0777	0.1082	0.0006
b12	0.6393	-0.1179	0.1445	-0.0482	-0.1274	0.0275
bmqs1	0.0383	0.6268	-0.0193	0.1344	0.0390	-0.0447
bmqs2	0.0139	0.5820	-0.0390	0.1453	-0.1117	0.1786
bmqs3	0.0152	0.5780	-0.0799	0.0960	0.0324	0.0846
bmqs4	0.0381	0.8039	0.2129	-0.0920	-0.0642	-0.1760
bmqs5	0.1413	0.4391	-0.1511	0.0646	0.1723	0.3833
bmqs6	0.2000	0.2233	0.0617	0.1793	-0.1622	0.3397
bmqs7	-0.0247	0.0256	0.3555	0.1390	-0.0014	0.2679
bmqs8	0.0128	0.1474	0.1587	0.3408	0.1316	0.0679
bmqs9	0.1122	-0.0009	0.4223	0.1472	0.0624	-0.0958
bmqs10	0.0932	-0.0070	0.4601	0.3265	-0.0603	0.0609
bmqg1	-0.0245	0.0318	0.2246	0.2147	0.1212	0.3902
bmqg2	0.3874	0.1345	0.1184	0.3595	0.1885	-0.0625
bmqg3	0.1131	0.0593	0.5527	-0.0888	0.0328	0.1965
bmqg4	-0.1592	0.0438	-0.0269	0.2466	0.1688	0.0621
bmqg5	-0.1772	0.0723	0.3637	0.2606	0.4782	0.2204
bmqg6	-0.0234	0.1418	0.1733	0.5737	-0.1057	0.1255
bmqg7	0.0419	-0.0607	0.2621	0.0214	0.0671	0.0158
bmqg8	-0.1463	-0.0315	0.1536	-0.0181	0.2176	0.3350
D1	0.0447	-0.0404	0.0732	0.0297	0.5285	0.0494

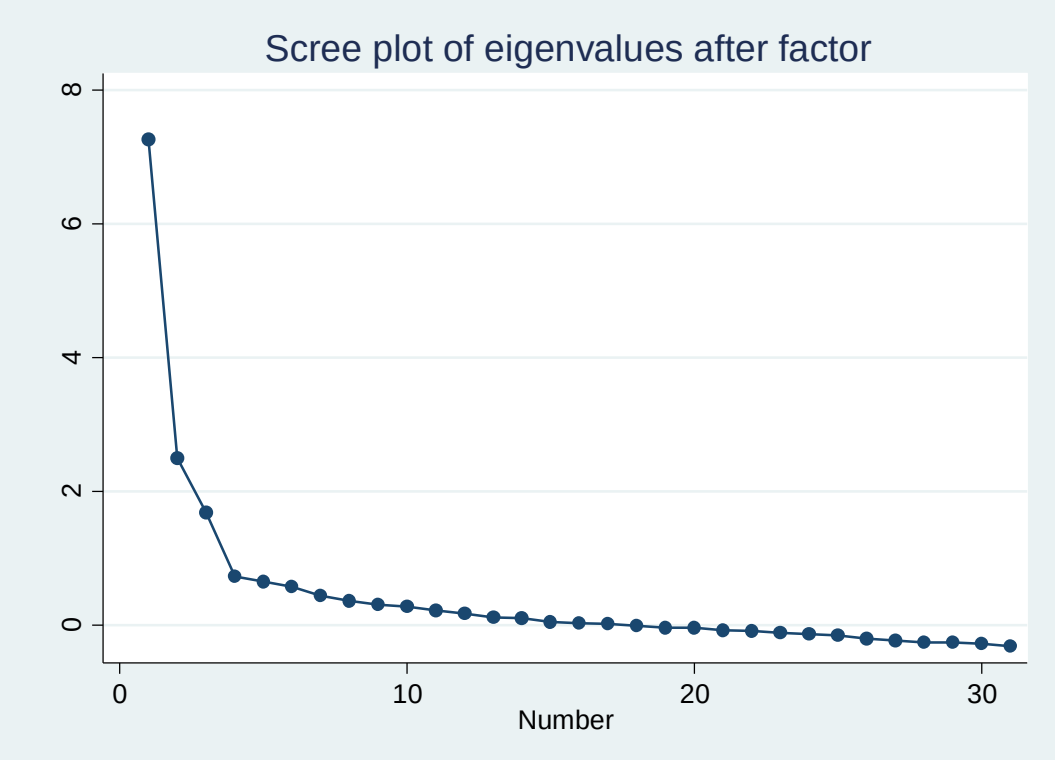
Unrotated factor loadings

Variable	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6
b1	0.7901	-0.1221	-0.0856	-0.0673	-0.1711	-0.0244
b2	0.8460	-0.1044	-0.0337	0.0863	-0.0885	-0.0346
b3	0.6942	-0.1028	-0.0441	0.0124	-0.0147	-0.0542
b4	0.7382	-0.0138	0.0739	0.1154	0.0866	-0.1070
b5	0.8040	0.0371	-0.0352	-0.0883	-0.0435	0.0647
b6	0.7894	0.0307	-0.0901	0.0800	0.0419	-0.1325
b7	0.7545	-0.1012	0.0627	-0.0411	0.0347	0.0450
b8	0.7194	-0.1136	-0.0649	-0.0392	-0.0352	0.1383
b9	0.7566	0.0382	0.0551	0.0622	0.1519	0.1209
b10	0.7021	-0.0310	0.1214	-0.0100	0.1395	0.0629
b11	0.7891	-0.0630	0.0487	0.1577	-0.0724	-0.0433
b12	0.6353	-0.1464	0.1249	-0.1289	0.0155	0.0731
bmqs1	0.1050	0.4844	-0.3917	0.0280	0.0450	-0.1202
bmqs2	0.0801	0.4957	-0.3651	-0.0527	-0.0672	0.1146
bmqs3	0.0711	0.4539	-0.3754	0.0754	0.0102	0.0178
bmqs4	0.1390	0.5369	-0.4852	-0.1907	0.3656	-0.1531
bmqs5	0.1729	0.4244	-0.2159	0.2908	-0.0500	0.2695
bmqs6	0.2400	0.3133	-0.0366	-0.1051	-0.1782	0.2601
bmqs7	0.0197	0.3042	0.2913	-0.1435	0.0138	0.1419
bmqs8	0.0527	0.3597	0.1332	0.0278	-0.1342	-0.1282
bmqs9	0.1543	0.1910	0.2837	-0.1761	0.1149	-0.2018
bmqs10	0.1489	0.3078	0.3500	-0.2805	-0.0729	-0.1050
bmqg1	0.0088	0.3561	0.2946	0.0436	-0.0930	0.2020
bmqg2	0.4161	0.2649	0.1115	0.0992	-0.1426	-0.2548
bmqg3	0.1692	0.2708	0.3300	-0.2083	0.3105	0.1367
bmqg4	-0.1502	0.2018	0.0781	0.1449	-0.1533	-0.0853
bmqg5	-0.1325	0.4930	0.4319	0.2319	0.0850	-0.0773
bmqg6	0.0317	0.4380	0.1371	-0.1814	-0.3884	-0.1066
bmqg7	0.0597	0.0793	0.2268	-0.0713	0.1074	-0.0381
bmqg8	-0.1357	0.1999	0.2572	0.1528	0.0837	0.2259
D1	0.0366	0.1285	0.2565	0.4180	0.1430	-0.1130

.
The comparison of the rotated and the un-rotated factors are similar and does not affect the interpretation.



The chart below showed that only 4factors will be needed to explain the relevant variability in your research



Kaiser-Meyer-Olkin measure of sampling adequacy

Variable	kmo
b1	0.9318
b2	0.9379
b3	0.9027
b4	0.9247
b5	0.8784
b6	0.9199
b7	0.9223
b8	0.8879
b9	0.9142
b10	0.8931
b11	0.8696
b12	0.9326
bmqs1	0.7670
bmqs2	0.7108
bmqs3	0.7287
bmqs4	0.6370
bmqs5	0.7237
bmqs6	0.7905
bmqs7	0.6589
bmqs8	0.7503
bmqs9	0.6041
bmqs10	0.6673
bmqg1	0.6607
bmqg2	0.8145
bmqg3	0.7619
bmqg4	0.6446
bmqg5	0.7172
bmqg6	0.7001
bmqg7	0.5845
bmqg8	0.6686
D1	0.4329
Overall	0.8586

Overall estimate of KMO show measure of sampling adequacy.

ANNEXURE H

MULTIPLE REGRESSION ANALYSIS

ALL PARTICIPANTS

```
----------------- STEP 1 ------------------
Determinant of correlation matrix =   0.7570

SOURCE    DF        SS      MS        F        Prob.>F
Regression   3  2116.121   705.374     4.223     0.006
Residual   228 38083.568   167.033
Total      231 40199.689

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.229     0.053     4.223     0.006    3  228
Adjusted R Squared = 0.040

Std. Error of Estimate =     12.924

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
       SES     0.038     0.204     0.349     0.585     0.559     1.031
0.969
     BMQ-S    -0.070    -2.187     2.246    -0.974     0.331     1.250
0.800
     BMQ-G     0.247     6.416     1.846     3.476     0.001     1.215
0.823

Constant =     81.783

Partial Correlations

Variables        SES       BMQ-S       BMQ-G
                0.039      -0.064       0.224


Variable 1 (SES) eliminated


Backward Stepwise Multiple Regression

----------------- STEP 1 ------------------
Determinant of correlation matrix =   0.7570

SOURCE    DF        SS      MS        F        Prob.>F
Regression   3  2116.121   705.374     4.223     0.006
Residual   228 38083.568   167.033
Total      231 40199.689

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.229     0.053     4.223     0.006    3  228
Adjusted R Squared = 0.040

Std. Error of Estimate =     12.924
```

```
Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
       SES     0.038     0.204     0.349     0.585     0.559     1.031
0.969
     BMQ-S    -0.070    -2.187     2.246    -0.974     0.331     1.250
0.800
     BMQ-G     0.247     6.416     1.846     3.476     0.001     1.215
0.823

Constant =     81.783

Partial Correlations

Variables        SES       BMQ-S       BMQ-G
                0.039      -0.064       0.224


Variable 1 (SES) eliminated

----------------- STEP 2 ------------------
Determinant of correlation matrix =   0.7820

SOURCE    DF        SS      MS        F        Prob.>F
Regression   2  2058.862  1029.431     6.181     0.002
Residual   229 38140.826   166.554
Total      231 40199.689

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.226     0.051     6.181     0.002    2  229
Adjusted R Squared = 0.043

Std. Error of Estimate =     12.906

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
     BMQ-S    -0.063    -1.963     2.210    -0.888     0.375     1.213
0.824
     BMQ-G     0.245     6.375     1.842     3.461     0.001     1.213
0.824

Constant =     82.323

Partial Correlations

Variables      BMQ-S       BMQ-G
               -0.059       0.223


Variable 1 (BMQ-S) eliminated


Backward Stepwise Multiple Regression

----------------- STEP 1 ------------------
Determinant of correlation matrix =   0.7570

SOURCE    DF        SS      MS        F        Prob.>F
Regression   3  2116.121   705.374     4.223     0.006
Residual   228 38083.568   167.033
```

```
Total      231 40199.689

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.229     0.053     4.223     0.006    3  228
Adjusted R Squared = 0.040

Std. Error of Estimate =     12.924

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
       SES     0.038     0.204     0.349     0.585     0.559     1.031
0.969
     BMQ-S    -0.070    -2.187     2.246    -0.974     0.331     1.250
0.800
     BMQ-G     0.247     6.416     1.846     3.476     0.001     1.215
0.823

Constant =     81.783

Partial Correlations

Variables        SES       BMQ-S       BMQ-G
                0.039      -0.064       0.224


Variable 1 (SES) eliminated

----------------- STEP 2 ------------------
Determinant of correlation matrix =   0.7820

SOURCE    DF        SS      MS        F        Prob.>F
Regression   2  2058.862  1029.431     6.181     0.002
Residual   229 38140.826   166.554
Total      231 40199.689

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.226     0.051     6.181     0.002    2  229
Adjusted R Squared = 0.043

Std. Error of Estimate =     12.906

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
     BMQ-S    -0.063    -1.963     2.210    -0.888     0.375     1.213
0.824
     BMQ-G     0.245     6.375     1.842     3.461     0.001     1.213
0.824

Constant =     82.323

Partial Correlations

Variables      BMQ-S       BMQ-G
               -0.059       0.223
```

```
Variable 1 (BMQ-S) eliminated

----------------- STEP 3 ------------------
Determinant of correlation matrix =   0.9521

SOURCE    DF        SS      MS        F        Prob.>F
Regression   1  1927.486  1927.486    11.583     0.001
Residual   230 38272.203   166.401
Total      231 40199.689

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.219     0.048    11.583     0.001    1  230
Adjusted R Squared = 0.044

Std. Error of Estimate =     12.900

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
     BMQ-G     0.219     5.689     1.672     3.403     0.001     1.000
1.000

Constant =     76.553

Partial Correlations

Variables      BMQ-G
                0.219
```

NON-ADHERENT PARTICIPANTS:

```
Backward Stepwise Multiple Regression

----------------- STEP 1 ------------------
Determinant of correlation matrix =   0.3411

SOURCE    DF        SS      MS        F        Prob.>F
Regression   3  1341.134   447.045     1.779     0.167
Residual    39  9798.436   251.242
Total       42 11139.570

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.347     0.120     1.779     0.167    3   39
Adjusted R Squared = 0.053

Std. Error of Estimate =     15.851

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
       SES     0.438     4.052     1.981     2.045     0.048     2.037
0.491
     BMQ-S    -0.220    -8.315     8.464    -0.982     0.332     2.220
0.450
     BMQ-G     0.082     3.317     6.848     0.484     0.631     1.273
```

0.785

Constant = 68.540

Partial Correlations

Variables	SES	BMQ-S	BMQ-G
	0.311	-0.155	0.077

Variable 3 (BMQ-G) eliminated

Backward Stepwise Multiple Regression

---------- STEP 1 ----------
Determinant of correlation matrix = 0.3411

SOURCE	DF	SS	MS	F	Prob.>F
Regression	3	1341.134	447.045	1.779	0.167
Residual	39	9798.436	251.242		
Total	42	11139.570			

Dependent Variable: ADHERE

R	R2	F	Prob.>F	DF1	DF2
0.347	0.120	1.779	0.167	3	39

Adjusted R Squared = 0.053

Std. Error of Estimate = 15.851

Variable	Beta	B	Std.Error	t	Prob.>t	VIF	TOL
SES	0.438	4.052	1.981	2.045	0.048	2.037	0.491
BMQ-S	-0.220	-8.315	8.464	-0.982	0.332	2.220	0.450
BMQ-G	0.082	3.317	6.848	0.484	0.631	1.273	0.785

Constant = 68.540

Partial Correlations

Variables	SES	BMQ-S	BMQ-G
	0.311	-0.155	0.077

Variable 3 (BMQ-G) eliminated

---------- STEP 2 ----------
Determinant of correlation matrix = 0.4370

SOURCE	DF	SS	MS	F	Prob.>F
Regression	2	1282.194	641.097	2.601	0.087
Residual	40	9857.375	246.434		
Total	42	11139.570			

Dependent Variable: ADHERE

R	R2	F	Prob.>F	DF1	DF2
0.339	0.115	2.601	0.087	2	40

```
Adjusted R Squared = 0.071

Std. Error of Estimate =     15.698

Variable       Beta      B          Std.Error t          Prob.>t   VIF
TOL
       SES     0.446     4.124     1.956     2.108     0.041     2.025
0.494
     BMQ-S    -0.188    -7.101     8.007    -0.887     0.380     2.025
0.494

Constant =     72.918

Partial Correlations

Variables        SES       BMQ-S
                0.316      -0.139


Variable 2 (BMQ-S) eliminated


Backward Stepwise Multiple Regression

----------------- STEP 1 ------------------
Determinant of correlation matrix =   0.3411

SOURCE    DF        SS      MS        F        Prob.>F
Regression   3  1341.134   447.045     1.779     0.167
Residual    39  9798.436   251.242
Total       42 11139.570

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.347     0.120     1.779     0.167    3   39
Adjusted R Squared = 0.053

Std. Error of Estimate =     15.851

Variable       Beta      B          Std.Error t          Prob.>t   VIF
TOL
       SES     0.438     4.052     1.981     2.045     0.048     2.037
0.491
     BMQ-S    -0.220    -8.315     8.464    -0.982     0.332     2.220
0.450
     BMQ-G     0.082     3.317     6.848     0.484     0.631     1.273
0.785

Constant =     68.540

Partial Correlations

Variables        SES       BMQ-S       BMQ-G
                0.311      -0.155       0.077


Variable 3 (BMQ-G) eliminated

----------------- STEP 2 ------------------
Determinant of correlation matrix =   0.4370

SOURCE    DF        SS      MS        F        Prob.>F
```

```
Regression   2  1282.194   641.097     2.601     0.087
Residual    40  9857.375   246.434
Total       42 11139.570

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.339     0.115     2.601     0.087    2   40
Adjusted R Squared = 0.071

Std. Error of Estimate =     15.698

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
       SES     0.446     4.124     1.956     2.108     0.041     2.025
0.494
     BMQ-S    -0.188    -7.101     8.007    -0.887     0.380     2.025
0.494

Constant =     72.918

Partial Correlations

Variables        SES       BMQ-S
                0.316      -0.139


Variable 2 (BMQ-S) eliminated

----------------- STEP 3 ------------------
Determinant of correlation matrix =   0.9023

SOURCE    DF        SS      MS        F        Prob.>F
Regression   1  1088.377  1088.377     4.440     0.041
Residual    41 10051.192   245.151
Total       42 11139.570

Dependent Variable: ADHERE

       R        R2         F     Prob.>F  DF1  DF2
   0.313     0.098     4.440     0.041    1   41
Adjusted R Squared = 0.076

Std. Error of Estimate =     15.657

Variable       Beta      B         Std.Error t         Prob.>t   VIF
TOL
       SES     0.313     2.889     1.371     2.107     0.041     1.000
1.000

Constant =     52.294

Partial Correlations

Variables        SES
                0.313
```