

**FACTORS AFFECTING THE ADHERENCE TO ANTIRETROVIRAL
THERAPY BY HIV POSITIVE PATIENTS TREATED IN A COMMUNITY
BASED HIV/AIDS CARE PROGRAMME IN RURAL UGANDA**

A CASE OF TORORO DISTRICT

by

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submitted in fulfilment of the requirements

for the degree of

MASTER OF PUBLIC HEALTH

in the subject

HEALTH STUDIES

at the

UNIVERSITY OF SOUTH AFRICA

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NOVEMBER 2010

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List of abbreviations

ADQ	Adherence Determinants Questionnaire
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
CD4	Cluster of Differentiation 4
CDDP	Community Drug Distribution Points
EDM	Electronic Drug Monitoring
HAART	Highly Active Antiretroviral Therapy
HBM	Health Belief Model
HIV	Human Immunodeficiency Virus
MEMS	Medication Event Monitoring System
NNRTI	Non-Nucleoside Reverse transcriptase Inhibitors
PEPFAR	Presidential Emergency Fund for AIDS Relief
PI	Protease Inhibitors
RNA	Ribonucleic Acid
TASO	The AIDS Support Organisation
TB	Tuberculosis
UNAIDS	United Nations Joint Programme on HIV/AIDS
WHO	World Health Organization

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CHAPTER 1

Orientation to the study

1.1 INTRODUCTION

Access to antiretroviral therapy has increased tremendously in Sub-Saharan Africa with the World Health Organization (WHO) estimates pointing to an increase from 100,000 people receiving treatment at the end of 2003 to over two millions in December 2007 representing a 20-fold increase. This has changed the clinical course of Human Immunodeficiency Virus (HIV) with significant decline in morbidity and mortality. Now the challenge has shifted from access to adherence since with increased access to antiretroviral therapy(ART), HIV has become a chronic disease where patients have to take antiretroviral drugs for a long time with substantial side effects and sometimes with complex regimens (WHO 2003a:5; WHO 2008b:16).

In one study, a 95% level of adherence to antiretroviral therapy was reported as the minimum level necessary to maintain viral load suppression and improve immune status. Unfortunately taking more than 95% of the prescribed regimen is a difficult goal to achieve and maintain. Therefore the long term success of treatment programs in resource-limited settings requires establishing the levels and long term determinants of adherence to antiretroviral therapy among HIV patients (Paterson, Swindells, Mohr, Brester, Vergis, Squier, Wagener & Singh 2000:27-28).

This study therefore described factors that affect adherence to ART in adult HIV Positive patients in rural Uganda.

1.2 THE RESEARCH PROBLEM

Burns and Grove (2005:70) define a research problem as an area of concern where there is a gap in the knowledge base needed for nursing practice. Through questioning and a review of literature, a research problem emerges that includes a specific area of concern and the knowledge gap that surrounds this concern.

1.2.1 Source of the research problem

In a study about adherence to ART in a resource limited setting, Weidle, Nafuna, Solberg, Liechty, Sendagala, Mermin, Were, Buchacz, Behumbiize, Ransom and Bunnell (2006:1591) report that majority of patients were adherent to therapy. According to the findings, 97.4% of participants had a pill count adherence of more than 95% and 88.9% had a medication possession ratio of more than 95% in the first year of treatment with antiretroviral therapy in the Home Based Aids Care Program in rural Uganda. It should however be noted that this was a short period of monitoring in a research setting with intensive counselling and support for adherence. This is typical of many ART and care research programs worldwide to counter the assumed high levels of non adherence to antiretroviral drugs at the start of therapy. Many participants in the cited study were still on a simple first line regimen. Two participants had switched to second line regimens within the first year and had not started experiencing long term side effects of antiretroviral therapy like lipo atrophy and lipodystrophy which are known to affect the adherence to therapy.

However, adherence to antiretroviral therapy has been shown in Africa through a number of studies. Mills, Nachega, Buchan, Orbinski, Attaran, Singh, Rachlis, Wu, Cooper, Thabane, Wilson, Guyatt and Bangsberg (2006:685) in a meta-analysis indicate that favourable levels of adherence much of which was assessed via patient self report can be achieved in Sub-Saharan settings better than in North America.

Therefore, there is a need to establish whether such adherence levels can be achieved and maintained in another community based Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) care setting outside a research environment in rural Uganda and what are the determinants of adherence in the patients over a prolonged period of time.

1.2.2 Background to the problem

The HIV pandemic is one of the most serious health crises the world faces today. Globally there was an estimated 33 million people living with HIV by the end of 2007 and more than 25 million people since 1981 have died from AIDS. In 2007 there were 2.7 million new infections and 2 million HIV-related deaths (WHO 2008a:15, 31-32).

Sub-Saharan Africa region is by far the worst affected in the world by the epidemic. The region has just over 10% of the world population but it is home to 67% of all people living with HIV and for 75% of AIDS deaths in 2007. HIV prevalence varies considerably across this region ranging from less than 1% in Madagascar to over 26% in Swaziland (WHO 2008a:30, 39-40).

Currently there are an estimated 940,000 people (adults and children) living with HIV in Uganda .HIV prevalence was estimated to be 5.4% among adults in 2007 showing a decline from an estimated adult prevalence of 7.9% in 2001(WHO 2008a:214-215).

Through combined efforts of affected countries and international partners, there is substantial ongoing progress towards providing HIV interventions in low and middle income countries in the following regions: Sub-Saharan Africa; Latin America and the Caribbean; East, South and South-East Asia; Europe and central Asia plus North Africa and the Middle East. One of the interventions is access to antiretroviral therapy for HIV infected people (WHO 2007:17).

In 2003 due to concerns of limited access to ART, the WHO '3 by 5' initiative was launched as a strategy for ensuring that 3 million people living with HIV/AIDS in low- and middle income countries have access to treatment by the end of 2005 which meant meeting 50% of the estimated need. Although the WHO target of providing access to ART for 3 million people by 2005 was not achieved, by the end of June 2005 an estimated 1million people in low and middle income countries had access to ART (WHO 2003a:6; WHO 2005:7).

Despite progress, global access to antiretroviral therapy remains low. Only 31% of people in need of ART in the world were receiving it in 2007 and an estimated 2.5 million people were newly infected with HIV in the same year. About 3 million people were receiving ART in the low and middle income countries at the end of 2007 which is nearly 950,000 more compared with end of 2006 (WHO 2008b:17).

The greatest increase was in Sub-Saharan Africa where about 2.12 million people were receiving ART at the end of 2007 compared to 1.38 million people in 2006 (an increase of 54%). At 32%, coverage is higher in eastern and southern Africa than West and central Africa at 25%. Sub-Saharan Africa represents 71% of the estimated total

treatment need in low and middle-income countries and 72% of the total number of people receiving treatment at the end of 2007(WHO 2008b:18).

Increases in treatment coverage have been extraordinary in many countries of the Sub-Saharan Africa. For example in Namibia where treatment coverage was less than 1% in 2003, 88% of individuals in need were on ART by the end of 2007. In Rwanda, ART coverage increased from 1% in 2003 to almost 71% in 2007(WHO 2008b:135).

For most ART programs in Sub-Saharan Africa including Uganda, the emphasis has been on initiating people on ART than ensuring effective use of medicines. This is because their performance is measured in terms of access rather than the adherence/retention which is necessary for sustained health benefits and to safe guard public health against the risk of drug resistance caused by non adherence to the antiretroviral drugs (WHO 2006a:17, 25-27).

Uganda was the setting for one of the first test programs in Africa distributing the life-saving antiretroviral drugs. The HBAC programme began in 1998 with the aim of assessing the feasibility of setting up and running an antiretroviral drug clinic in a resource-poor country. The patients involved had to pay for the medications although at a reduced price (Avert 2009).

It was not until June 2004 that Uganda began to offer free antiretroviral medications to people living with HIV as part of a five year pilot program. This was initially funded by World Bank with future drugs to be paid for by grants from Global fund and the Presidential Emergency Fund for HIV/AIDS Relief initiative. Although the initial roll out was slow by December 2006, 41% of those in need were receiving HIV treatment. By February 2008, the number of people on treatment rose to 110,000 of which 8,532 were children (50% of the need) and around 1,000 new patients being put on treatment per month (Avert 2009; Wasswa 2008:349; WHO 2007:16).

Lucas (2005:415) notes that, the clinical goals of HIV treatment are optimally accomplished through consistent high-levels of adherence to ART and durable suppression of the viral load. However, it is not still clear how much adherence is enough. Paterson et al (2000:27-28) report that 95% of adherence to therapy as the minimum level necessary to maintain viral load suppression whereas Martin, Del Cacho,

Codina, Tuset, De Lazzari, Mallolas, Miro, Gatell and Ribas (2008:1267) report a differing view that virologic success is possible with less than 95% adherence and that adherence cut off value depends on the type of Highly Active Antiretroviral Therapy (HAART). Patients who are taking Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI) or boosted Protease Inhibitors (PI) based regimens with adherence rates of 80%, have a failure rate which is less than 10%.

In patients purchasing generic HIV antiretroviral therapy in Uganda, Oyugi, Byakika-Tusiime, Charlebois, Kityo, Mugerwa, Mugenyi and Bangsberg (2004:1101) report a mean adherence of 91-94% by all measures. Weidle et al (2006:1591) in their ART adherence study in a home based AIDS care programme in rural Uganda report a good adherence (more than 95%) and response to ART in 98% of the participants within 6 months of ART treatment.

Non-adherence to HAART can lead to inadequate suppression of viral replication, continued destruction of CD4 cells, progressive decline in immune function and disease progression. In public health interests, drug resistance can develop and be transmitted to other persons during high risk activity which can limit therapeutic options in the future. Studies have reported that as many as 80% of viral isolates from newly infected people are resistant to at least one class of currently approved antiretroviral medications and that 27% of viral isolates are resistant to several classes of medications (Boden, Hurley, Zhang, Cao, Guo, Jones, Tsay, Ip, Farthing, Limoli, Parkin & Markowitz 1999:1140; Voelker 2000:169).

The critical factors that influence adherence fall into four main categories: patient factors such as use of drugs and alcohol, age, sex, cultural beliefs or ethnicity; medication regimen such as dosing complexity, side effects, number of pills or food requirements; patient-health care provider relationship and the system of care. Patients' behaviour is the critical link between a prescribed regimen and treatment outcome. The most effective regimen will fail if the patient does not take the medication as prescribed or refuses to take it at all. Consequently all things being equal, the most important factors influencing adherence are patient-related (Chesney 2000:172-173; WHO 2003a:97-100).

In the medical world, it is believed that pill burden strongly influences adherence. However, the effect of pill burden on adherence is closely associated with disease stage. Symptomatic individuals perceive a higher risk for complications as a result of non adherence to medication than do asymptomatic patients. It is however noted that, dosing schedule and food restrictions appear to have more influence on adherence than pill burden. Patients on twice-daily doses or less report better adherence (>80%) and were more likely to take their medications when away from home (Gao, Nau, Rosenbluth, Scott & Woodward 2000:396; Eldred, Wu, Chaisson & Moore 1998:120-121).

Lipodystrophy (fat redistribution) which is defined as abnormal fat changes or disturbance of fat metabolism is one serious side effect that may affect adherence to HIV medications. Kasper, Arboleda and Halpem (2000:1380) found that 37% of their respondents either stopped or changed their medications because they developed lipodystrophy. Of those who were adherent, 57% stated that they had seriously considered discontinuation of therapy while 46% stated that they would change medications if symptoms worsened.

With such a background, it shows that perfect or near adherence to ART is critical for the success of ART providing programmes throughout the world.

1.2.3 Statement of the research problem

With the advent of ART, HIV/AIDS is becoming a chronic disease, therefore adherence to HIV medication is an extremely complicated process that includes both the drugs themselves and the adjustments to daily life necessary to provide the conditions for effective drug therapy. Some regimens require several doses of medication per day together with various requirements or restrictions on food intake (Chesney 2000:173; WHO 2003a:97-99).

Side effects have also been consistently associated with decreased adherence and patients who experience more than two aversive reactions are less likely to continue their treatment. HAART regimens usually have temporary side effects including transient reactions like diarrhoea and nausea as well as longer lasting side effects like lipodystrophy and neuropathy. Patients quickly discontinue therapy or request changes

in medications if they experience side effects. Whether real or perceived, side effects account for more regimen changes than treatment failure. Research findings from a large study of more than 860 HIV-positive patients in Italy reported more than 25% of treatment naïve patients discontinued their treatment within their first year because of toxicity and other side effects (D'Armino, Lepri, Rezza, Pezzoti, Antinori, Phillips, Angarano, Colangeli, De luca, Ippolito & Caggese 2000:502; Mocroft, Youle, Moore, Sabin, Madge, Lepri, Tyrer, Chaloner, Wilson, Loveday, Johnson & Phillips 2001:192; Stone 2001:869).

Good adherence is crucial for maximum clinical benefit from antiretroviral therapy. Therefore despite increasing access to antiretroviral drugs, the long-term success of treatment programs in resource limited settings requires establishing the optimum levels of adherence. Factors that make patients on ART fail to obtain good adherence had to be determined and addressed.

Therefore, the statement of the research problem for this study was:

What are the factors that affect adherence to antiretroviral therapy by HIV patients treated in a community based HIV/AIDS care programme in rural Uganda?

1.3 PURPOSE OF THE STUDY

The study aimed at conducting a survey in order to describe factors that affect adherence to antiretroviral therapy so that they can be considered and taken care of in the planning of ART and care programmes for HIV positive patients in rural Uganda.

1.3.1 Research question

What are the factors that affect the adherence to antiretroviral therapy by HIV positive patients treated in a community based HIV/AIDS care programme in rural Uganda?

1.3.2 Research objectives

The objectives of this study were to:

- describe factors that influence adherence or non-adherence to antiretroviral therapy by HIV positive patients
- make recommendations to ART and care programs on how to achieve and maintain adequate levels of adherence to ART in HIV positive patients
- design a research poster for presentation of findings to interest groups

1.4 SIGNIFICANCE OF THE STUDY

The current public health arena is grappling with issues of treatment adherence for chronic diseases. Knowledge gained from this study about factors in the population associated with adherence or non-adherence to antiretroviral therapy by HIV positive patients will help in making recommendations regarding the development of appropriate health education strategies to empower patients about the importance of adherence to ART.

The information will be used to develop guidelines and education materials that can be used in adherence counselling before patients are started on ART and during the follow-up period after starting.

The findings will also contribute to the review of the HIV/AIDS treatment protocols and policies, related in-service education for medical personnel and review of health education programs for HIV positive patients so as to improve the clinical management of HIV/AIDS. A research poster based on the results was also developed for presentation in seminars, workshops and related conferences to empower the medical personnel on issues of adherence to ART.

1.5 DEFINITION OF KEY CONCEPTS

In this study, the following concepts were conceptually and operationally defined as follows:

Adherence: According to the WHO (2003a:3), adherence to long-term therapy is defined as the extent to which a person's behaviour (taking medication, following a diet and/or executing lifestyle changes) corresponds with agreed upon recommendations from a health care provider. The *Oxford Advanced Learner's Dictionary* (2000:14) defines adherence as the fact of behaving according to a particular rule or of following a particular set of beliefs whereas the National Institute of Health (2008) defines adherence as to how closely you follow a prescribed treatment regimen which includes the willingness to start treatment and the ability to take medications exactly as directed.

Fogarty, Roter, Larson, Burke, Gillespie and Levy (2002:95) in their review of 20 articles and 74 conference abstracts reporting HIV medication adherence or interventions designed to increase HIV medication adherence noted that relatively few studies explicitly defined adherence in operational terms. Some studies used a categorical definition of adherence as "no missed or reduced doses" during a given time period and others set the criterion for adherence as meeting minimum level of drug consumption, for instance, greater than 70%,80% or 90%.

With reference to this study, adherence was measured as self reported adherence to ART by the HIV positive patient in the last two weeks.

Affect. According to the *Oxford Advanced Learner's Dictionary* (2000:25), to affect is to produce a change in or to have an influence on somebody or something. In this study, affecting refers to factors that would affect HIV positive patients to adhere or not adhere to antiretroviral treatment.

Antiretroviral therapy: According to the WHO (2006a:24), antiretrovirals are drugs that act at different stages of the HIV life cycle to stop the multiplication of the HIV virus. In therapy to treat HIV infection, three or more drugs from the different classes of antiretrovirals are used in combination.

In this study, antiretroviral therapy referred to treatment of HIV infection with three antiretroviral drugs in combination which are Zidovudine, Lamivudine and Nevirapine or Efavirenz as first line combination and Truvada plus Alluvia as second line combination.

Community-based HIV/AIDS care programme. According to Joint United Nations Programme on HIV/AIDS (UNAIDS1997:3), a community is defined as a group of people who have something in common and will act together in their common interest. Many people belong to a number of different communities which include the place where they live or the people they work with. The *Oxford Advanced Learner's Dictionary* (2000:225) defines a community as all the people who live in a particular area or country. The *Oxford Advanced Learner's Dictionary* (2000:931) defines a programme as a plan of things that will be done or included in development of something.

Applied to this study, community-based HIV/AIDS Care programme referred to a health care program that looks after HIV infected and affected people through providing counselling and treatment care at an HIV/AIDS clinic at The Aids Support Organisation (TASO) - Tororo Centre or community outreach centres. ART delivery and monitoring is done at these community outreaches by Medical and field staff of TASO Tororo.

Factors: A factor is defined by the *Oxford Advanced Learner's Dictionary* (2000:415) as one of the several things that cause or influence something.

For this study, a factor was anything that affects how a patient takes or adheres to his/her antiretroviral drugs.

Patient: The *Oxford Advanced Learner's Dictionary* (2000:855) defines a patient as a person who is receiving medical treatment especially in a hospital or clinic.

In this study, an adult patient referred to any patient 18 years and older who is HIV positive, on ART for more than two years and attends HIV/AIDS treatment clinics at TASO Tororo Centre or at Community outreach centres managed by the staff of TASO Tororo.

Rural Uganda: The *Oxford Advanced Learner's Dictionary* (2000:1035) defines rural as connected with or like the country side.

In this study rural Uganda referred to the remote parts of Uganda accessed only through murram roads where most of the local people are peasants who depend on

subsistence farming with limited access to electrical power, clean water and health facilities.

1.6 FOUNDATION OF THE STUDY

The foundation of a study is its philosophical bases, concepts and theories. It includes the conceptual or theoretical frameworks on which the study is based and the meta-theoretical assumptions under which the study is also grounded. (Burns & Groove 2005:60; Polit & Beck 2008:683).

1.6.1 Theoretical framework

In many fields, theories and propositions about concepts and relationships have been formulated to help give some kind of theoretical background about any study phenomena. Abel and Mugenda (1999:225) stipulate that this is done by using an existing theory or model to give a background and show how the study in question is related to the theoretical background or to a few selected concepts from a particular theory or model.

With reference to this study, the Health Belief Model (HBM) was used. It is a psychological model that attempts to explain and predict health behaviour. The major components of this model are perceived susceptibility, perceived severity, perceived benefit, perceived barriers, cues to action and self-efficacy (Hayden 2009:31, Stanhope & Lancaster 2005:271-272). In this study, the assumptions referred to are epistemological, ontological and methodological assumptions as presented in the ensuing discussions.

1.6.2 Meta-theoretical assumptions

According to Polit and Beck (2008:15), assumptions are basic principles that are assumed to be true based on logic and reason without proof or verification. Sources of assumptions include universally accepted truths such as theories, previous research and medical practice. In research studies, assumptions are embedded in the philosophical base, study design and interpretation of the findings (Burns & Grove 2005:39). Assumptions influence the logic of the study and their recognition leads to

more rigorous study development. In this study, epistemological, ontological and methodological assumptions were posited.

Epistemological assumptions are statements that embody the ideal of science, namely the quest for the truth (Mouton & Marais 1994:14-15). In this regard the epistemological assumptions were that:

- Asking questions objectively through use of questionnaires can elicit an understanding of the factors that influence adherence to antiretroviral therapy.
- The Health Belief Model can form a basis for a conceptual framework through which the empirical data on adherence to ART can be organised.
- Although it is difficult to ascertain when truth has been attained, it is however necessary to strive for reality as close as possible.
- Theories deductively generated from data are likely to offer insight, enhance understanding and provide meaningful action, to improve adherence to antiretroviral therapy by HIV positive patients.

Ontological assumptions, according to Mouton and Marais (1994:11-12), refer to the study of being or reality. The ontological assumptions regarding reality underlying this study were that:

- Phenomena are not random events but rather have antecedent causes and outcomes.
- Non adherence to antiretroviral therapy by the patients is a result of influence by some factors.
- The longer the patient is on antiretroviral therapy the more the chances of decrease in adherence.

Methodological assumptions, according to Mouton and Marais (1994:15-16), this concerns what may be called the how of research. In other words, how the research should be planned, structured and executed to comply with the criteria of science. It refers to the logic of implementing scientific methods in the study of reality. Methodological assumptions regarding this study were:

- Quantitative research is often associated with precise measurement of phenomena and quantification, often involving a rigorous and controlled design (Polit & Beck 2008:763).
- Quantitative research supports the collection of structured data with close ended type of questions.
- Descriptive survey research designs aim at portraying and exploring people's views on a particular phenomena accurately.

Burns and Grove (2005:39) conclude that assumptions are embedded (unrecognised) in thinking and behaviour, and uncovering these assumptions requires introspection and strong knowledge base in the particular field of study as it was purposed in the study.

1.7 RESEARCH DESIGN AND METHODOLOGY

A quantitative, non-experimental descriptive survey study design was employed to determine the factors that affect adherence to antiretroviral therapy of HIV positive patients in a community based HIV/AIDS care programme in rural Uganda.

The study population was adult HIV positive patients on ART for more than two years in rural Uganda. A research context of **20 Community Drug Distribution Points(CDDP)** was used. The researcher used multistage cluster sampling to select the sample for the study.

A two stage cluster sampling procedure was used. First stage, a sampling frame was developed including all the 45 Community Drug Distribution Points classified as clusters and alphabetically arranged. Using random numbers generated by MSExcel, **20 CDDPs** were randomly selected. Within the selected CDDPs, the number of respondents to be randomly selected was determined using proportions. In second stage, a sampling frame for each randomly selected CDDP consisting of a list of all patients that meet the eligibility criteria that came to pick ARVs on the data collection day at the CDDP was established. A systematic random sampling method was used to select respondents within the selected CDDP making a total of **275 respondents** for the study.

After obtaining informed consent (see Annexure D) from the respondents, data was collected using a structured interview questionnaire to elicit information from the respondents with the help of two trained research assistants.

To ensure validity, the researcher conducted extensive literature review of journal articles and publications addressing the concept of adherence to ART and selected items to be included in the questionnaire with care. The questionnaire was reviewed by the statistician, senior medical colleagues and the study supervisor. Stratified random sampling and systematic random sampling were used to draw the study sample. Reliability of the data collection tool was evaluated by the statistician using the Cronbach's alpha coefficient test.

Data was analysed using both descriptive and inferential statistics. With the help of a statistician, the researcher calculated descriptive statistics like mean, range, frequency distributions and percentages of age, gender, marital status, source of income, educational level, HIV status disclosure to spouse, alcohol use and adherence level to therapy for the sample population. For inferential statistics, bivariate analysis using Fisher's exact tests were used for categorical data and independent *t*-tests were conducted for continuous variables. Multivariate analysis using logistic regression test was done for all variables reaching significance during the bivariate analyses ($p < 0.05$). Multivariate analysis using logistic regression test was also done for all variables reaching a 95% level of confidence during the bivariate analyses ($p < 0.05$).

1.8 ETHICAL CONSIDERATIONS

For any research, the research process starting with identification of the study to publication of the findings should adhere to ethical standards of research. This means that the rights of the research institution, respondents' rights and the rights of others in the setting are protected. This should include aspects such as informed consent, confidentiality, anonymity, respect and dignity. Research integrity was also maintained (Burns & Grove 2005:83, 176).

In this study, the following were done to ensure ethical standards of research: protection of the rights of the participants and the institution; maintenance of scientific integrity of

the research and dissemination of the research findings. Details are presented in chapter 3.

1.9 STRUCTURE OF THE DISSERTATION

The dissertation has been organised according to five chapters as shown in the table 1:

Table 1:1 Structure of the dissertation

Chapter	Title	Content description
1	Orientation to the study	Overview of the research problem, purpose and significance of the study. Introduction of the theoretical foundation of the study and research design and method, ensuring validity and reliability, and ethical consideration.
2	Literature review	An in-depth review of the literature related to the topic under investigation to give the researcher information on what is published or discussed in the literature about the phenomenon.
3	Research design and methodology	The overall plan for addressing the research question, objectives which included data collection, ensuring validity and reliability, data analysis and the ethical considerations.
4	Data presentation, analysis and interpretation	Presentation, analysis and interpretation of the research findings
5	Conclusions and recommendations	Discussions, conclusions and recommendations based on the research findings

1.10 CONCLUSION

This chapter introduced and gave a comprehensive overview of the study. Background information on HIV/AIDS and adherence in the world, Sub-Saharan and Ugandan context was discussed. The problem statement, significance, purpose and research objectives of the study were indicated. Conceptual and operational definitions of concepts were presented. The foundation of the study based on the Health Belief Model (HBM) and the conceptual framework of the study derived from it were introduced. The research design and methodology with regard to study population, sampling, data collection and analysis were given and the ethical considerations were briefly mentioned. An outline of the structure of the chapters of the dissertation was presented.

Chapter 2 discusses the literature review conducted on the phenomenon under study and the theoretical framework suggested as a basis for the study.

CHAPTER 2

Literature review

2.1 INTRODUCTION

A literature review is an organised written presentation of what has been published on a topic of study by scholars. It is conducted to generate a picture of what is known about a particular situation and the knowledge gaps that exist in it. Through literature review, the researcher is able to clarify which problems have been investigated, require further investigation or replication or have not been investigated at all. Its purpose in a quantitative research is to direct the development and implementation of the study by aiding the researcher in designing the study and interpreting the outcomes in comparison to prior research (Burns & Grove 2005:37, 93-95).

The primary rationale for reviewing literature relevant to this study was to gain an understanding of the information available on factors related to adherence to ART within the context of HIV/AIDS, HAART, adherence measurement methods and theoretical framework. Reviewed documents on adherence were obtained from websites (online) and research articles from journals that are peer reviewed.

2.2 ADHERENCE TO ANTIRETROVIRAL THERAPY

The relationship between adherence and therapeutic success has been demonstrated across a range of highly active antiretroviral therapy (HAART) regimens including Nucleoside reverse transcriptase inhibitors, Protease inhibitors and Non-nucleoside reverse transcriptase inhibitors. Through the suppression of plasma HIV-1 RNA, HAART has been shown to improve CD4 cell counts and, in turn to decrease morbidity and mortality among HIV-infected patients. These benefits of HAART in the management of HIV are well established in a number of settings (Conway 2007:17; Paterson et al 2000:25; Wood, Hogg, Yip, Harrigan, O'Shaughnessy & Montaner 2004:266).

However, the success will depend on the patients' ability to adhere to ART which is influenced by factors which may be within or beyond the clinical environment. An extremely high level of adherence (<95%) is required to guarantee treatment effectiveness due to rapid replication and mutation rate of HIV. Some reports have a differing view, that virologic success is possible with less than 95% adherence. (Bangsberg, Hecht, Charlebois, Zolopa, Holodniy, Sheiner, Bamberger, Chesney & Moss 2000:360-362; Martin et al 2008:1267; Paterson et al 2000:27-28).

Poor adherence can lead to clinical, immunological and virological failure with the later resulting into the spread of drug resistant forms of the virus which is of public health concern. It can also lead to increased costs to health and society as a result of direct financial costs of failed treatment and higher hospitalisation rates. Indirectly there are costs of lost productivity of patients and a burden on family caregivers. Non adherence or sub-optimal adherence to ART is of concern particularly in countries that lack capacity to monitor drug resistance and in shortage of second line regimens that are prohibitively expensive (Bangsberg, Perry, Charlebois, Clark, Roberts, Zolopa & Moss 2001:1182; Cohen 2007:84; Stevens, Kaye & Corrah 2004:281-282; Sokol, McGuigan, Verbrugge & Epstein 2005:524-525).

In Sub Saharan Africa, initial findings about adherence have been promising. A meta-analysis found that a pooled estimate of 77% of patients in African settings achieved adequate adherence (most often measured as taking 95% of prescribed pills) compared with just 55% of patients in North American settings. In addition, high levels of adherence and positive outcomes of ART have been observed in some home based ART care studies and in a multi-site studies including Botswana, Tanzania and Uganda (Mills et al 2006:685; Weidle et al 2006:1591; WHO 2006a:79, 174).

2.2.1 Measuring adherence

There is no gold standard for measuring adherence. Across diseases, medication adherence is an individual, complex and dynamic behaviour that presents measurement challenges. Accurate measurement of antiretroviral therapy adherence is essential for evaluating interventions aimed at improving adherence and prevents viral resistance. Measurement of medication adherence is further complicated by the diversity of

available measures, which have different utility in clinical and research settings (Berg & Arnsten 2006:79; Chesney 2006:154).

Commonly used methods for measuring adherence include indirect measures, such as self-reports, electronic drug monitoring, pill counts, and pharmacy refill records and direct measures, including detection of drugs or drug metabolites in plasma (Berg 2006:79, Osterberg & Blaschke 2005:488).

2.2.1.1 Self-report

Self-report is the most commonly used adherence measure in clinical and research settings because it has a low staff and respondent burden. It is also inexpensive and flexible, and takes little time. In clinical settings, self-report allows for a discussion of reasons for missed doses and potential solutions.

A systematic review of 77 studies employing various self-report measures of antiretroviral therapy adherence reported that self-reported adherence was significantly correlated with HIV viral load in 84% of recall periods. In a meta-analysis of 65 studies, the odds of having a detectable HIV viral load was more than double in nonadherent patients compared with adherent patients (adjusted odds ratio=2.31, 95% confidence interval: 1.99 to 2.68) despite significant heterogeneity in point estimates (Berg & Arnsten 2006:81; Nieuwkerk & Oort 2005:446; Simoni, Kurth, Pearson, Pantalone, Merrill & Frick 2006:239).

There are several limitations associated with self-report including non standardised questions, reliance on recall of forgotten events and its vulnerability to social desirability in patients' given reports on adherence. They also tend to reflect only short-term or average adherence and often over estimate it. Despite these limitations, a study in Uganda showed that self-report as a measure of adherence has a high degree of correspondence with other objective measures such as electronic medication monitoring thus more applicable as a measure of adherence in resource limited settings (Berg & Arnsten 2006:80; Chesney 2000:171; Oyugi et al 2004:1101).

2.2.1.2 Pill counts

Pill counts which involve counting the number of pills that remain in the patients' bottles or vials have been widely used to measure adherence to medications in clinical settings. The patient brings back the actual pill containers in order for the clinicians to physically count the left over pills. The return of excess pills provides tangible evidence of non adherence. However, firstly this method has shortcomings because patients can deliberately remove and dump some pills before their next visit so as to appear adherent since they are aware of the pill counts. As a result, pill counts will typically overestimate adherence. Secondly the method does not provide information on other aspects of taking medication, such as dose timing and drug holidays which are important in determining the clinical outcome. Sometimes the patients may perceive pill counting as threatening and suggestive of lack of trust in their self-reported adherence (Berg & Arnsten 2006:82; Chesney 2000:171; Osterberg & Blaschke 2005:488).

In research settings, unannounced pill counts have been used to minimise the risk of pill dumping and have shown in some studies to predict viral load slightly better than the electronic drug monitoring (Bangsberg et al 2001:279).

2.2.1.3 Pharmacy refill records

Using pharmacy refill records to measure adherence is common among settings in which medications are provided and financed in a single location especially in a closed pharmacy system provided that the refills are measured at several points in time. With electronic medical records, a closed pharmacy system can provide the clinician or research scientist with objective information on the rates of refilling prescriptions that can be used to assess whether a patient is adhering to the drug regimen or not (Osterberg & Blaschke 2005:488; Steiner & Prochazka 1997:110).

The underlying premise of this method is that if patients do not receive timely refills from the pharmacy, they are missing doses as measured by prolonged periods between refills or not taking the medication at all. Adherence rates from pharmacy refills records are determined by comparing the actual with expected refill dates or by identifying "medication gaps", defined as periods during which the patient's supply of medication is

assumed to have been exhausted (Inciardi & Leeds 2005:794; Steiner, Koepsell, Fihn & Inui 1988:816).

Further, this method of measuring adherence level relies on the major assumption that patients who receive timely pharmacy refills ingest their medications correctly. The validity of this assumption has been evaluated by examining the association between pharmacy refill adherence and biologic outcomes. In several studies, pharmacy refills has been shown to correlate significantly with HIV viral load (Grossberg, Zhang & Gross 2004:1109; Low-Ber, Yip, O'Shaughnessy, Hoggs & Montaner 2000:361).

In a study comparing long term adherence to HAART as measured by two practical inexpensive methods (self reports and pharmacy refills records) at an HIV clinic in Melbourne- Australia, there was correlation between self reports and pharmacy refill records using <95% level of adherence as non adherent for pharmacy refill records and <97% as non-adherent for self reports. However, pharmacy refills identified about twice as many individuals to be non adherent as had been identified with self reports as 27% versus 14% statistic showed (Fairly, Permana & Read 2005:368).

2.2.1.4 *Electronic drug monitoring*

Electronic drug monitoring (EDM) has been used for several years to measure adherence in several chronic diseases and is frequently used by HIV researchers. It uses monitoring devices such as the medication event monitoring system (MEMS) cap which is a pill bottle, embedded with a microprocessor that records the time and date of each bottle opening as a presumptive dose. The cap stores the information until it is downloaded (Cramer, Mattson, Prevey, Scheyer & Ouellette 1989:3274; Diaz, Levine, Sullivan, Sernyak, Hawkins, Cramer & Woods 2001:327; McNabb, Nicolau, Stoner & Ross 2003:1764).

Electronic drug monitoring is often treated as the adherence "gold standard" because it produces adherence rates with lower central tendencies and more variance than other measures and correlates more closely with HIV viral load than other individual measures. Benefits include the ability to examine the patterns of adherence and detailed aspects of medication taking such as dose interval adherence (Arnsten, Demas, Farzadegan, Grant, Gourevitch, Chang, Buono, Eckholdt, Howard &

Schoenbaun 2001:1422; Liu, Golin, Miller, Hays, Beck, Sanandaji, Christian, Maldonado, Duran, Kaplan & Wenger 2001:973).

There are potential limitations to EDM including underestimation of adherence resulting from not using the cap consistently plus the “pocket dosing effect” that is to say the act of removing more than one dose for each bottle opening and pocketing the extra dose to ingest at a later time. In contrast, “curiosity opening” referring to respondents opening the monitored pill bottle without removing any pills, can lead to overestimates of adherence (Bova, Fennie, Knafl, Dieckhaus, Watrous & Williams 2005:107; McNabb et al 2003:1765).

2.2.1.5 Therapeutic drug monitoring

Monitoring of drug levels (*in vivo* drug concentrations) is a well known therapeutic intervention considered as a direct objective measure of medication adherence that is feasible in clinical and research settings most especially if inadequate plasma drug levels arising from pharmacokinetics or adherence factors are the major cause of treatment failure. Some drugs like antiepileptics, their serum concentrations levels will reflect the level of adherence to these medications (Hugen, Langebeek, Burger, Zomer, Leusen, Schuurman, Koopmans & Hekster 2002:332; Osterberg & Blaschke 2005:488).

Low drug levels in the plasma have been associated with self-reported nonadherence and virologic failure. For example, in a cross-sectional study done to examine the relationship between untimed drug levels and adherence in 83 individuals, an abnormally low drug level had a specificity of 88% for detecting adherence of 90% or less (Liechty, Alexander, Harrigan, Guzman, Charlebois, Moss & Bangsberg 2004:128; Murri, Ammassari, Gallicano, Deluca, Cingolani, Jacobson, Wu & Antinori 2000:126).

Therapeutic drug monitoring is expensive and cumbersome in addition to lack of technological standardisation across various settings. Further, factors other than those affecting adherence may affect drug levels such as drug-drug interactions and diet. Technically it is limited by the fact that serum drug levels only reflect adherence over the past 24 hours and patients who are aware of a planned visit may ingest medication in anticipation of the test (Berg & Arnsten 2006:83; Chesney 2000:171).

2.2.2 Factors affecting adherence to ART

Chesney (2000:172) states that before measures are implemented to improve adherence, it is essential to identify the main factors that contribute to the inability of patients to take their medications as expected or suggested.

Many factors including behavioural, socio-demographic and provider related characteristics have been reported to influence non-adherence to HAART. Some of the factors identified in these studies that positively or negatively affect adherence include costs of treatment, risks of illness like recurrence and severity of disease symptoms, benefits of treatment like decreased symptom frequency and severity plus prevention of hospitalisation, barriers like complex drug regimens and cues to act like symptom exacerbation, pillboxes plus appointment reminders, knowledge about the target disease and prior contact with it. These factors are normally grouped into the following categories: Patient-related factors, treatment regimens, disease characteristics, patient-provider relationship and clinical settings. There is an interrelationship among these factors (Ammassari, Trotta, Murri, Castelli, Narciso, Noto, Vecchiet, Monforte, Wu & Antinori 2002:123; Chesney 2000:171; Ickovics & Meade 2002:99).

Ammassari et al (2002:126) reviewed published studies conducted in different settings that reported that the most common reasons for skipping HAART included complexity of medication regimens (7-52%), difficulty of integrating treatment schedules into their daily activities (36-57%), fear of side effects (13-42%), worries about disclosure (14-33%), and forgetfulness about taking medications (30-66%).

2.2.2.1 Patient related factors

A patient's behaviour is the critical link between a prescribed regimen and treatment outcomes. Consequently, the most important factors influencing adherence are patient related and under the patient's control, so attention to them is a necessary and important step in improving adherence (Chesney 2000:174).

From studies done, sociodemographic factors generally do not predict adherence behaviour although some studies have found that male sex, white ethnicity; older age, higher income, higher education, and literacy correlate with better adherence (Eldred et

al 1998:121; Gifford, Bormann, Shively, Wright, Richman & Bozzette 2000:388-389; Kleeberger, Phair, Strathdee, Detels, Kingsley & Jacobson 2001:87-88; Weidle et al 2006:1591).

Psychological factors have been related to adherence behaviour including depression and psychiatric illness, active substance abuse especially alcohol and intravenous drugs, social support, self-efficacy, body image and weight concerns. Of note is that some studies have demonstrated that a history of substance abuse is unrelated to adherence, although active substance abuse is one of the stronger predictors of nonadherence (Chesney 2000:174; Kleeberger et al 2001:89; Gordillo, Del Amo, Soriano & Gonzalez-Lahoz 2000:1766-1767; Ostrop, Hallet & Gill 2000:706; Roberts & Mann 2000:383).

Patient's knowledge and beliefs about disease and medicine can influence adherence. Understanding the relationship between adherence and viral load and between viral load and disease progression is integral to good adherence. In addition, negative beliefs regarding the efficacy of HAART may also affect adherence behaviour for example in one study conducted by Wenger, Gifford, Liu and Chesney (1999) report that better adherence was found in patients who believed antiretroviral medication to be effective. A study conducted by Siegel, Karus and Schrimshaw (2000:429), showed that African American men were more likely than Caucasian men to report scepticism about medications and their ability to adhere to those medications thus giving a racial dimension to patients' beliefs and knowledge (Chesney, Ickovic, Chambers, Gifford, Neidig, Zwickl & Wu 2000:263).

2.2.2.2 Treatment regimen

Complexity of ART regimens is a fundamental challenge to adherence. Some regimens require several doses of medication per day together with various requirements or restrictions on food intake or other activities. These complexities, in addition to the problems of toxicity and side-effects can greatly influence an individual's willingness and ability to adhere to therapy (Chesney, Morin & Sherr 2000:1603; D'Armino et al 2000:505).

Dosing schedules and food restrictions appear to have more influence on adherence than pill burden. Eldred et al (2000:121) found that patients on twice daily doses or less reported better adherence (>80%) and were more likely to adhere to their medication when away from home. Paterson et al (2000:26) also found that twice daily dose was associated with better adherence than thrice daily dosages.

Side-effects have also been consistently associated with decreased adherence and patients who experience more than two adverse reactions are less likely to continue their treatment. HAART can lead to serious adverse events including transient reactions such as nightmares, hallucinations, diarrhoea and vomiting; longer-lasting effects such as peripheral neuropathy, lipodystrophy and metabolic changes are also likely to be a factor. The literature on side-effects clearly shows that optimal adherence occurs with medications that remove symptoms whereas adherence is reduced by medications that produce side effects (Chesney 2000:173; Max & Sherer 2000:98-108; Roberts & Mann 2000:380; Stone 2001:869).

Patients quickly discontinue therapy or request changes of medications if they experience side-effects. Both real and perceived side-effects account for more regimen changes than does treatment failure. The symptoms that cause the most distress are fatigue, diarrhoea, nausea and stomach pains of which most can be successfully treated (D'Armino et al 2000:502-505; Mocroft et al 2001:191-192).

One serious side-effect that may affect adherence to ART in the long term is lipodystrophy. Lipodystrophy affects between 30% and 60% of persons on HAART. Its physical manifestation varies greatly but can include fat accumulation on the upper back and neck (buffalo hump), under the muscles of the abdomen (crix belly or protease pauch), lipomas and breast enlargement. There might also be peripheral wasting of the fat in the face, legs, arms and buttocks (Carr, Samaras, Burton, Law, Freund, Chisholm & Cooper 1998:53; Gervasoni, Ridolfo, Trifiro, Santambrogio, Norbito, Musicco, Clerici, Galli & Moroni 1999:469; Graham 2000:5-9).

2.2.2.3 Disease characteristics

Based on evidence from other chronic diseases, investigators have speculated that the degree of symptoms and immunologic status are negatively associated with adherence.

However, few HIV studies have examined this directly except in one study which showed that prior opportunistic infections increased adherence suggesting that illness severity motivated patient adherence (Singh, Squire, Sivek, Wagener, Hong-Nguyen & Yu 1996:266).

2.2.2.4 Patient-provider relationship

A meaningful and supportive relationship between the patient and health care provider can help to overcome significant barriers to adherence. Factors that have been identified as strengthening the patient-health care provider relationship include perception of provider competence, quality and clarity of communication, compassion shown by the provider, involving the patient as an active participant in treatment decisions and convenience of the regimen. Patients become frustrated with health care providers when misunderstandings occur, treatment becomes complex, side-effects go unmanaged and the patient is blamed for being a “bad patient”. In a study done by Gao et al 2000:395, difficulty in following physician’s instructions was a significant barrier to medications adherence. This suggests that patients’ medication adherence can be improved by enhancing the relationship and communication between patients and health care providers (Chesney 2000:173; Stone, Clarke, Lovell, Steger, Hirschhorn, Boswell, Monroe, Stein, Tyree & Mayer 1998:591; WHO 2003a:100).

2.2.2.5 Clinical setting

Access to reliable primary health care is related to increased adherence to HAART, whereas missed clinic appointments are associated with virologic failure. There are a number of aspects of a clinical setting that may be associated with adherence including transportation, waiting time, convenience of scheduling appointments, integrated services and confidentiality. In a study done in Botswana by Weiser et al 2003:285, 30% of patients cited frequency of clinic visits as a barrier to treatment adherence and there were patients who missed out on clinical tests and medication refills because of confidentiality concerns (Ickovics & Meade 2002:S99; Lucas, Chaisson & Moore 1999:84).

2.3 THEORETICAL FRAMEWORK

A theoretical framework or model suggested as a basis for this study is the Health Belief Model (HBM). It is a social psychological model that attempts to explain and predict individual health behaviours. This is done by focusing on the attitudes and beliefs of individuals. The model was developed in the 1950s by Rosenstock (Kozier, Erb, Blais & Wilkinson 2008:247) with an intention to predict which individuals would or would not take specific actions to avoid illness. Rosenstock (Kozier et al 2008:247) assumed that to be in good health and to stay so is an objective common to all people. Since then, the HBM has been adapted to explore a variety of long- and short-term health behaviours. The Model is based on three major components namely individual perceptions, modifying factors and variables affecting the likelihood of taking recommended health action. The model assumes that an individual will take a health - related action if that person perceives susceptibility, severity of the condition, benefits in taking the actions to reduce the risk, and believes in being able to successfully execute the action required to produce the desired outcome without barriers (Hayden 2009:32-35; Stanhope & Lancaster 2005:271-272).

With reference to the concepts introduced about the HBM, adherence can be taken to be a desired health related action or behaviour that can be influenced by the perceptions, beliefs and cues to action of an individual. If these perceptions and beliefs are not re-enforced or addressed they may lead to non adherence. Therefore, the HBM provides an important framework for understanding the psychosocial factors that may contribute to medication adherence.

The specific components of the HBM have been analysed in several studies to predict medication adherence and the factors that influence it for other chronic diseases like hypertension, tuberculosis, psychiatric disorders and cancer. It has also been used as a basis for developing compliance-promotion interventions and health education programs. However, in a study done by Gao et al 2000:396, not all the components of the HBM were shown to predict adherence behaviour among the HIV patients (Perkins 1999:26; Tabor & Lopez 2004:168-169; Turner, Kivlahan, Sloan & Haselkorn 2007:1148).

2.3.1 Conceptual framework

The conceptual framework illustrated below is developed and adapted from the HBM and the literature review to give a deeper understanding of related concepts of the study phenomena (Hayden 2009:32-35; Stanhope & Lancaster 2005:271-272).

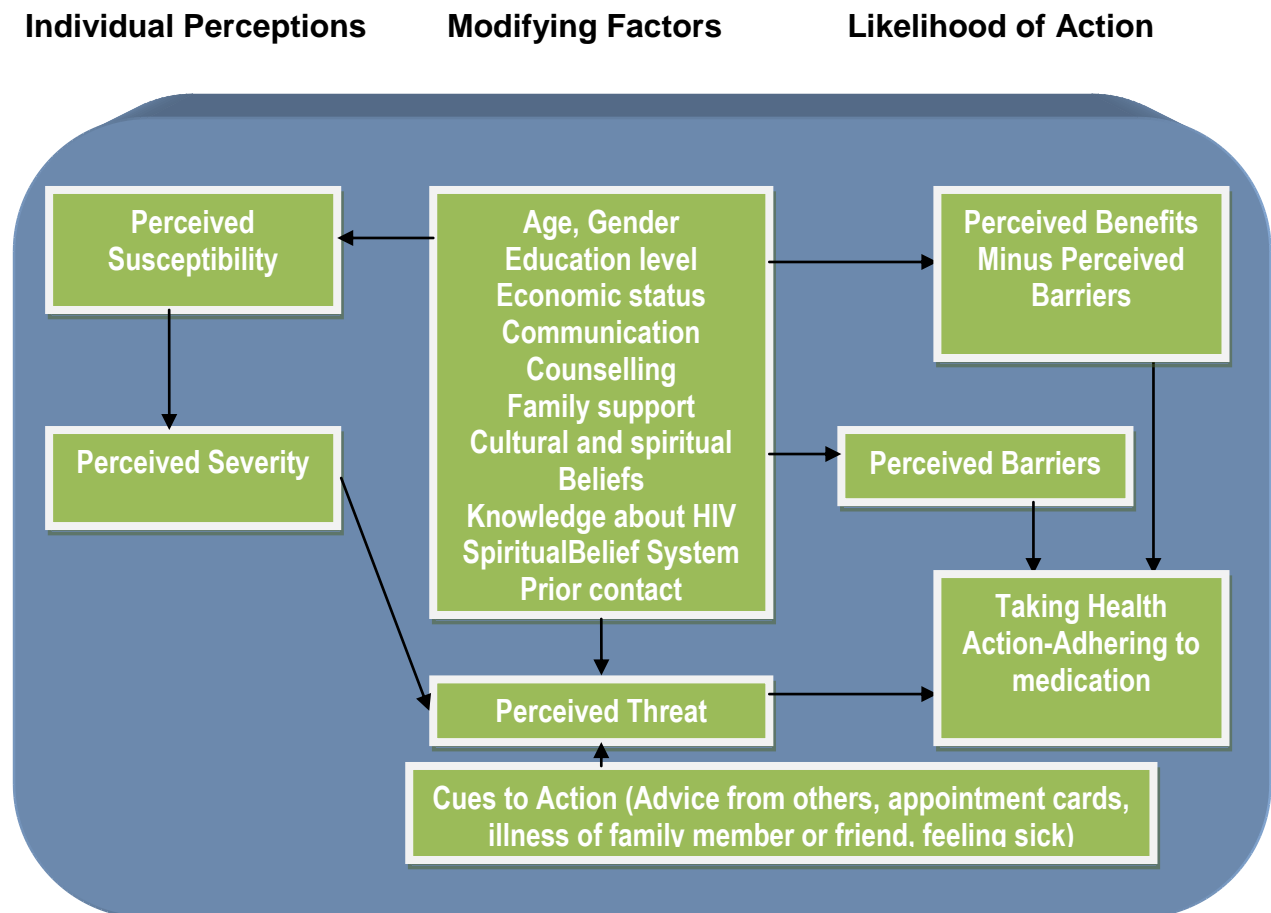


Figure 2.1 The Conceptual Framework

2.3.1.1 Individual perceptions

Individual perceptions include the following variables:

- **Perceived susceptibility:** When people believe they are at risk for a disease, they will be more likely to do something to prevent it from happening and when they are not at risk or have a low risk of susceptibility they will do the opposite. Therefore HIV positive patients' belief that they are susceptible to AIDS when they don't take their ARVs well will enhance their adherence to their medication and if they don't feel susceptible, adherence will be low (Hayden 2009:32). This

perception is influenced by various factors as indicated on figure 2.1 such as gender or cultural beliefs as they may feel helpless and susceptible as they may not have decision making powers or authority on issues related to sex.

- **Perceived severity:** This indicates an individual's belief about the seriousness or severity of the disease. It may also come from the beliefs a person has about the difficulties a disease would create or the effects it would have on his or her life in general. When the perception of susceptibility is combined with seriousness, it results in perceived threat. Knowledge and beliefs of the consequences of having AIDS include wasting (slim), skin rashes (black spots), hospitalisation, loss of job due to absenteeism and early death (Hayden 2009:31-32). This perception is likely to influence an individual to take a health action of adherence due to the experience of contact with the disease which leads to a perceived threat of deterioration or even death.
- **Perceived threat:** When the perception of susceptibility to a disease is combined with seriousness with which the disease is viewed, perceived threat to the disease such as HIV results. If the perception of threat is to a serious disease as HIV/AIDS for which there is a real risk, behaviour often changes. However, perception of increased threat does not always lead to a desired health behaviour change. Perception of threat to disease is also influenced by the modifying factors and cues to action (Hayden 2009:33; Stanhope & Lancaster 2005:271).

2.3.1.2 Modifying factors

Modifying factors that modify a person's perceptions include the following:

- **Demographic variables** such as age, gender, marital status and ethnicity. An unmarried person may adhere better to treatment regimens than married people because of the freedom they might have to make choices and decisions.
- **Sociopsychological variables:** Cultural and spiritual beliefs may encourage or hinder engaging in preventative health behaviours such as use of a condom. Women's motivation may be low because of cultural pressure to obey their husbands.
- **Structural variables such as** education level, past experiences, knowledge about HIV and prior contact with it were found to have positive influence on compliance (Hayden 2009:33). Other factors indicated are economic status;

communication and prior contact with the disease have influence on decisions and choices made by individuals on health actions.

- **Cues to action:** These are events, people or things that move people to change behaviour. Cues can either be internal or external. Internal cues include feeling of fatigue, uncomfortable symptoms or thoughts about the condition of another HIV positive person who is close. External cues that may affect adhering to drugs could be advice from others, pill taking reminders and illness of a family member or friend (Hayden 2009:33; Koziar et al 2008:250).

2.3.1.3 Likelihood of action

This is the behaviour adopted in order to reduce the threat based on the perceived benefits and barriers of the behavioural change. In this case, the patient will either adhere or not adhere depending on own perception of the effect of disease and the treatment.

- **Perceived benefits of the action:** This is the person's opinion of the value or usefulness of adopting a new behaviour in decreasing the risk of developing the disease or alleviating the existing symptoms. Patient's belief that they will recover from sickness, able to work again and live longer to raise their children if they take their ARVs properly will influence their adherence behaviour (Hayden 2009:33).
- **Perceived barriers of the action:** This is an individual's own evaluation of the obstacles in the way of adopting a new behaviour or continuing with the same behaviour. Perceived barriers to adhering to ARVs include pill burden, food restrictions, dosing schedule, side effects and stigma (Hayden 2009:33). They may lack support of family members or friends as the disease has a social stigma.

According to the HBM, modifying factors and cues to action affect perception of susceptibility, seriousness, benefits, and barriers and therefore the likelihood of a person taking or not taking the recommended health action in this instance of adhering or not to medication against HIV. Doctors and nurses play a major role in helping patients implement healthy behaviours. They can also help to reduce threats and

barriers to action by improving communication with patients, minimising inconvenience and support positive actions (Kozier et al 2008:249).

2.4 CONCLUSION

This chapter gave an overview of the role of adherence to ART in the effective treatment of HIV/AIDS. Different methods of adherence measurement used both in clinical and research setting and their advantages and disadvantages when used in different study settings were highlighted. Factors that affect adherence to medications as per findings from different studies were reviewed although for most of the studies the study settings were in developed countries and few had been done in Sub-Saharan Africa.

Lastly, the HBM as the basis for the conceptual framework of the study was highlighted and developed to act as a guide for the study particularly in the development of the questionnaire.

Chapter 3 discusses the research design and method.

CHAPTER 3

Research design and method

3.1 INTRODUCTION

This chapter covers the overall research plan for obtaining answers to the research questions and objectives being studied. The focus of the study was to investigate factors that affect adherence to antiretroviral therapy of HIV positive patients in a community home based care program in rural Uganda. The discussion included the research design and the research methodology on aspects such as study design, research context, population, sample and sampling technique, data collection, validity and reliability, data analysis, scope and limitation and ethical considerations.

3.2 RESEARCH DESIGN

Burns and Grove (2005:40) define a research design as a blue print for the conduct of a study that maximises control over factors that could interfere with the study's desired outcome or findings. Polit and Beck (2008:66) define research design as the overall plan for obtaining answers to the research question being studied including specifications for enhancing the study's scientific integrity. It is essentially the architectural backbone of the study.

The researcher used a non-experimental quantitative, explorative and descriptive research design, using the survey approach.

3.2.1 Quantitative approach

It is a formal, objective, systematic process utilised to describe and test relationships and to examine cause-and-effect interactions among variables. It involves investigations of phenomena that lend themselves to precise measurement and quantification often

involving a rigorous and controlled design where the researcher is independent from what is being researched (Burns & Grove 2005:747; Polit & Beck 2008:763).

Quantitative research is characterised by the use of structured interviews, questionnaires or observations; scales; or physiological instruments to generate numerical data. Statistical analyses are conducted to reduce and organise data, determine significant relationships and identify differences among groups. Control, instruments and statistical analyses are used to render the research findings an accurate reflection of reality so that the study findings can be generalised (Burns & Grove 2005:25).

Advantages

The quantitative approach is associated with *advantages* such as being systematic where research is through a logical process according to a prespecified plan of action, control mechanism are employed to minimise bias and maximise precision and validity and reliability. Empirical evidence gathered through this approach is the basis for knowledge thus findings are grounded in objective reality rather than in the researchers' personal beliefs or expectations and the numeric information gathered from formal measurements is easy to analyse with statistical procedures (Polit & Beck 2008:16-17).

Disadvantages

Some of the *disadvantages* of the quantitative approach are: inflexibility, inability to answer the "how" and "why" of phenomena, the lack of accurate measures in numerical form of psychological phenomena such as pain. Too much control of the research may sometimes obscure insights into complex environments and qualitative experiences of people (Polit & Beck 2008:16-17).

The quantitative approach is suitable for this study because its aims which are to describe and explore the factors that affect adherence to ART by HIV positive patients which are amenable to statistical analysis. Generalisation of the findings to the target population can be easily achieved with this approach. It is also compatible with the resources available especially time.

3.2.2 Explorative design

According to Babbie and Mouton (2001:79-80), a research is exploratory when the researcher examines a new area of interest or topic especially where a phenomenon under study is persistent. Polit and Beck (2008:20-21) add that exploratory studies are useful if the researcher wishes to assess and understand a phenomenon in a new light, ask questions, and search for new insights. This notion concurs with Burns and Grove's (2005:357) view about exploratory studies that they are designed to increase the knowledge of the field of study.

The study sought to explore the factors contributing to good or poor adherence to antiretroviral therapy in the study population.

3.2.3 Descriptive design

Descriptive research is research is described by Burns and Grove (2005:239) as a research design that provides an accurate portrayal or account of characteristics of a particular individual, situation, or group. It is a way of describing what exists, discovering new meaning, determining the frequency with which something occurs and categorising information. They are usually conducted when little is known about a phenomenon. The purpose of descriptive studies is to observe, describe, and document aspects of a situation as it naturally occurs and sometimes to serve as a starting point for hypothesis generation or theory development (Burns & Grove 2005:26; Polit & Beck 2008:274).

A descriptive design was chosen for the study in order to describe the factors that influence adherence or non-adherence to antiretroviral therapy in the study population.

3.2.4 Survey approach

It is a technique of data collection in which questionnaires or personal interviews are used to gather data about an identified population or it is a design used to obtain information about the prevalence, distribution and interaction of variables within a population. It is a nonexperimental research that obtains information about people's activities, beliefs, preferences, and attitudes via direct questioning (Burns & Grove 2005:239; Polit & Beck 2008:323, 767).

The researcher chose a survey approach for the study because of its advantages such as its flexibility and broadness of scope which can be applied to large samples of populations. A further advantage is that, it can focus on a wide range of topics and its information can be used for varied purposes like description, exploration and explanation of the phenomena. However, its main disadvantage is that the information obtained tends to be relatively superficial (Polit & Beck 2008:323-324).

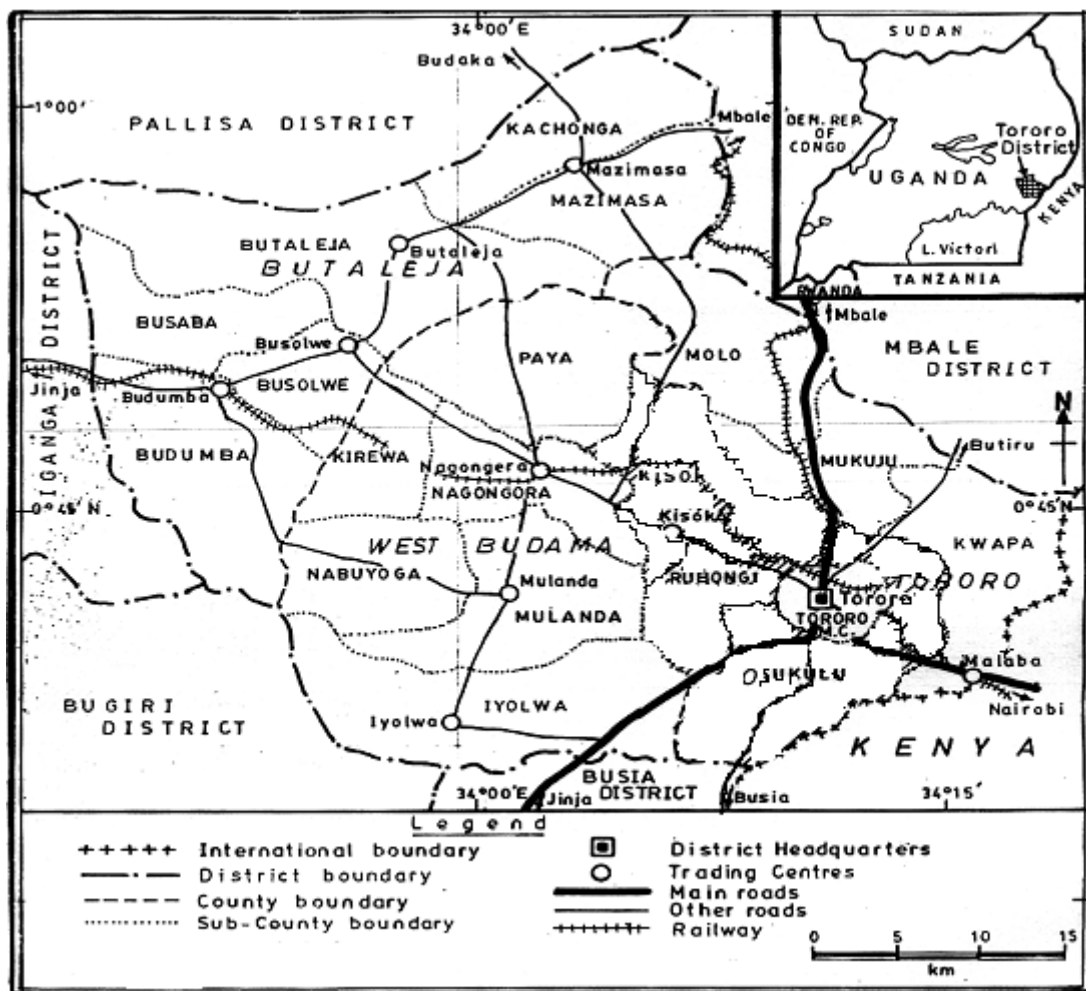
3.3 RESEARCH METHOD

The research methodology outlined a logical process of the research and what processes and procedures are followed to answer the research question and achieve the research objectives (Mouton 2001:56). It included the research context, study population, sample and sampling technique, data collection and the data analysis techniques, ensuring validity and reliability and ethical considerations.

3.3.1 Research context

According to Polit and Beck (2008:57), a research context is defined as a specific place where data collection occurs. The Aids Support Organisation (TASO) is a non-governmental organisation with branches in all the regions of Uganda that has been providing care and support services free of charge to HIV-infected individuals since 1987. Services provided by TASO to HIV positive patients include counselling, ART and social support.

The study was conducted at one of the TASO Centres located in Tororo district.



Source : The 1991 Population and Housing Census Report.

Figure 3.1 Map of the Tororo district.

The district is located in Eastern Uganda near the border with Kenya (see figure 3.1). According to Uganda Bureau of Statistic (2006:46), the 2002 national census estimated the population of Tororo district at 536,888 with an annual population growth rate of 2.7% and population density of 218-330 per km². With those statistics, it is estimated that the population of the district in 2009 was approximately 646,959. It is a multi ethnic district with two main tribes; the Adholas and the Itesots. Agriculture is the main source of the district's economy.

TASO Tororo centre caters for HIV positive patients within four districts i.e. Tororo, Busia, Busolwe and Bugiri. It has seven ART clinics of which two ART clinics are in Tororo district with one at the TASO Tororo centre and the other is an outreach clinic located in Mulanda Sub County. At these clinics, patients can access their ARV drugs

and other medical/counselling services. At initiation of ART, patients are started on any of the four first line regimens (AZT/3TC/NVP, AZT/3TC/EFV, TNF/3TC/NVP and TNF/3TC/EFV) depending on the doctor's medical assessment at recruitment. If the patient fails on the first line regimen then they are switched to the second line regimen consisting of Alluvia and Truvada.

To decrease congestion at the ART clinic, TASO management introduced Community Drug Distribution Points (CDDPs). At these points, all patients who have been on drugs for more than 6 months and have no medical or counselling problem pick their refills for ARVs. In Tororo district, there are 45 CDDPs spread all around the district.

At the time when this study was conducted, TASO Tororo had already offered services to approximately 8083 HIV positive patients of which 7509 are adults and 574 are children <18 years. A total of 2403 patients were on antiretroviral therapy.

3.3.2 Population

Babbie and Mouton (2001:174) define a population as an aggregation of elements from which the sample is actually selected. According to Polit and Beck (2008:337), the study population is defined as the entire aggregation of cases in which the researcher is interested.

Target population

Burns and Grove (2005:342) define a target population as the entire set of individuals or elements who meet the sampling criteria whereas Polit and Beck (2008:338), define it as the total group of subjects about whom a researcher is interested and to whom results could reasonably be generalised.

For this study, the target population was all adult male and female HIV positive patients on ART for more than two years in rural Uganda.

Accessible population

According to Polit and Beck (2008:338), accessible population is the aggregate of cases that conform to designated criteria and are available as subjects for a particular study. Burns and Grove (2005:342) define it as the portion of the target population to which the researcher has reasonable access.

For this study, the accessible population was all adult, male and female HIV positive patients accessing ART from TASO-Tororo Centre, resident in Tororo district and have been on ART for more than 2 years.

Eligibility criteria

According to Burns and Grove (2005:342), eligibility criteria are a list of characteristics essential for membership or eligibility in the study population.

Polit and Beck (2008:338) refer to it as the criteria that designate the specific attributes of the target population by which people are selected for inclusion in a study.

The following *inclusion* criteria were used to identify the study population:

- Adult patients both male and female (>18 years of age)
- Registered at TASO Tororo centre
- Receiving ART from CDDPs located in Tororo district
- Been on ART for more than two years (>2 years)
- Reside within the Tororo district

3.3.3 Sample and sampling technique

A sample is a subset of the study population that is selected for a particular study and the members of the sample are the respondents. Sampling is defined by Burns & (Grove 2005:41) as the process for selecting a group of people, events, behaviour or other elements with which to conduct a study. A sampling technique is the method used to select a sample from the study population. In this study a multistage cluster sampling technique was used which was advantageous because it was more practical and less costly (Burns & Grove 2005:41; Polit & Beck 2008:339-340).

A sample size of 275 (33%) adult HIV positive patients receiving ART from the TASO Tororo- Community Drug Distribution Points located in Tororo District and had been on ART for more than 2 years was considered adequate.

Multistage cluster sampling

A multistage cluster sampling strategy is defined by Polit and Beck (2008:758-759) as a sampling method that proceeds through a set of stages from larger to smaller sampling units. This approach was utilised as a sampling technique of choice to obtain a sample for the study. Based on the description by Burns and Grove (2005:349), of what a multistage cluster sampling is, a sampling frame was developed that included a list of all units/clusters with which elements of the identified population would be linked. In this study the units/clusters were randomly selected from which to obtain the elements of the sample. The random selection continued through several stages until the study sample was obtained. This was the appropriate method because patients who have been on drugs for more than 6 months without medical problems receive their ARV drugs from the 45 Community Drug Distribution Points within the district and data collection was done at these Points thus the need to cluster the accessible population according to the site of drug delivery.

The advantage of clustering was that, it provided the researcher with a means for obtaining a larger sample at a lower cost. However, data from respondents associated with the same cluster were likely to be correlated and thus not completely independent. This process had disadvantages such as a decrease in precision and an increase in sampling error. However, use of a larger sample to some extent did offset these disadvantages (Burns & Grove 2005:349).

The study used a probability (random) sampling approach so as to obtain a representative sample and also to be able to perform inferential statistics during data analysis.

Probability (random) sampling is a selection process in which each element in the population has an equal, independent chance of being selected. In nonprobability sampling, not every element of the population has an opportunity to be included in the

sample. Non probability sampling compared to probability sampling, increases the likelihood of obtaining samples that are not representative of their target population. However, probability sampling has limitations of being inconvenient and complex more especially when the study population is not clearly defined (Burns & Grove 2005:346, 350).

How sampling was done

A two stage cluster sampling procedure was used. First stage, a sampling frame was developed including all the 45 Community Drug Distribution Points classified as clusters and alphabetically arranged. Using random numbers generated by MS Excel, 20 CDDPs were randomly selected. Within the selected CDDPs, the number of respondents to be randomly selected was determined using proportions. This was because the total patients per CDDP varied from one to another.

Second stage, a sampling frame for each randomly selected cluster/CDDP consisting of a list of all patients that meet the eligibility criteria that came to pick ARVs on the data collection day was established and the respondents consecutively numbered.

According to Polit and Beck (2008:344), a sampling frame is a list of the elements from which the sample will be chosen. Babbie & Mouton (2001:174) define it simply as a list of the study population in case of single-stage sampling design.

A systematic random sampling method was used to select the sample of respondents within each randomly selected cluster. According to Polit and Beck (2008:347-348), systematic sampling involves the selection of every k th case from a list or group and ensures that an essentially random sample is drawn. Twenty CDDPs were thus visited with a varying number of patients which constituted a total of 826 patients. A random sample of respondents was randomly selected from each cluster using a sampling frame by selecting every 3rd ($k=3$) patient to make a sample total of 275 respondents for the study as presented in table 3.1.

Table 3.1 The cluster random sample according to the selected CDDP

Location of CDDP	Number of Patients at the CDDP	Proportional sample
Sop Sop	25	8
Mukujju 1	75	25
Kisoko 1	39	13
Namwaya HU	30	10
Namwanga	20	7
Serena	23	8
St Peter 1	24	8
Molo HC	43	14
St Peter 3	19	6
Katajula	31	10
Secret Heart	83	28
L yolwa	66	22
Petta	43	14
Maundo HC	24	8
Malaba 1	77	26
Kirewa SC	44	15
Bison 1	49	16
St Peter 2	43	14
Pei Pei	15	5
Rubongi SC	53	18
Total = 20	826	N=275

Table 3.1 exhibits the number of respondents included in the study from all the units which constituted 33% of the total number of patients who attended at the clinics on the day when data was collected.

3.3.4 Data collection

According to Burns and Grove (2005:42), data collection is defined as the precise, systematic gathering of information relevant to the research purpose or the specific objectives, questions, or hypotheses of a study.

3.3.4.1 Data collection approach and method

The study used a structured data collection approach in form of a questionnaire with close-ended questions that was administered to all the sampled respondents.

According to Polit and Beck (2008:371), structured data collection involves a fixed set of questions to be answered in a specified sequence and with pre-designated response options. Fisher and Foreit (2002:74) also define it as an approach that uses a standard questionnaire or interview schedule to ensure that all respondents are asked exactly the same set of questions in the same sequence. While Katzenellenbogen, Joubert and AbdoolKarim (1997:83), define this approach as whereby interviewers follow a well-defined structure to prevent them from placing their own interpretation on the question. Questions are asked in the same way with clarification while doing the recording.

Burns and Grove (2005:398) define a questionnaire as a printed self-report form designed to elicit information that can be obtained through the written responses of the respondent. The questionnaire can be designed to determine facts about the respondent or persons known by the respondent. Examples of such facts can be about events or situations known by the respondent; or beliefs, attitudes, opinions, levels of knowledge, or intentions of the respondent.

The use of a questionnaire is associated with advantages such as less cost, respondent anonymity, absence of interviewer bias, easy to administer and data yielded are easy to analyse. However, it has disadvantages including low response rates, the questions tend to have less depth especially if they are closed-ended questions and the respondent is unable to elaborate on the responses or ask for clarification of the questions (Burns & Grove 2005:398-399; Polit & Beck 2008:423-424).

In this study a structured questionnaire was utilised so as to focus the research process and also be able to quantify the results of the study phenomenon.

3.3.4.2 Development of the data collection instrument

The researcher developed the questionnaire using the literature review as a frame of reference. The items were close-ended and worded in such a way that respondents

were limited to specified mutually exclusive response options. The assistance of the study supervisor and statistician was sought for in the design of the questionnaire. Some of the Items to measure the respondents' health beliefs, perceptions and attitudes towards adherence to ART treatment were adapted from the Adherence Determinants Questionnaire (ADQ) Scale developed and validated by DiMatteo and colleagues. The designed questionnaire is also based on the HBM and consists of 38 brief statements rated on a Likert scale. (Barclay, Hinkin, Castellon, Mason, Reinhard, Marion, Levine & Durvasula 2007:42; DiMatteo, Hays, Gritz, Bastani, Crane, Elashoff, Ganz, Heber, McCarthy & Marcus 1993:110-111).

The questionnaire was in English and some of the words and phrases were clarified and explained in the respondents' local languages to facilitate understanding.

Structure of the questionnaire

The questionnaire was divided into 6(Six) sections. These sections were designed to elicit information from the respondents about the factors that affect adherence to ART in HIV positive patients in rural Uganda.

- Section A* Personal Data including demographic data such as age, gender, marital status, highest level of education, occupation, role in the family and HIV status.
- Section B* Aspects of care related to the clinic
- Section C* Interpersonal relationships with care providers
- Section D* Knowledge and experience about HIV/AIDS
- Section E* Perceptions about the treatment plan
- Section F* Adherence to antiretroviral therapy

3.3.4.3 Pre-test

According to Polit and Beck (2008:380, 762), a pre-test is a trial administration of a newly developed instrument to identify flaws or assess time required to complete the questionnaire. During the pre-test, it is possible to identify questions that are ambiguous or that respondents may find objectionable or difficult to understand. It assists the

researcher to determine whether the sequencing of the questions is sensible or not and needs for training of the two volunteer research assistants on data collection.

After the approval of the questionnaire, a small scale pilot study was conducted to pre-test the questionnaire with ten respondents who met the eligibility criteria for the main study. This was done to identify gaps in the questionnaire. The respondents who participated in the pre-test were not included in the main study.

This exercise assisted in editing the questionnaire to rectify questions that were too ambiguous in terms of language or conceptualisation, estimating the time required to complete the questionnaire and in the training of the two research assistants in how to administer the questionnaire. There were minor changes done on the questionnaire especially on the sequence of the questions asked for better flow and understanding.

3.3.4.4 *Data collection process*

Permission to collect the data was already sought for and granted. A separate quiet room/area designated for this purpose was used to complete the questionnaire.

The researcher used two research assistants to administer the questionnaire to the respondents at the various CDDPs. The research assistants were trained and equipped with the know how of obtaining consent from respondents, administration of the questionnaire, interaction with respondents, random sampling, data collection techniques and issues of confidentiality and anonymity during the process of conducting the research. After completion of the questionnaires (see annexure E), they were passed on to the researcher for verification and data capturing. The presence of the researcher and the trained volunteers enhanced the success of 100% return of the questionnaires.

3.4 VALIDITY AND RELIABILITY

Validity and reliability are important concepts and of concern throughout the research process. They are important to the researcher during the research process and to those who read the study report as they provide a basis for making decisions as they consider using the findings in their practice.

3.4.1 Validity

According to Polit and Beck (2008:457-458), validity is defined as the degree to which an instrument measures what it is supposed to measure. On the other hand Burns and Grove (2005:376) define the validity of an instrument as the extent to which the instrument actually reflects the abstract construct being examined. Validity is a concept that broadly concerns the soundness of the study's evidence that is whether the findings are cogent, convincing and well grounded. Another aspect of validity concerns the quality of the researcher's evidence regarding the effect of the independent variable on the dependent variable. It is an important criterion for assessing the methods of measuring the variables.

Validity varies from one sample to another and from one situation to another; therefore, validity testing actually validates the use of an instrument for a specific group or purpose rather than the instrument itself. In this study, the degree of face, content, internal and external validity of the instrument for the intended purpose and the context where the study was conducted was determined (Burns & Grove 2005:377).

3.4.1.1 Face validity

Face validity refers to whether the instrument looks like it is measuring the appropriate construct or not. It verifies basically that the instrument looks like it is valid or gives the appearance of measuring the content. It is an important aspect of the validity of the instrument because the willingness of respondents to complete the instrument is related to their perception that the instrument measures the content they agreed to provide (Burns & Grove 2005:379; Polit & Beck 2008:458).

In this study, face validity was ensured by careful selection of items to be included in the questionnaire. These items reflected the concept of adherence to ART and the factors that affect it in HIV positive patients. It was also established by consulting the medical colleagues of the researcher and study supervisor to make an input.

3.4.1.2 Content validity

Burns and Grove (2005:377) define content validity as the extent to which the method of measurement includes all the major elements relevant to the construct being measured. Polit and Beck (2008:458) define it as the degree to which an instrument has an appropriate sample of items for the construct being measured. Content validity is relevant for both affective and cognitive measures.

To ensure content validity, the researcher conducted an extensive literature review especially journal articles and publications addressing the concept of adherence to ART. With a thorough conceptualisation of the construct from literature review, a questionnaire that can capture the entire content domain was designed.

Secondly items from the Adherence Determinants Questionnaire (ADQ) scale that has been tested in a number of adherence studies were incorporated into the questionnaire to measure aspects of the adherence behaviour of the respondents.

To enhance the content validity, the questionnaire was presented for review to the statistician, senior colleagues in clinical practice and the study supervisor to make an input because of their experience in practice and quantitative research. This helped in refining the questions for better meaning, clarity and conceptualisation.

3.4.1.3 Internal and external validity

Internal validity refers to the extent to which it is possible to make an inference that the independent variable is truly causing or influencing the dependent variable and the relationship between the two is not the spurious effect of an extraneous variable. For this study the dependent variable was the adherence level to ART and the independent variables were age, gender, marital status, level of education, occupation, role in the family, HIV status, duration on ART, ARV regimen, dosing schedule, medication changes, interpersonal relationships aspects of care, aspects of care related to the clinic, knowledge and experience about HIV/AIDS and perceptions about the treatment plan. *External validity* is defined as the generalisability of the research findings to other settings or samples. In other words, it is the degree to which the conclusions in the

proposed study would hold for other persons in other contexts and at other times (Polit & Beck 2008:287, 295, 301).

In this study, the anticipated threats to internal and external validity included sample selection, expectancy effect, and instrumentation and researcher effect.

To enhance the internal and external validity the researcher did the following:

- Used multistage cluster random sampling to draw a sample that is representative of the study population.
- Made sure that the accessible population is as much as possible similar in characteristics to the target population.
- Trained two research assistants on how to administer and interpret the questionnaires.

However, the expectancy effect could not be avoided as the respondents' participation in the study could not be hidden since their consent to participate had to be sought. However, it was minimised by emphasizing to the respondents before the interview the importance of the research and what it meant to give the correct answers to the questions asked most especially about the self reported adherence levels.

3.4.2 Reliability

According to Polit and Beck (2008:452), reliability refers to the accuracy and consistency with which an instrument measures the target attribute. It is often associated with the method used to measure the research variables. Burns and Grove (2005:374) define the reliability of a measure as the consistency of measures obtained in the use of a particular instrument. Reliable instruments enhance the power of the study to detect significant differences or relationships actually occurring in the population under study. Reliability exists in degrees and is usually expressed as a form of correlation coefficient with 1.00 indicating perfect reliability and .00 indicating no reliability. A reliability coefficient of 0.80 is considered the lowest acceptable value for a well developed psychosocial measurement instrument and for a newly developed psychosocial instrument, a reliability of 0.70 is considered acceptable.

Reliability testing is concerned with characteristics such as dependability, consistency, precision and comparability.

The researcher used in consultation with a statistician the Cronbach's alpha co-efficient to test reliability for this study.

3.5 DATA ANALYSIS

According to Burns and Grove (2005:43), data analysis is defined as a process that is conducted to reduce, organise and give meaning to the collected data.

Quantitative data management and analysis was done using Epi Info and STATA (Version 10) in consultation with the statistician.

3.5.1 Statistical analysis

Medication adherence was dichotomised on the basis of whether participants were able to adhere to at least 95% of prescribed doses or not.

Descriptive statistics like mean, standard deviations, range, frequency distributions, contingency tables and percentages were obtained. The variables of the respondents such as age, gender, marital status, source of income, educational level, HIV status disclosure to spouse, alcohol use and adherence level were used in the analysis of data to describe and make inference to the sample population.

For inferential statistics, bivariate analysis using Fisher's exact tests were used for categorical data and independent *t*-tests were conducted for continuous variables. Multivariate analysis using logistic regression test was done for all variables reaching significance during the bivariate analyses ($p < 0.05$).

For accuracy of findings, a statistician was consulted (see annexures F & H) on all the statistical tests (see annexure H).

3.6 SCOPE AND LIMITATION OF THE STUDY

There were a number of possible limitations to the study as illustrated below:

- The study used structured questionnaires which limited the possibility of in-depth understanding of the phenomenon under study since there were fixed responses to the questions that could not allow probing questions.
- With a survey the accuracy of responses to the questions by the respondents may be affected by recall bias. Adherence to long term therapy and its determinants is not a single incident but a continuous process over a period of time thus respondents may not be able to recall accurately their medication taking history.

3.7 ETHICAL CONSIDERATIONS

Polit and Beck (2008:753) define ethics as a system of moral values concerned with the degree to which research procedures adhere to professional, legal and social obligations to the study participants.

For any research, the research process starting with identification of the study to publication of the findings should adhere to ethical standards of research which means that the respondents' rights and the rights of the institution should be protected. Scientific integrity should also be maintained. In this study it included aspects such as informed consent, confidentiality, anonymity, respect and dignity (Burns & Grove 2005:83, 176).

3.7.1 Protecting the rights of the participants

The study involved human subjects as respondents thus the following were done to protect their rights:

Informed consent

Obtaining informed consent (see annexure D) from human subjects is essential for the conduct of ethical research. It involves the transmission of essential ideas and content

of the research from the investigator to the prospective subject and then the prospective subject's agreement to participate in the research as a subject is reached after assimilation of the essential information. Informed consent consists of four elements i.e. disclosure of essential information, comprehension, competency and voluntarism (Burns & Grove 2005:193).

To ensure adherence to this stated ethical standard, a written informed consent explaining the objectives, the benefits and potential risks of the study was obtained from each respondent. The respondents signed or put a thumb print to the consent after voluntarily accepting to participate in the study.

Confidentiality and anonymity

Confidentiality is defined as the management of private data so that subjects' identities are not linked with their responses and are never publicly disclosed whereas anonymity is when the subject's identity cannot be linked even by the researcher with his or her individual responses (Burns & Grove 2005:728, 731).

To ensure confidentiality and anonymity, respondents were assured that all their responses and information obtained from them during the study will not be disclosed to anyone. All study materials like questionnaires were free from personal identifiers and no addresses of the respondents were included on the data collection tools to avoid any unfair treatment or possible exploitation of the respondent. For the purpose of confidentiality, data was coded with numbers instead of names.

Respect for human dignity

Respect for human dignity includes the right for self-determination and the right for full disclosure. A respondent's right to self-determination includes freedom from any explicit or implicit threats of penalty from failing to participate in a study or excessive rewards from agreeing to participate. Full disclosure means that the researcher has fully described the nature of the study; the person's right to refuse to participation, the researcher's responsibilities, and the likelihood of risks and benefits (Polit & Beck 2008:171-172).

To ensure *respect and dignity* for the respondents, all respondents before signing the consent had to be briefed about the study objectives, their rights, the benefits and potential risks. Data collection was done in a socially conducive environment and secluded venue. The researcher avoided any form of coercion to force the respondents to participate and no rewards were given to those who accepted to participate in the study.

Right to withdraw from the study

Prospective respondents in a study have a right to self-determination i.e. they have a right to ask questions, refuse to give information, ask for clarification and discontinue participation or withdraw from a study at any time without penalty or loss of benefits (Burns & Grove 2005:194, Polit & Beck 2008:172).

In this study, the respondents were informed of their right to withdraw from the study at any time they wish so if they feel uncomfortable. They were also assured that their withdrawal will not affect their access to all health services offered by TASO Tororo to themselves and their families.

3.7.2 Protecting the rights of the institutions

To conform to bioethical standards, approvals to carry out the study were obtained from the research committee of TASO (see annexure C). This is the institution from which the study participants receive their medical care. Approval was also obtained from UNISA Research and Ethics Committee and a clearance certificate (see annexure A) was issued to carry out the research (see annexure A).

3.7.3 Scientific Integrity of the research

When carrying out the study, the researcher avoided any form of plagiarism by ensuring that all the sources of the scientific information that was quoted in the study were acknowledged and correctly referenced.

3.7.4 Dissemination of the research findings

On completion of the study, the researcher ensured that all the information gained from the research was made available to TASO by providing a copy of the results to the management of the institution and to the respondents themselves through a health talk.

The findings were disseminated to the scientific world through writing an article and submitting it for publication of the findings in scientific journals. A poster was also developed for presentation in workshops, conferences and seminars of same like minded scholars.

3.8 CONCLUSION

This chapter described and discussed the research design and methodology used in the study, including population, sample and sampling technique, data collection instrument, validity and reliability, data collection and analysis, limitation of the study and ethical considerations.

Chapter 4 discusses the data analysis and interpretation of the findings.

CHAPTER 4

Data presentation, analysis and interpretation

4.1 INTRODUCTION

The study was a quantitative, nonexperimental explorative and descriptive investigation to determine the factors that affect adherence to antiretroviral therapy of HIV positive patients in a community home based HIV/AIDS care programme in rural Uganda.

The objectives of this study were to

- explore and describe the factors that influence adherence or non-adherence to antiretroviral therapy by HIV positive patients
- make recommendations to ART and care programs on how to achieve and maintain adequate levels of adherence to ART in HIV positive patients
- design a research poster for presentation of findings to interest groups

4.2 DATA ANALYSIS

The researcher and two trained volunteer research assistants administered the questionnaire to the respondents (see chapter 3). The items on the questionnaire were coded as indicated on the questionnaire (see annexure E). The questionnaire consisted of six sections with 56 items, namely:

- Section A* Personal Data including demographic data such as age, gender, marital status, level of education, occupation and HIV status
- Section B* Aspects of care related to the clinic
- Section C* Interpersonal relationships with the care provider
- Section D* Knowledge and experience about HIV/AIDS
- Section E* Perceptions about the treatment plan
- Section F* Adherence to antiretroviral therapy

The data was analysed using STATA statistical software package (version 10) in consultation with a statistician. Data was collected from 257 respondents (patients) who attended the selected Community Drug Distribution Points (CDDP) with 18 patients not responding thus a 6.5% non-response rate. Descriptive statistics like mean, range, frequency distributions, contingency tables and percentages were obtained. For inferential statistics, bivariate analysis using Fisher's exact tests were used for categorical data and independent *t*-tests were conducted for continuous variables.

4.3 SECTION A: GENERAL INFORMATION

Section A of the questionnaire consisted of 12 questions, covering respondents' personal data including demographic data such as age, gender, marital status, level of education, occupation and HIV status. Some of the percentages were recorded to the second decimal as indicated in the statistician's report.

4.3.1 Gender

Of the respondents, 182 (70.8%) were females and 75 (29.2%) were males. Thus more female respondents than male were interviewed in the study. Table 4.1 depicts the respondent's gender.

In this study there was no association between gender and the respondents' adherence levels (*Fishers' exact=0.307*). Some authors have reported that there was no correlation between gender and adherence which affirms the findings from this study (Haubrich, Little, Currier, Forthal, Kemper, Beall, Johnson, Dube, Hwang and McCutchan 1999:1103). Despite this, Lucas et al (1999:84) observed that women did suffer more allergic reactions, gastrointestinal complications and non-specific symptoms when taking antiretroviral treatment and suggested that this may influence their adherence levels.

4.3.2 Respondents' age

The oldest respondents (1.2%; n=3) were 75 years and older; and the youngest (0.8%; n=2) respondents were less than 25 years. The median age (41.3%; n=106) was between 35 and 44 years.

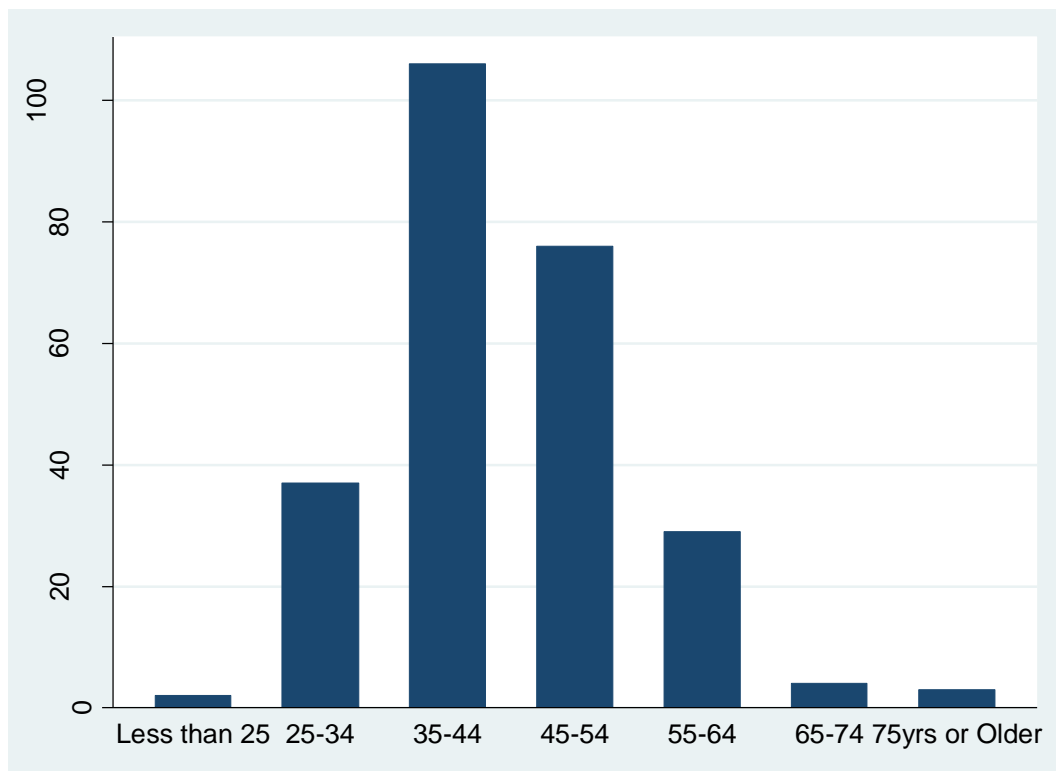


Figure 4.1 Age distribution of the respondents

The respondents were mostly between the ages of 25 and 54 years (85.2%; n=219), which signified a group that is made up of young sexually active and reproductive respondents. This age group is particularly relevant because awareness information about adherence to ART targeted at them can have a significant impact on the decrease in the transmission of drug resistant strains of the HIV virus.

In this study, there was no association found between adherence levels and the age of respondents (*Fisher's exact=0.087*). This finding agrees with a study done by Weidle et al (2006:1591) which found no association between age and adherence to ART. However, there are some studies that have shown old age to be associated with good adherence than younger age (Barclays et al 2007:44; Gordillo et al 1999:1766).

4.3.3 Respondents' marital status

Of the respondents, 44.8% (n=115) indicated that they were married, 34.6% (n=89) were widowed, 3.9% (n=10) were separated, 4.3% (n=11) were divorced, 1.6% (n=4) were never married and only 0.4% (n=1) was cohabiting. Of note, 10.5% (n=27) indicated otherwise.

Of note is the percentage of respondents who were widowed (34.6%; n=89). For an old epidemic, this could be explained by the recency of the introduction of the universal ART access program or a high unmet need for the ART treatment in the district.

There was no association between marital status and adherence to ART (*Fisher's exact=0.393*). This finding agrees with a study done by Weidle et al (2006:1591) which found no association between socio demographic factors such as marital status and adherence to ART.

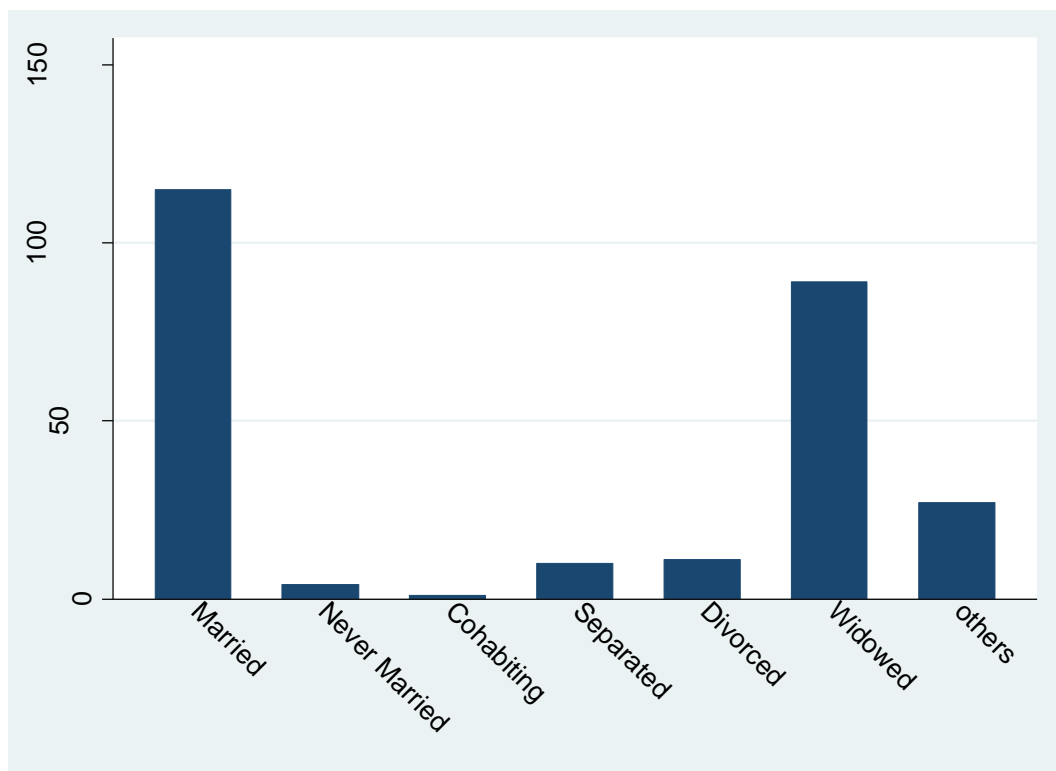


Figure 4.2 Marital statuses of the respondents

4.3.4 Respondents' education level

Of the respondents 28.8% (n=74) indicated that they had no schooling; 40.9% (n=105) had a primary education; 23% (n=59) had a secondary education and 7.4% (n=19) had some form of post-secondary school education.

As expected of the rural population, there are low education levels with the majority of the respondents (69.6%; n=179) having completed at most a primary education level. This was reflected in the number of respondents being either peasants (61.9%; n=159) or business/self employed (16%; n=41) by occupation.

In this study, there was no significant association between education levels and adherence to ART (*Fisher's exact=0.666*). This finding is in agreement with the studies that have been done and found no relationship. (Barclays et al 2007:44, Weidle et al 2006:1591). However, Gifford et al 2000:388 in their study found an association between a college degree and better adherence to ART.

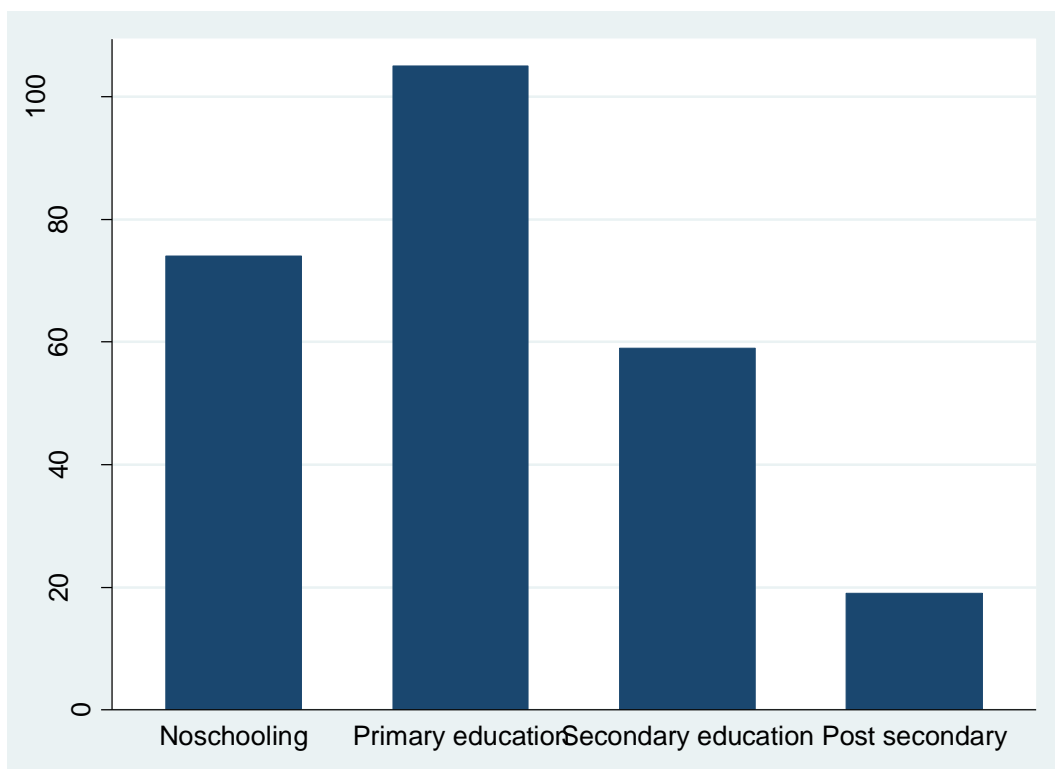


Figure 4.3 Education levels of respondents

4.3.5 Occupation of respondents

Of the respondents 61.9% (n=159) were peasants; 7.4% (n=19) were labourers/house workers; 1.6% (n=4) were in business/company; 16% (n=41) were in business/self employed; 4.7% (n=12) were professional/company; 2.7% (n=7) were professional/self employed; 3.5% (n=9) were unemployed and 2.3% (n=6) were into other occupations.

In this study there was no association between occupation of respondents and adherence to ART (*Fisher's exact=0.980*). This finding concurs with a study done by Paterson et al (2000:26), who found no association between employment and adherence. However, Gordillo et al (1999:1767) in their study found having a job was associated with better compliance to treatment.

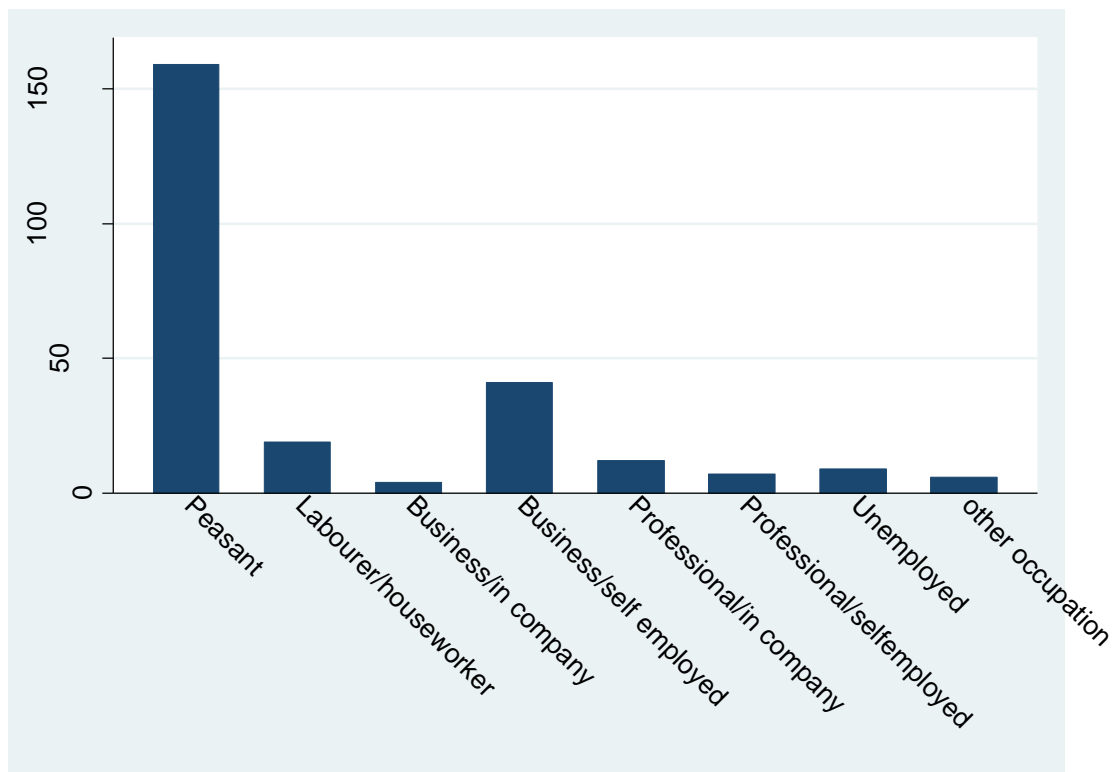


Figure 4.4 Occupations for the respondents

4.3.6 Head of household

Of the respondents 79.38% (n=204) were household heads and 20.62% (n=53) were not household heads. This shows that majority of the respondents had many responsibilities and this could affect their adherence to ART. This was reflected in the reasons given by respondents for missing their doses as forgetfulness 5.8 % (n=15) and pills not available 3.9% (n=10).

4.3.7 Sole provider for family

Of the respondents 79.38% (n=204) were sole provider for the family. With majority of them (64.6%; n=166) having children under 12 years of age. This shows that majority of the respondents were the bread winners for their household and had minors to look after. This could be a motivation factor for the respondents to adherence to their treatment so as to stay health and look after their families.

However on bivariate analysis, there was no association between being a sole provider for the family or having children below 12 years and adherence to ART (*Fisher's exact = 0.702 and 0.057 respectively*). This is in contrast to findings by Eldred et al 1998:121, where there was an association between adherence to ART plus PCP prophylaxis and the presence of family.

4.3.8 Respondents' disclosure to spouses

Of the respondents who had spouses 88.4% (n=130) their spouses knew their HIV status and 11.6% (n=17) had never disclosed their HIV status. This shows that majority of the respondents had disclosed their HIV status to their partners. This could be explained by couple testing and disclosure to the partner by the patients before starting ART done by TASO as a strategy to avoid drug sharing and maintain good adherence to ART. In addition, having disclosed to the partner could help the respondents to adherence to their treatment as they can get both physical and psychological support from their spouses with regards to adhering to their treatment.

Although there are few studies that have tried to established an association between disclosure of health status and adherence to treatment, one qualitative study that

explored tuberculosis patients' adherence to treatment regimen found that fear of disclosing the health status by the patient was hindering adherence to the treatment (Naidoo, Dick & Cooper 2009:62).

Of note is that 34.7% of the respondents with partners were in discordant relationships. This is of public health importance in that there is need to emphasise prevention among discordant couples within ART programs to prevent transmission of drug resistant virus to the negative partner.

4.3.9 Reminders for the HIV clinic day visits and as aid in adhering to ART at home

Of the respondents 42.8% (n=110) posted reminders for the HIV Clinic day Visits and 57.2% (n=147) posted no reminders. In addition, 40.5% (n=104) of the respondents posted reminders to aid them in adhering to ART at home and 59.5% (n=153) posted no reminders. This shows that a big number of respondents are prone to forgetting their clinic days and dose taking times. This is reflected in the main reasons given by respondents of why they missed their doses with forgetfulness 5.8% (n=15) and pills not being available 3.9 % (n=10) ranking high on the list.

In this study, posting reminders for the HIV clinic day visits and as an aid to adhering to ART at home had no association to adherence to ART (*Fisher's exact=0.360 and 1.00 respectively*). This concurs with a study whose findings did not find any association between 95% or greater adherence and use of a timer or alarm as a reminder to take therapy (Paterson et al 2000:26). However, a study done by Weidle et al (2006:1591), found that having daily events as reminders was one of the most important aids to taking drugs on schedule.

4.4 SECTION B: ASPECTS OF CARE RELATED TO THE CLINIC

This section dealt with the perception of the respondents to the aspects of care related to the clinic. It consisted of seven item statements on a likert scale scoring from 1 to 5 (*strongly agree to strongly disagree respectively*). Each statement elicited a response to one of the aspects of the ART clinic like accessibility, transport costs, waiting time, convenience of the appointments, staffing, drug availability and the clinic environment.

In terms of the individual statements, some findings of note are highlighted in the table below.

Table 4.1 Aspects of care related to the clinic

Aspects of care related to the clinic	Perceptions on care related to the clinic			Total
	Agree	Disagree	Undecided	
The ART clinic is easily accessible	235 (91.44%)	16 (6.23%)	6 (2.33%)	257 (100%)
Transport costs to the ART clinic are affordable	196 (76.26%)	40 (15.56%)	21 (8.17%)	257 (100%)
The waiting time is short	138 (53.70%)	87 (33.85%)	32 (12.45%)	257 (100%)
My appointment dates for drug refills are convenient	229 (89.11%)	13 (5.06%)	15 (5.84%)	257 (100%)
The clinic is adequately staffed	165 (64.20%)	27 (10.51%)	65 (25.29%)	257 (100%)
The drugs are always available at the ART clinic	253 (98.44%)	2 (0.78%)	2 (0.78%)	257 (100%)
The physical environment of the clinic appears neat and welcoming	193 (75.10%)	23 (8.95%)	41 (15.95%)	257 (100%)

With regard to the perceptions on aspects of care related to the clinics, described in item 13 to 19, frequency distributions indicated general agreement on most of the aspects by the respondents that:

- The ART clinic is easily accessible (91.44%)
- Transport costs to the ART clinic are affordable (76.26%)
- The waiting time is short (53.70%)
- Their appointment dates for drug refills are convenient (89.11%)
- The clinic is adequately staffed (64.20%)
- The drugs are always available at the ART clinic (98.44%)
- The physical environment of the clinic appears neat and welcoming (75.10%)

TASO is well funded and uses the Community Drug Distribution Points (CDDPs) to deliver the ART drugs as near as possible to its patients thus this could explain the near perfect agreement of the respondents to easy accessibility and availability of drugs at the clinic. However, the medical team that runs these CDDPs has to travel longer distances to reach the CDDP and this might increase the waiting time for the patients to receive their drugs thus the lower percentage of respondents who agree with waiting time being short.

On the composite scale measurement, the average score was 12.15 (7-27) given that the individual score on this scale of 7 and 35 represents extreme positivity and negativity respectively. This showed that majority of the respondents were positive about the aspects of care related to the clinic like accessibility, physical environment, drug availability, etc.

Being positive about the different aspects of care related to the clinic could be a motivating factor for the respondents to adherence to their ART thus the high levels of adherence observed in the study respondents. This is in agreement to some studies done that found a number of aspects of a clinical setting that may be associated with adherence including transportation, waiting time, convenience of scheduling appointments, integrated services and confidentiality (Ickovics & Meade 2002:S99; Lucas, Chaisson & Moore 1999:84).

However on the composite scale (average score on all the seven items), there was no significant association between the respondents' perception about the aspects of care related to the clinic and their adherence levels ($t=-0.9496$, $p=0.3432$).

4.5 SECTION C: INTERPERSONAL RELATIONSHIP WITH THE CARE PROVIDERS

This section dealt with the perception of the respondents about their relationship with the doctors and other healthcare professionals. It consisted of 12 item statements on a likert scale scoring from 1 to 5 (*strongly agree to strongly disagree respectively*). Each statement elicited a response to one of the aspects of the interpersonal relationship between the respondent and the care providers like show of respect for their confidentiality, positive approach to life by health professionals, medical knowledge-ability, etc.

In terms of the individual statements, some findings of note are highlighted in the table below.

Table 4.2 Interpersonal relationship with the care providers

Aspects of interpersonal relationship with the care provider	Perception			Total
	Agree	Disagree	Undecided	
They listen carefully to what I have to say	236 (91.83%)	14 (5.45%)	6 (2.72%)	257 (100%)
They are patient with me	226 (87.94%)	17 (6.61%)	21 (5.45%)	257 (100%)
They answer all my questions	227 (88.33%)	15 (5.84%)	15 (5.84%)	257 (100%)
The health professionals' responses to my queries attest to their medical knowledgeability	212 (82.49%)	11 (4.28%)	34 (13.23%)	257 (100%)
They use medical terms which I easily understand	235 (91.44%)	9 (3.50%)	13 (5.06%)	257 (100%)
They show respect for my confidentiality	226 (87.94%)	10 (3.89%)	21 (8.17%)	257 (100%)
Am always treated in a friendly and courteous manner	229 (89.11%)	11 (4.28%)	17 (6.61%)	257 (100%)
They give clear instructions on how medications should be taken	246 (95.72%)	7 (2.72%)	4 (1.56%)	257 (100%)
The staff treat me with dignity	218 (84.82%)	12 (4.67%)	27 (10.51%)	257 (100%)
The health professionals radiate a positive approach towards life	231 (89.88%)	11 (4.28%)	15 (5.84%)	257 (100%)
The health professionals show respect for life	233 (90.66%)	15 (5.84%)	9 (3.50%)	257 (100%)
The health professionals are empathetic	203 (78.99%)	34 (13.33%)	20 (7.78%)	257 (100%)

With regard to the perceptions on the interpersonal relationship between the respondents and the care providers described in item 20 to 31, frequency distributions indicated general agreement on most of the aspects by the respondents that:

- They listen carefully to what they have to say (91.83%)
- They are patient with them (87.94%)
- They answer all their questions (88.33%)
- The health professionals' response to the respondents' queries attest to their medical knowledgeability (82.49%)
- They use medical terms which respondents easily understand (91.44%)
- They show respect for their confidentiality (87.94%)
- The respondents are always treated in a friendly and courteous manner (89.11%)
- They give clear instructions on how medications should be taken (95.72%)
- The staffs treat them with dignity (84.82%)

- The health professionals radiate a positive approach towards life (89.88%)
- The health professionals show respect for life (90.66%)
- The health professionals are empathetic (78.99%)

On the composite twelve item likert scale measurement (*strongly agree to strongly disagree*), the average score was 18.02 (12-58) given that the individual score on this scale of 12 and 60 represents extreme positivity and extremely negativity respectively. This showed that on average majority of the respondents were positive about their interpersonal relationship with the care providers like showing respect for their confidentiality, answering their questions etc. This could be explained by TASO's organisational approach to HIV Care whereby they strive to offer a comprehensive and defined package of quality counseling, medical and social support services to people living with HIV and their families through well-trained health workers.

This general positivity about the interpersonal relationship with care providers could explain the high levels of adherence shown in the findings of this study (95.72% of the respondents above 95%). This is in conformity to findings from some studies done which indicated that absence of a meaningful and supportive relationship between the patient and healthcare provider plus poor attitude of the health care team at the clinic can be a significant barrier to adherence (Chesney 2000:173; Naidoo et al 2009:62; Stone et al 1998:591; WHO 2003a:100).

Of note is that on the composite scale (average score on all the twelve items), there was no significant association between the respondents' perception about interpersonal relationship with the care providers and their adherence levels ($t=-1.2514$, $p=0.2119$).

4.6 SECTION D: KNOWLEDGE AND EXPERIENCE ABOUT HIV/AIDS

Using a ten item statement Likert scale scoring from 1 to 5 (*strongly agree to strongly disagree*), this section dealt with the knowledge and experience of the respondents about HIV/AIDS. Each statement elicited a response to one of the statements about HIV/AIDS as a disease, mode of transmission and its treatment.

In terms of the individual statements, some findings of note are highlighted in the table below.

Table 4.3 Knowledge and experience about HIV/AIDS

Item	Response			Total
	Agree	Disagree	Undecided	
HIV/AIDS is a curable disease	78 (30.35%)	134 (52.14%)	45 (17.51%)	257 (100%)
The risk of contracting other diseases increase if one is HIV positive	217 (84.44%)	13 (5.06%)	27 (10.51%)	257 (100%)
HIV/AIDS treatment has many side effects	212 (82.49%)	23 (8.95%)	22 (8.56%)	257 (100%)
Life expectancy of HIV/AIDS patients improve once they receive ARV treatment	247 (96.11%)	2 (0.78%)	8 (3.11%)	257 (100%)
The HIV virus can be transmitted to a baby who is breast fed	208 (80.93%)	6 (2.33%)	43 (16.73%)	257 (100%)
Compliance to diet as suggested by the health professional is important	256 (99.61%)	0 (0.00%)	1 (0.39%)	257 (100%)
Compliance to the ARV treatment prescribed by the health professional is essential	256 (99.61%)	0 (0.00%)	1 (0.39%)	257 (100%)
Substance and/or alcohol abuse will not impair the effectiveness of the ARV treatment	26 (10.12%)	212 (82.49%)	19 (0.42%)	257 (100%)
I expect to be cured from HIV in the future	159 (61.87%)	35 (13.62%)	63 (24.51%)	257 (100%)
ARV drugs are the only effective treatment plan available to combat the effect of HIV/AIDS	195 (75.88%)	17 (6.61%)	45 (17.51)	257 (100%)

With regard to the knowledge and experience about HIV/AIDS, described in item 32 to 41, frequency distributions indicated that almost all respondents are knowledgeable about compliance to the ART prescribed by the health professional as being essential (99.61%), that life expectancy of the respondents improves once they receive ARV treatment (96.11%) and the effectiveness of ARV drugs in combating HIV/AIDS (75.88%). This could be explained by the fact that majority of the respondents had been on ART for more than 5 years (figure 4.5) plus the continuous provision of HIV/AIDS education and Counseling to the patients at any encounter with the healthcare providers at the TASO clinics.

These high levels of knowledge about compliance to and the effectiveness of ART, could explain the high levels of adherence shown in the findings of this study (95.72% of the respondents above 95%). These findings in this study are consistent with a study done by Wenger et al 1999 which reported better adherence in patients who believed

antiretroviral medication to be effective. As regards the Health Belief Model(HBM), this outcome shows that structural variables for example past experience, knowledge of the disease etc as modifying factors that modify a person’s perceptions about a disease might be predictors of or influence adherence to ART (Hayden 2009:32-35; Stanhope & Lancaster 2005:271-272).

However, there are unexplainable high percentages of respondents who seem to agree that HIV/AIDS is curable (30.35%) and they expect to be cured from HIV/AIDS in the near future (61.87%).

4.7 SECTION E: PERCEPTIONS ABOUT THE TREATMENT PLAN

This section dealt with the perception of the respondents about their treatment plan. It consisted of 8 item statements on a likert scale scoring from 1 to 5 (*strongly agree to strongly disagree respectively*). Each statement elicited a response to one of the aspects of the treatment plan like its convenience, compatibility with other activities and whether it is essential to follow it.

In terms of the individual statements, some findings of note are highlighted in the table below.

Table 4.4 Perceptions about the treatment plan

Item	Perceptions			Total
	Agree	Disagree	Undecided	
The suggested ARV treatment plan is convenient for me and my family	247 (96.11%)	7 (2.72%)	3 (1.17%)	257 (100%)
The treatment plan is not difficult to follow	250 (97.28%)	5 (1.95%)	2 (0.78%)	257 (100%)
Following my treatment plan will help me to be healthy	254 (98.83%)	0 (0.00%)	3 (1.17%)	257 (100%)
I have made a commitment to follow my treatment plan	257 (100%)	0 (0.00%)	0 (0.00%)	257 (100%)
I need assistance from the health professionals in order to stick to my treatment plan	217 (84.44%)	7 (2.72%)	33 (12.84%)	257 (100%)
If I stick to my treatment plan rigorously, I find that I am able to deal with daily personal problems	246 (95.72%)	3 (1.17%)	8 (3.11%)	257 (100%)
I realize that strict adherence to the treatment plan is essential for the ARV treatment to be	252 (98.05%)	0 (0.00%)	5 (1.95%)	257 (100%)

effective				
ARV drugs will be effective even if I do not take them regularly	23 (8.95%)	223 (86.77%)	11 (4.28%)	257 (100%)

With regard to the perception about the treatment plan, described in item 42 to 49, frequency distributions indicated general agreement on most of the aspects by the respondents that:

- The suggested ARV treatment plan is convenient for the respondents and their families (96.11%)
- The treatment plan is not difficult to follow (97.28%)
- Following their treatment plan will help them to be healthy (98.83%)
- They have made a commitment to follow their treatment plan (100%)
- They need assistance from the health professionals to stick to their treatment plan (84.44%)
- If they stick to the treatment plan rigorously, they find that they are able to deal more effectively with their daily personal problems (95.72%)
- They realize that strict adherence to the treatment plan is essential for the ARV treatment to be effective (98.05%)
- ARV drugs will not be effective when they are not taken regularly (86.77%)

With regard to the respondents' perceptions about the treatment plan, respondents indicated a positive perception about the treatment plan on the composite scale with an average score on the eight item scale of 13.16(8-22). This high level of positivity to the treatment on the both the individual items and the composite scale could explain the high levels of adherence shown in the findings of this study (95.72% of the respondents above 95%).

These findings concur with some studies done which showed that the extent of complexity of the ART regimens and treatment plan greatly influenced an individual's willingness and ability to adhere to therapy plus patients with higher self-efficacy beliefs about using antiretroviral agents had better adherence (Chesney et al 2000:1603; D'Armino et al 2000:505; Gifford et al 2000:389).

Of note is that on the composite scale (average score on all the 8 items), there was no significant association between the respondents' perception about the treatment plan and their adherence levels ($t= 0.6270$, $p= 0.5312$).

4.8 SCALE RELIABILITY MEASURE OF RESPONDENTS' PERCEPTIONS OF ART

The four sections (B, C, D and E) consisted of socio-psychological scales developed to measure: aspects of care related to the clinic, interpersonal relationships with the care providers, knowledge and experience about HIV/AIDS and perceptions about the treatment plan.

Reliability was measured by means of the Cronbach's alpha coefficient, calculated as part of item analysis or scale reliability testing for each of the four scales that measured: aspects of care related to the clinic, interpersonal relationships with the care provider, knowledge and experience about HIV/AIDS and perceptions about the treatment plan.

Table 4.5 Mean score, standard deviation, minimum score, maximum score and Cronbach's alpha coefficient for the scales (N=257)

Scale	Mean score	Standard deviation	Minimum Score	Maximum Score	Cronbach's Alpha
Aspects of care related to the clinic	12.15	4.97	7	27	0.78
Interpersonal relationships with the care providers	18.02	7.85	12	58	0.92
Knowledge and experience about HIV/AIDS	20.17	3.70	10	31	0.50
Perceptions about the treatment plan	13.16	2.31	8	22	0.60

Of note is that all the four scales were newly developed and two of them had a low Cronbach's alpha coefficient that is to say knowledge and experience about HIV/AIDS (=0.50) and perceptions about the treatment plan (=0.60) on the measure of reliability compared to the required acceptable minimum of 0.70 for a newly developed psychosocial instrument (Burns & Grove 2005:374).

4.9 SECTION F: ADHERENCE TO ANTIRETROVIRAL THERAPY

Section F of the questionnaire consisted of 7 questions covering the respondent’s ARV drug history and adherence profile.

4.9.1 Respondents’ current ARV regimen

Of the respondents 81.3% (n=209) are on AZT/3TC/NVP; 8.6% (n=22) are on AZT/3TC/EFV; 7.4% (n=19) are on TNF/3TC/NVP; 2.0% (n=5) are on TNF/3TC/EFV and <1% (n=2) are on second line i.e. TRUVADA/ALLUVIA.

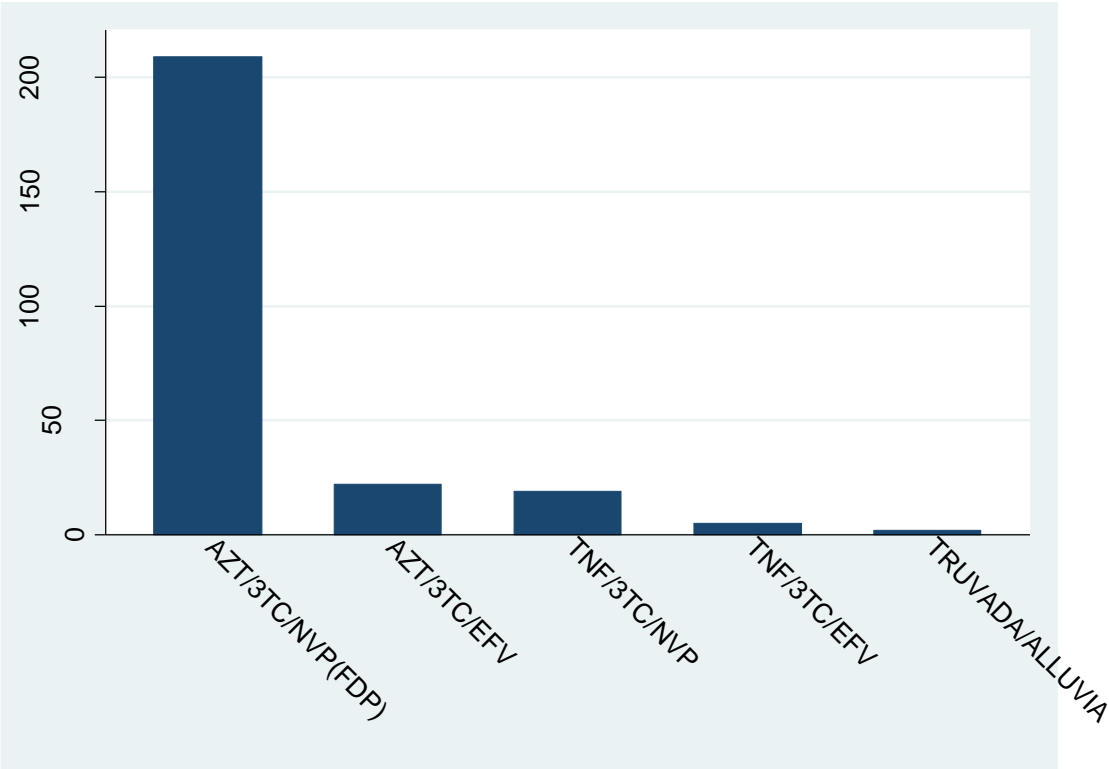


Figure 4.5 Respondents’ current ARV regimen

This shows that majority of the respondents (81.3%) are still on first line regimen of Zidovudine, Lamivudine and Nevirapine. These drugs are known to have no profile of long term side effects like peripheral neuropathy, lipodystrophy and metabolic changes that may affect adherence to ART thus this could explain the high levels of adherence seen in this study (Chesney 2000:173; Max & Sherer 2000:98-108; Roberts & Mann 2000:380; Stone 2001:869).

However, there was no association noted between the respondents current ARV regimen and the adherence levels (*Fishers' exact=0.331*).

4.9.2 Respondents' duration on ARV drugs

Of the respondents 29.2% (n=75) had been on ARV drugs for 2 to <3years; 12.5% (n=32) for 3 to <4 years; 17.9% (n=46) for 4 to <5 years and 40.5% for more than 5 years.

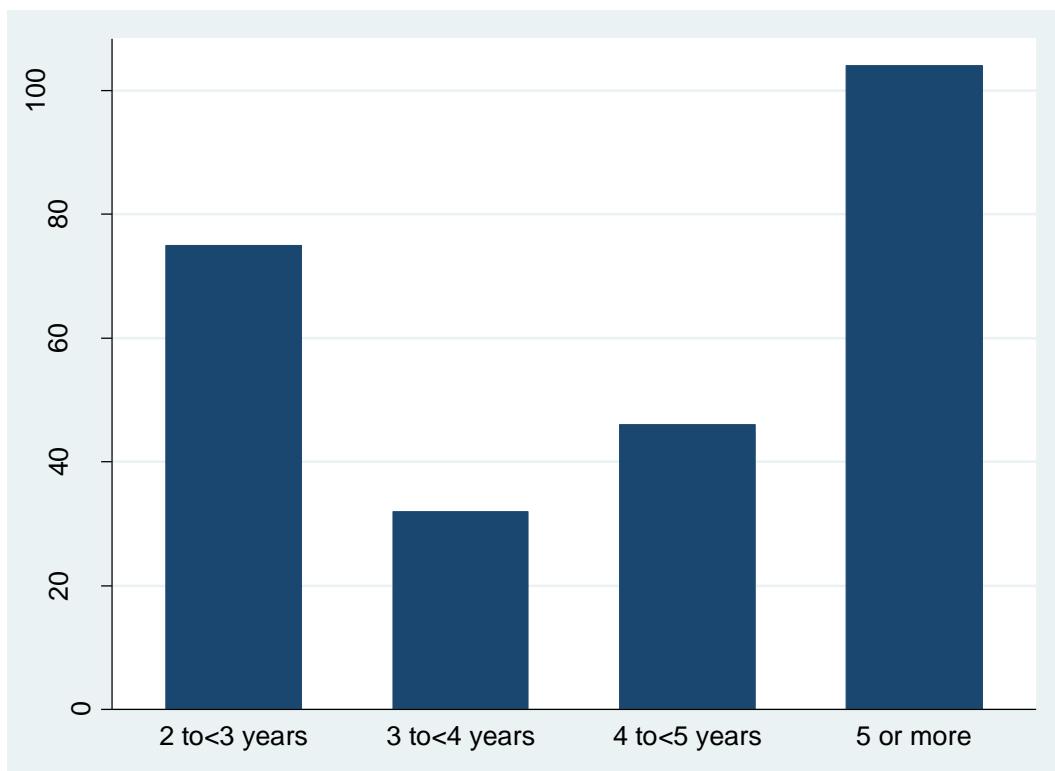


Figure 4.6 Duration on ARV drug by the respondents

In this study, 40.5% (n=104) of the respondents had been on drugs for five or more years and the majority (99.2%; n=255) are still on first line regimens containing Zidovudine, lamivudine, Tenofovir, Efavirenz and Nevirapine. This is of significance in that with limited resources and few drug options available to choose from, this prolonged stay on first line treatment if its maintained then sustainability of ART programs can be guaranteed.

Of note is that, there was no association between respondents' duration on ARV drugs and the adherence levels (*Fishers' exact=0.940*). This concurs with a study done by

Gordillo et al (1999:1767) where the length of time the patient had been on treatment was not statistically associated with adherence. However, Mo and Mak (2009:789) in their study found that patients with longer length of medication were more likely to be classified as non-adherent at follow-up.

4.9.3 Improvement in the quality of life of respondents

Of the respondents 99.6% (n=256) reported improvement in the quality of life after starting ARV drugs and 0.4% (n=1) reported no improvement. This could have been one of the motivating factors for the respondents to adherence to their ART as they saw the improvement in their health status comparing before and after starting treatment thus the high levels of adherence observed in this study. This is re affirmed from the high percentage of respondents (98.83%) in this study who agreed that following their treatment plan would help them to be healthy (table 4.5).

However, no association was observed between improvement in the quality of life of the respondents and the adherence levels (*Fishers' exact=1.00*). Few HIV studies have examined this directly except in one study which showed that prior opportunistic infections increased adherence suggesting that illness severity motivated patient adherence (Singh et al 1996:266).

4.9.4 Number of times per day respondents takes their ARV drugs

Of the respondents 98.8% (n=254) take their ARV drugs twice per day and 1.2% (n=3) take them once in a day. This shows that all the respondents are not on a complex regimen with regards to the frequency of medication. This could be one of the reasons to explain the high levels of adherence observed in this study.

Of note in this study is that, there was no significant association between the frequency of medication taking and the adherence levels (*Fishers' exact=1.000*). This is in total contrast to studies which found that frequency of medication dosing was associated with adherence to antiretroviral therapy whereby patients who were prescribed twice daily therapy reported greater adherence than those prescribed ≥ 3 times/day.

Since all the respondents were on twice or less frequency of medication dosing, this could explain the variation of findings between this study and those in literature.

4.9.5 Doses missed by the respondents' in the last two weeks

Of the respondents 5.5% (n=14) missed one dose in the last two weeks; 2.0% (n=5) missed two doses; 1.2% (n=3) missed three doses; 1.2% (n=3) missed many doses and 90.3% (n=232) did not miss any doses.

Table 4.6 Doses missed by the respondents' in the last two weeks

Doses	N	%
One	14	5.5
Two	5	2.0
Three	3	1.2
Many	3	1.2
None	232	90.3
Total	257	100.0

Missed doses are inversely related to the level of adherence whereby the more the doses a patient misses the lower the levels of adherence. Paterson et al (2000:25) note that CD4 counts were significantly associated with degree of adherence at whatever length of follow-up whereby changes in CD4 counts differed significantly between patients with 95% or greater adherence and those with less than 95% adherence. This shows that there is a relationship between missed doses and adherence levels.

In this study majority of respondents (90.3%) had missed no doses in the last 14 days. This correlates well with the high levels of adherence observed in this study (95.7% had an adherence level above 95%).

4.9.6 Reasons for respondents missing their treatment dosages

The main reasons given by respondents for missing their doses were: forgetfulness (n=15); toxicity or side effects (n=1); pills not working (n=1); pills not available (n=10) and medication fatigue (n=1).

Table 4.7 Association between reasons for missing treatment doses and respondents' adherence levels: Fisher's exact test

Reason	Fisher's Exact
Forgetfulness	<0.001(sig.)
Toxicity or side effects	0.043
Pills are not working	0.043
Pills are not available	<0.001(sig.)
Too sick to take medications	-
Instructions from medical workers	-
Medication fatigue	0.043

Among the reasons for missing treatment doses; forgetfulness and pills not being available were significantly associated with the adherence levels (table 4.9). However, toxicity or side effects, pills not working, too sick to take medications, instructions from medical workers and medication fatigue were not significantly associated with adherence levels.

These findings are consistent with the results from a study done by Weidle et al (2006:1592) where the commonest reasons for missing doses were being away from home (3.2-5.9%) and forgetting (3.5-5.7%). Of note is that, in this study we regarded being away from home as a subset of pills not available. In a systematic review done by Ammassari et al (2002:126), forgetfulness about taking medications appeared prominent (30-66%) in published studies conducted in different settings that reported the most common reasons for skipping HAART thus further reaffirming the study findings.

These results could be explained by the substantial number of respondents who did not post any reminders for both HIV clinic day visits (57.2%) and as an aid in adhering to ART treatment at home(59.5%).

Of note is the single respondent who gave toxicity or side effects as a reason for missing the doses given that majority of the respondents had been on ART for a long duration. The expectation would have been for toxicity or side effects appearing prominent as a reason for missed doses as per findings from various studies which show side-effects as being consistently associated with decreased adherence whereby

optimal adherence occurs with medications that remove symptoms than medications that produce side effects. This could be explained by the fact that majority of the respondents (81.3%) were still on first line regimen of Zidovudine, Lamivudine and Nevirapine (figure 4.6). These drugs are known to have no profile of long term side effects like peripheral neuropathy, lipodystrophy and metabolic changes that affect adherence to ART (Chesney 2000:173; Max & Sherer 2000:98-108; Roberts & Mann 2000:380; Stone 2001:869).

4.9.7 Times respondents’ medications were changed

Of the respondents 41.3% (n=106) had their medications changed once; 12.5% (n=32) were changed twice; 6.6% (n=17) were changed thrice and 39.7% (n=102) had not been changed.

Table 4.8 Times respondents’ medications were changed

Number of times	N	%
Once	106	41.3
Twice	32	12.5
Thrice	17	6.6
None	102	39.7
Total	257	100.0

Changing medications in ART would be indicated either as a result of severe side effects, drug interactions as a result of co-morbidity with another disease like Tuberculosis or that medications are failing to control the HIV virus.

Of note is that no question in this study addressed the reasons for change of medication. However, medication failure as a reason for change is least in this study as shown by the few respondents on second line regimen (<1%) thus the possible reasons for change of medication would be severe side effects and drug interactions due to co-morbidity. Secondly there was a change in policy whereby Stavudine was stopped from being used and replaced by Zidovudine as a drug of choice prompting majority of HIV care providers to switch all their patients from Stavudine to Zidovudine(MOH 2009:23-27).

4.9.8 Adherence levels of respondents

Of the respondents 95.7% (n=246) had an adherence level above 95% and 4.3% (n=11) had less than 95%.

The study revealed that 95.7% of the respondents reported a good adherence to ART with adherence levels above 95%. This is comparable to an adherence study done in rural Uganda where 97.4% of participants had a pill count adherence of more than 95% although for this study the period of patients being on treatment was less than 2 years (Weidle et al 2006:1590). This also reaffirms the conclusion from a meta-analysis done by Mills et al (2006:685) that favourable levels of adherence much of which was assessed via patient self report can be achieved in Sub-Saharan settings.

The high levels of adherence could be explained by unlimited counseling support that is offered to the patients by the TASO medical team, the use of a medicine companion within the family of the patients to provide adherence support and the delivery of ARV drugs as near as possible to the patients in the community. This is supported by findings from a study by Weidle et al (2006:1591) where patients indicated support from the medicine companion and counselors as important aids to taking the drugs on schedule daily.

In summary: The study revealed that 95.7% of the respondents reported a good adherence to ART with adherence levels above 95%. Respondents were generally positive about the aspects of care related to the clinic, interpersonal relationship, perception about the treatment plan and were knowledgeable about HIV/AIDS. Two reasons for missing treatment doses i.e. forgetfulness and pills not being available were significantly associated with the adherence levels.

However, it was noted with concern that 9.7% of the respondents had missed at least one dose in the last 14 days and there are unexplainable high percentages of respondents who seem to agree that HIV/AIDS is curable (30.35%) and they expect to be cured from HIV/AIDS in the near future (61.87%). Although majority of the respondents (99.6%; n=256) reported improvement in the quality of life since starting ART.

4.10 CONCLUSION

This chapter discussed the data analysis and interpretation with the use of frequency tables, graphs, descriptive and inferential statistics. The results of the study reveal generally positive perceptions and satisfaction by the patients about the quality of health care provided by the staff at the CDDPs managed by TASO Tororo and a wider knowledge and experience about HIV/AIDS.

Chapter 5 concludes the study, discusses its limitations, and makes recommendations for practice, education and research. A layout of the developed poster is also included.

CHAPTER 5

Conclusions and recommendations

5.1 INTRODUCTION

This chapter discusses the conclusions of the study and makes recommendations to health care providers of the ART and facilitators of health care programs on how to achieve and maintain adequate levels of adherence to ART in HIV positive patients.

5.2 OBJECTIVES OF THE STUDY

The objectives of this study were to

- describe the factors that influence adherence or non-adherence to antiretroviral therapy by HIV positive patients
- make recommendations to ART and care programs on how to achieve and maintain adequate levels of adherence to ART in HIV positive patients
- design a research poster for presentation of findings to interest groups

5.2 ADHERENCE TO ART TREATMENT

For any programme that is involved in care and treatment of HIV positive patients using ARV drugs, their clinical goals of HIV treatment are optimally accomplished through consistent high-levels of adherence to ART and durable suppression of the viral load (Lucas2005:415). According to Paterson et al 2000: 27-28, 95% of adherence to therapy is the minimum level necessary to maintain viral load suppression. This is well reflected in the findings of the study where the majority of the respondents (95.7%) reported an adherence level above 95%.

However, for those who missed doses, two reasons i.e. forgetfulness and pills not being available were significantly associated with their adherence levels. This is consistent with findings from others studies that showed forgetfulness and none availability of pills

as the main reasons given by HIV patients for missing their doses (Ammassari et al 2002:126; Weidle et al 2006:1592).

According to the Health Belief Model (HBM), perception of benefit in an intervention/ health action can lead to increase in the taking up the action. The findings from the study show that majority of respondents (99.6%) reported improvement in the quality of life after starting ARV drugs which could explain the high levels of adherence among respondents since they appreciated some benefit from their ART . This adds evidence to the assumption that perceived benefit could be a predictor of or can influence adherence to medications.

5.3 FACTORS AFFECTING ADHERENCE TO ART

5.3.1 Demographic data

In this study, none of the demographic variables/personal related factors showed significant association to the adherence levels of the respondents. This is consistent with studies done where socio demographic factors generally did not predict adherence behaviour although some studies did find that male sex, white ethnicity; older age, higher income, higher education, and literacy correlate with better adherence (Eldred et al 1998:121; Gifford, Bormann, Shively, Wright, Richman & Bozzette 2000:388-389; Kleeberger, Phair, Strathdee, Detels, Kingsley & Jacobson 2001:87-88; Weidle et al 2006:1591).

Secondly, as regards to the HBM, these findings show that demographic factors for example age, gender, marital status, education level etc as one of the modifying factors that modify a person's perceptions about a disease might not be predictors of or influence adherence to ART (Hayden 2009:32-35; Stanhope & Lancaster 2005:271-272).

5.3.2 Aspects of care related to the clinic

With regards to perceptions on aspects of care related to the clinic, the responses indicated general agreement on most of the aspects asked. These might have had great positive influence on the levels of adherence as evidenced by high percentages of

respondents, who were positive about aspects of the ART clinic like accessibility (91.44%), transport costs (76.26%), waiting time (53.70%), convenience of the appointments (89.11%), adequate staffing (64.2%), drug availability (98.44%) and the clinic environment (75.10%). In some studies done, a number of aspects of a clinical setting were associated with adherence including transportation, waiting time, convenience of scheduling appointments, integrated services and confidentiality (Ickovics et al 2002:S99; Lucas et al 1999:84).

In reference to the HBM, aspects of care related to the clinic can be seen as modifying factors or barriers to good adherence. These findings show that perceptions about aspects of care related to clinic like accessibility, transport costs, waiting time, convenience of the appointments, staffing, drug availability and the clinic environment might be predictors of adherence to ART. Welch, Bannett, Delp and Agarwal 2006: 175 in their study about benefits of and barriers to dietary sodium adherence noted the influence of perceived barriers on adherence by patients to the specified treatment regimen.

5.3.3 Interpersonal relationships with the care providers

Health Professionals play a major role in helping patients to implement healthy behaviours. This can be through helping to reduce threats and barriers to action by improving communication with patients, minimizing inconveniences and support positive actions (Kozier et al 2008:249).

In this study, the findings show that there was a general positive attitude towards the interpersonal relationships between the respondents and the care providers. This is evidenced by the high percentage of respondents who indicated that the care providers listen carefully to what they have to say (91.83%), are patient with them (87.94%), answer all their questions (88.33%), use medical terms which they easily understand (91.44%), give clear instructions on how medication should be taken (95.72%), etc. This emphasised the importance of interpersonal relationship between the patient and the health professionals as regards to the levels of adherence to treatment. Therefore the patient's perception of their interpersonal relationship with the care provider as a modifying factor could predict or influence their adherence to treatment as regards to the HBM.

5.3.4 Knowledge and experience about HIV/AIDS

In reference to the HBM, items in this section sought the respondents' perceptions of severity e.g. HIV/AIDS is curable disease, susceptibility e.g. the risk of contracting other disease increases if one is HIV positive, barriers e.g. HIV/AIDS has many side effects and benefit e.g. life expectancy of HIV/AIDS patients improve once they receive ARV treatment.

The findings from this study show that majority of respondents had good knowledge and experience about HIV/AIDS as a disease, the mode of transmission and its treatment. In addition the findings indicate that respondents perceived HIV/AIDS as severe (52.14%) and they were susceptible (84.44%) plus there were perceived benefits (96.11%) and barriers (82.49%) to ART irrespective of the high adherence rate obtained.

This shows that perceived severity, susceptibility and benefit of a health action may be good predictors of or influence adherence to treatment even in the presence of barriers.

5.3.5 Perceptions about the treatment plan

A treatment plan includes aspects such as convenience of the dosing interval, number of pills to be taken, dietary restrictions etc. These in reference to the Health Belief Model constitute barriers that can prevent patients to adherence to their treatment if an individual perceives them as obstacles in the way of adopting a new behaviour or continuing with the same behaviour (Hayden 2009:33).

With regard to the perception about the treatment plan, the findings from this study indicated a general agreement on most of the aspects. This could have had a positive influence on the adherence levels of the respondents. Therefore perceptions about the treatment plan if taken as barriers to health action can be used to predict the levels of adherence among the patients. This reaffirms findings from some studies done which showed that the extent of complexity of the ART regimens and treatment plan greatly influenced an individual's willingness and ability to adhere to therapy plus patients with higher self-efficacy beliefs about using antiretroviral agents had better adherence (Chesney et al 2000:1603; D'Armino et al 2000:505; Gifford et al 2000:389).

5.4 RESEARCH POSTER

Information for the design of an academic poster for presentation of findings to interest groups:

FACTORS AFFECTING THE ADHERENCE TO ANTIRETROVIRAL THERAPY BY HIV POSITIVE PATIENTS TREATED IN A COMMUNITY BASED HIV/AIDS CARE PROGRAMME IN RURAL UGANDA

A CASE OF TORORO DISTRICT

INTRODUCTION AND BACKGROUND

Good adherence is crucial for maximum clinical benefit from antiretroviral therapy. With the advent and increasing access to antiretroviral drugs, HIV/AIDS is becoming a chronic disease; therefore adherence to HIV medication has become critical to the long-term success of treatment programs in resource limited settings. This requires establishing the optimum levels of adherence and the factors that influence it.

Research question

What are the factors that affect the adherence to antiretroviral therapy by HIV positive patients treated in a community based HIV/AIDS care program in rural Uganda?

Research objectives

- Describe the factors that influence adherence or non-adherence to antiretroviral therapy by HIV positive patients.
- Make recommendations to ART and care programs on how to achieve and maintain adequate levels of adherence to ART in HIV positive patients.
- Design a research poster for presentation of findings to interest groups.

RESEARCH DESIGN AND METHOD

A non-experimental, quantitative and descriptive study. The Health Belief Model (HBM) used as the theoretical framework.

Population

Adult HIV positive patients on ART for more than two years in rural Uganda

Sampling methods

Two stage multiple cluster sampling

Data collection methods

A structured interview questionnaire administered to 275 respondents

Data analysis methods

Used both descriptive and inferential statistics

Descriptive statistics like mean, range, frequency distributions and percentages

Inferential Statistics: Bivariate analysis using Fishers' exact test for categorical data, independent *t*-tests for continuous variables and Multivariate analysis using logistic regression test.

Findings

Of the respondents, 95.7% reported adherence levels above 95%.

Among the reasons for missing treatment doses, forgetfulness and pills not being available were significantly associated with the adherence levels (fishers' exact <0.001).

Respondents had generally a positive perception about the aspects of care related to the ART clinic, interpersonal relationship with the care providers and the treatment plan.

Respondents were generally knowledgeable about HIV/AIDS as a disease, mode of transmission and its treatment.

Conclusion

There were high levels of adherence among the research patients. This could be explained by the fact that majority of the patients were positive about the aspects of care related to the ART clinic, interpersonal relationship with their care providers and their treatment plan plus being knowledgeable about HIV/AIDS.

The constructs of the Health Belief Model like perceived severity, susceptibility, benefit, barriers and modifying factors could be used as a basis to predict adherence behaviours.

5.5 SCOPE AND LIMITATION OF THE STUDY

The questionnaire was in English, which required the researcher or the research assistants to interpret the questions for the respondents in their own local languages which were commonly Luganda, Swahili, Ateso, Samia and Adhola. This could have affected the uniformity of the presentation of the questions to the respondents thus a variance in the meaning and understanding of the questions.

Adherence was measured by self report of the respondents' missed doses in the last 14 days from the date of the interview. There are several limitations associated with self-report including non standardised questions, reliance on recall of forgotten events and its vulnerability to social desirability in patients' given reports on adherence. They also tend to reflect only short-term or average adherence and often over estimate it. Because of these limitations, the study might not have captured the actual adherence levels of the respondents.

Of note is that the data collection tool was newly developed for this study and some scales used to measure the respondents' perceptions about ART like knowledge and experience about HIV/AIDS had low Cronbach's alpha coefficient (*0.50 and 0.60 respectively*) on the measure of reliability compared to the required acceptable minimum of 0.70 for a newly developed psychosocial instrument (Burns & Grove 2005:374). The low reliability of the scale might have lowered the power of the study to detect significant differences or relationships actually occurring in the population under study between the adherents and the non-adherents.

5.6 RECOMMENDATIONS

The findings provided valuable information on the level of adherence and the factors that affect it among the study population. Overall the adherence levels to ART by the HIV positive patients treated in this community based HIV/AIDS care program is good. Accordingly, based on the findings, the researcher makes the following main recommendations for maintaining or improving the levels of adherence to ART by HIV/AIDS positive patients at TASO Tororo centre and for further research.

Clinical implications

For maximum clinical benefit from antiretroviral therapy, it is essential that good adherence to ART is maintained in all patients. The results of this study have implications for the policy-makers, ART program planners and practitioners to ensure availability of ARV drugs to patients at all times and emphasise the essence of taking ARVs on time. This can be done through encouraging patients to post reminders for the clinic days when drugs are picked and when drugs are to be taken per day. Reminders can be in the form of calendars, alarm clocks and pill boxes.

Secondly transmission of the drug experienced HIV virus to HIV negative persons is of public health concern as it may lead to the spread of drug resistant HIV mutants into the population. This will increase the cost of HIV treatment thus necessitating additional emphasis on prevention among discordant couples of which one is on ART.

Research implications

Further research should be undertaken on the following topics:

- A similar study in a community based HIV/AIDS care program but using other methods like pill counts or electronic drug monitoring in conjunction with biological markers like CD4s and viral loads to measure the adherence levels.
- A qualitative research to get an in depth analysis of the factors that affect adherence to ART in the same study population.
- A scale development research to develop a scale that can reliably measure the perceptions to the ART plan and the knowledge and experience about HIV/AIDS.

Education Implications

During in-service training of all health workers involved in care and treatment of HIV/AIDS patients, more emphasis should be placed on health workers letting patients know the importance of treatment aides/reminders to promoting good adherence to ART during their counseling sessions before and after starting the patient on drugs.

Secondly, in the development of educational materials for HIV positive patients both on and not on treatment, information on benefits of and threats to adhering to ART should be clearly included.

The developed research poster will be presented in different research workshops and conferences to create awareness about issues of adherence to ART by HIV positive patients to different interest groups.

Although the study was conducted at the Community Drug Distribution Points run by TASO Tororo within Tororo district of the Republic of Uganda, the findings can be generalised to other districts in the country. Replication studies can be done to contribute to improvement on adherence to ART.

5.7 CONCLUSION

This study sought to answer the question “What are the factors that affect adherence to antiretroviral therapy by HIV patients treated in a community based HIV/AIDS Care program in rural Uganda?” The question was answered and the objectives of the study were met.

In this study, it was found that majority of the patients treated in the community based HIV/AIDS care program at TASO Tororo are adherent to their ART. At the same time the study identified certain gaps and made appropriate recommendations. Implications to clinical, research and education were also indicated.

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