ASSESSMENT OF THE COMPLIANCE OF PRIVATE HEALTH CARE PROVIDERS TO GUIDELINES FOR ANTIRETROVIRAL THERAPY IN THE MANAGEMENT OF HIV and AIDS PATIENTS IN WINDHOEK, NAMIBIA

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BY

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DECLARATION

I, Dawn Dineo Pereko, hereby declare that this study is a true reflection of my own research (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or shall be submitted for another degree at this or any other university, institution for higher education or examining body.

……. ……

Signature Date

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ABSTRACT

Since the identification of the first human immunodeficiency virus (HIV) case, developments have been underway to find treatment for the virus. Antiretroviral agents, especially when used in highly active antiretroviral therapy (HAART) regimens, have produced dramatic decreases in morbidity and mortality of HIV infected people and has made HIV a potentially treatable chronic disease. The success of HAART depends on the correct combination of drugs and on adherence to treatment regime. In April 2003, the Ministry of Health and Social Services published the first antiretroviral treatment guidelines which form the basis of HIV management in Namibia. However the actual availability of these guidelines and their application in the private sector was not known.

This study was conducted to determine the availability of Namibia Guidelines for Antiretroviral Treatment in the private sector and to assess the proportion of private health care providers who comply with the guidelines.

A survey to determine the practices of doctors and pharmacies providing ART services in the private sector in Windhoek, Namibia, was conducted, using the Ministry of Health *Guidelines for Antiretroviral Therapy,* a standard against which the private sector practices were measured.

The results of the study showed a general awareness (96% for doctors and 81% for pharmacists) and availability (92% for doctors and 50% for pharmacists) of MoHSS

guidelines. The overall proportion of private healthcare providers who adhere to guidelines is small although some aspects of the guidelines such as when to start therapy (61%), what to start with (96%), when to change (100%) and what therapy to use (73%) are well adhered to by doctors. The majority of the pharmacists (58%) do not dispense in accordance with the guideline recommendations.

This study has uncovered a wide diversity of practice in the different aspects of HIV management and significant deviations from the Namibia guidelines for antiretroviral therapy, first edition.

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LIST OF ABBREVIATIONS

ABC	Abacavir
AIDS	Acquired Immunodeficiency Syndrome
ANOVA	Analysis of variance
ART	Antiretroviral Therapy
ARV	Antiretroviral medicine
AZT	Zidovudine
CDC	Centre for Disease Control
D4T	Stavudine
Ddi	Didonasine
DLV	Delavirdine
DNA	Deoxyribonucleic Acid
EFV	Efavirenz
FBC	Full blood count
FTC	Emtricitabine
HAART	Highly Active Antiretroviral Therapy
HB	Haemoglobin
HIV	Human immunodeficiency virus
INH	Isoniazid
LFT	Liver Function Tests
MoHSS	Ministry of Health and Social services
NFV	Nelfanavir
NNRTI	Non-nucleoside reverse transcriptase inhibitors
NRTI	Nucleoside reverse transcriptase inhibitors
NtRTI	Nucleotide Reverse Transcriptase Inhibitors
NVP	Niverapine
OTC	Over-the-counter medicine
PI	Protease Inhibitor
PMTCT	Prevention from Mother-to-Child Transmission
RNA	Ribonucleic Acid
RTV	Ritonavir
SPSS	Statistical Package for the Social Sciences
SQV	Sequinavir
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USA	United States of America
USAID	United States Agency for International Development
VL	Viral Load
WHO	World Health Organisation

CHAPTER 1: INTRODUCTION

1.1 Background

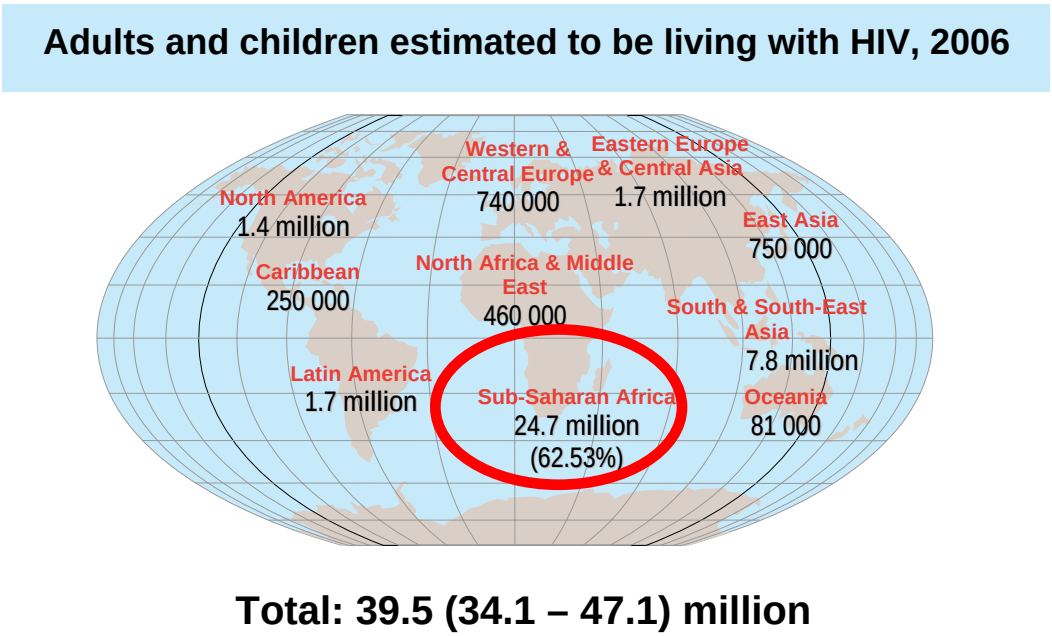
Human Immunodeficiency Virus (HIV) infection is a chronic life-threatening condition caused by the Human Immunodeficiency Virus (HIV). The virus damages and/or destroys the CD4 cells of the immune system thus weakening the immune system of the persons infected. This makes the persons infected susceptible to opportunistic infections that the body is unable to resist and eventually leads to death (Mayo Foundation for Medical Education and Research, Aug, 2004). The virus can be spread through sexual contact (excahnge of bodily fluids), direct exposure to contaminated blood, or transmission from mother to unborn child or breastfeeding infant (Ministry of Health and Social Services, p.4). The first cases of HIV were reported in the USA in 1981 (Vella and Palmisano 2005, p. S239).

Twenty seven years after the first cases of HIV/AIDS were recognized, the pandemic still continues to grow. Every day thousands of people are infected and many more families and communities are affected. The Joint United Nations Programme on HIV/AIDS (UNAIDS) 2006 Report estimates that as of December 2006, 39.5 million people were living with HIV, 4.3 million people were newly infected and 2.9 million people died of Acquired Immune Deficiency Syndrome (AIDS) globally. Southern Africa remains the epicentre of the epidemic, it is reported that there were 25.4 million people living with HIV (i.e. 63% of the global figure), 3.1 million new

infections and 2.3 million (34% of global figure) deaths due to HIV in sub-Sahara Africa thus making Sub-Sahara Africa the most massively affected region in the world (Bartlett, 2005).

In 2004, the 10 Southern African countries, Botswana, Lesotho, Swaziland, Angola, Malawi, Mozambique, Namibia, South Africa, Zimbabwe and Zambia, accounted for 30% of HIV positive individuals and 32% of HIV-AIDS deaths globally. Adult HIV prevalence in the region ranged from 3.9% in Angola to 38.8% in Swaziland (USAID, Dec 2004).

Figure 1: Global HIV/AIDS statistics 2006



Source: UNAIDS, 2006

In 2004, the ten (10) Southern African countries, namely, Botswana, Lesotho, Swaziland, Angola, Malawi, Mozambique, Namibia, South Africa, Zimbabwe and Zambia, accounted for 30% of HIV positive individuals and 32% of HIV-AIDS deaths globally. Adult HIV prevalence in the region ranged from 3.9% in Angola to 38.8% in Swaziland (USAID, Dec 2004). It is estimated that in 2006, Southern Africa accounted for 32% of HIV positive individuals and 34% of HIV-AIDS deaths globally. (UNAIDS, 2006).

The first few cases of HIV/AIDS in Namibia were reported in 1986 and by end of December 2003; a total of 136,068 cases had been recorded by the Ministry of Health and Social Services (Ministry of Health and Social Services, 2004, p.1).The 2006 sentinel sero-survey report revealed an overall HIV prevalence of 19.9% with site specific prevalence ranging from 7.9% in Opuwo to 39.4% in Katima Mulilo. It also reported that the highest prevalence rate was within the age group 20 -39 years. (Ministry of Health and Social Services, 2006).

Since the identification of the first ever HIV case in the world, a number of medications have been developed to treat HIV infection. These medicines called antiretrovirals (ARVs) are aimed at extending and improving the quality of life of infected persons. These, however, are not a cure for the disease (TheBody.com). These medicines work by blocking the replication of the human immunodeficiency virus at various stages of its life cycle in the human cells.

The strategy that is now widely applied in the management of HIV infection is Highly Active Antiretroviral Therapy (HAART) which uses a combination of three or four antiretroviral medicines. HAART has been found to be more useful than both mono- and dual therapy. With monotherapy where only one drug is used there is sub-optimal suppression of viral replication, resulting in the virus being able to replicate in the presence of the medicine leading to emergence of resistant viral strains. With dual therapy, where a combination of two drugs is used, viral suppression is not sufficient to achieve durable effect (Ministry of Health and Social Services, p.75).

In 2003 UNAIDS and WHO launched the "3 by 5" initiative which was a global target to provide three million people living with HIV/AIDS in low and middle-income countries with life-prolonging antiretroviral treatment (ART) by the end of 2005. It was a step towards the goal of making universal access of HIV/AIDS prevention and treatment accessible for all who need it (World Health Organization, 2003). As a result, international organizations and governments, such as the Global Fund and President's Emergency Funds for Aids Relief, have provided aid to low and middle income countries to promote accessibility of antiretroviral drugs (Blower, Bodine, Kahn and McFarland, 2005, p.1). This availability of aid increased availability and accessibility to treatment for low and middle-income countries. By the end of December 2004, WHO estimated the number of people receiving antiretroviral therapy to be 700 000 globally (310 000 in the African Region) (World Health Organization, 2004). In Namibia, the government launched the Antiretroviral Therapy (ART) roll-out plan in June 2003 and by March 2007, there were already 33

594 patients on ARVs in the public sector (Pharmaceutical Services Division - Ministry of Health and Social Services 2007).

The increased availability of a large number of antiretroviral medicines has introduced complexities (such as which medicine to choose, which combinations, what to start with, etc.) in the management of HIV positive patients. This led to the development of treatment guidelines. Treatment guidelines are recommendations whose goal is to provide evidence-based guidance for clinicians and other health-care providers in the management of specific clinical conditions. Guidelines are developed by a panel of experts in a particular field and reflect the consensus on the optimal treatment options within a health system. The advantages of treatment guidelines are that they ensure uniformity of care and reduce inappropriate care and the cost associated with it.

In April 2003, the Ministry of Health and Social Services in Namibia published the first antiretroviral treatment guidelines (Ministry of Health and Social Services, 2003). The guidelines were developed with input from clinical specialists and general providers from both the public and private sector and were developed for use in both sectors. These guidelines constitute the basis for HIV management in Namibia. The purpose of these guidelines is to ensure that HIV treatment programmes are based on scientific evidence and to avoid suboptimal treatment protocols which compromise treatment outcomes of the clients and create potential for the emergence of drug resistant strains of the virus.

To promote the knowledge and application of the Namibian guidelines for antiretroviral therapy, health care providers in the public sector undergo extensive training on HIV management and Namibia treatment guidelines prior to being allowed to manage HIV patients. In the private sector, members of the HIV Clinicians Society are also accorded training on the management of HIV positive patients. However, not all private health care providers treating HIV patients are members of the HIV Clinicians Society and not all have received any form of training on HIV management. Lack of training can lead to inappropriate care of patients.

Moreover, in their study on the impact of educational intervention to improve prescribing by private physicians in Uganda, Obua, Okeng, Waako, Aupoint and Ross-Degnan (2004) noted that prescriber's awareness of treatment guidelines is not sufficient to assure rational prescribing practices. Although the development and utilization of guidelines are promoted by healthcare organizations, health plans and individual researchers, research findings have demonstrated that practitioners often fail to use guidelines in daily practice (Maue, Segal, Kimberlin and Lipowski, 2004, p. 383).

Namibia has a very active private health sector, including private hospitals, doctors, nurses, pharmacists and social workers. Large and medium-sized companies and the public sector provide access to health insurance for their employees. Therefore a not insignificant number of Namibians are covered by a health insurance plan and use the private sector for health care (USAID/NAMIBIA Africa, 2004). Van der Veen

and Serfontein (2004) estimate that about 100,000 (5.6%) of the total population are covered by private medical insurance and, therefore, these patients are likely to be treated by private health care practitioners.

1.2 Problem Statement

Inappropriate management of HIV disease can lead to treatment failure for the clients, which can lead to resistance. Development of resistance can render current treatment regimens ineffective. Because of limitations in available alternative antiretroviral regimens that have documented efficacy, optimal changes in therapy might be difficult to achieve for patients in whom the preferred regimen has failed (Dybul, Fauci, Bartlett, Kaplan, and Pau, 2002). Also, the development of resistance can lead to requirements of more costly and potentially more toxic regimens. Resistance is a problem not only for the person infected but becomes a public health problem especially if the resistant strain of virus is passed on from person to person.

Studies in Amsterdam and Pune (India) undertaken by Reedijk, Wigersma, and Mohrs, (1998) and Sheikh, Rangan, Kielmann, Deshpande, Datye, and Porter, (2005) respectively, have shown that although clinical practice guidelines are generally accepted as "best practice" providers' compliance remains low.

However in Namibia, although ART guidelines are available there is no data on the availability of the guidelines in the private sector and their application. With studies elsewhere as cited above showing a low provider compliance to guidelines,

inappropriate treatment of HIV in the Namibian private sector can limit the available options to effectively manage the disease in the country.

1.3 Aims and Objectives of the Study

The purpose of this study was to explore and describe the proportion of private health care providers in Windhoek who comply with Ministry of Health and Social Services' HIV treatment guidelines.

Specific objectives were to:

- determine availability of "*Guidelines for antiretroviral therapy in Namibia*" in the private sector.
- determine the proportion of private health care providers who adhere to ART guidelines in the treatment and care of patients on ART.
- determine how patient adherence is being monitored in the private sector.

1.4 Significance of study

The study was both relevant and significant in Namibia since there was a gap in the knowledge of the management of HIV positive patients in the private sector (or by private health care providers).

The findings of this study will be used to give feedback to private health care providers, Ministry of Health and other stakeholders and will also be used to design interventions aimed at ensuring appropriate management of HIV and thus decreasing

the risk of resistance, cost of therapy to the patient and improving treatment outcomes for patients.

1.5 Definitions of key concepts

Adherence- refers to the ability of the person living with HIV/AIDS to be involved in choosing, starting, managing and maintaining a given therapeutic combination medication regimen to control viral (HIV) replication and improve immune function (Jani, 2004, p.1). In this study it will be used to describe the patient's ability to comply with the prescribed regimen.

Assessment – refers to the act of considering or examining something in order to judge its value, quality, importance, extent, or condition (Collins Dictionary and Thesaurus, 2003). In this study, it means examining the practices of private health care providers in the management of HIV positive patients on antiretroviral therapy.

Antiretrovirals – refers to those medicines that act by inhibiting the growth and replication of the virus at various stages of the life cycle (Mayo Foundation for Medical Education and Research).

Antiretroviral Therapy (ART) – refers to the use of pharmacological agents that have a specific inhibitory effect on HIV replication i.e. the use of antiretrovirals to treat HIV infected patients (New York State Department, 2005).

Compliance – refers to the action of following stipulated orders or directions. In this study it refers to following ART guidelines as stipulated with respect to starting therapy, choice of first line regimen, patient monitoring, switching therapy, and dispensing medicines to HIV positive patients.

Drug resistance – refers to as any change that improves viral replication in the presence of an inhibitor (Idemyor, 2002, p. 659) i.e. the inability of a combination of drugs to suppress replication of the virus.

Guidelines – refer to evidence-based recommendations which provide health care professionals with scientific information about the most appropriate strategy for the management of patients in specific conditions, in order to avoid unnecessary or inappropriate interventions. (Lauria, Vanacore and Casciello, 2001, p.310). In this study guidelines refer to the MoHSS *Guidelines for Antiretroviral Therapy*

Management of HIV patients – refers to the diagnosis, treatment and continuous monitoring of HIV patients.

Private Health Care Providers – refers to the doctors, nurses and pharmacists who are providing treatment to patients but are operating privately from the government. In this study it refers to doctors (also referred to as medical practitioners or private health care practitioners) and pharmacists who are providing antiretroviral therapy in the private sector of Namibia.

1.6 Summary of research design and methods

The research design of this study constitutes the research approach, population and sampling, data collection methods and data analysis. These aspects are described fully in Chapter 3.

- ***Design***

A quantitative, exploratory and descriptive approach was used for this study. This approach was found to be the most appropriate for this study, because the researcher wanted to explore the availability of ART guidelines in the private sector, whether they are used by private health care providers and if so, what proportion of health care providers comply to the guidelines as little is known about the above issues. The Ministry of Health *Guidelines for Antiretroviral Therapy* were used as a standard against which the private sector's practices were being measured.

- ***Research methods***

The population for this research included general practitioners and pharmacists in Windhoek who are currently practising and are managing HIV positive patients.

Because of the small number of the study population, no sampling was done. In order to obtain sufficient data, all 83 general practitioners and 30 pharmacies were included in the study. In each pharmacy, only one pharmacist was required to complete the questionnaire.

Data was collected using self-administered questionnaires consisting of both open and close-ended questions. In conducting the study, the researcher adhered to the ethical considerations of research. Overall permission was obtained from the University of Namibia prior to the study (see Annexure 1) and thereafter an introductory letter was sent to all identified candidates explaining the purpose of the study (see Annexure 2). The participation was voluntary and the participants could withdraw from the study at any time. The letter also had a section where the participants could give consent. All responses were anonymous.

- ***Measures to ensure validity and reliability***

It is important that the results should be accepted as authentic beyond reasonable doubt by members of the scientific community. Thus the researcher developed questionnaires that corresponded to the criteria being evaluated and experts in the medical and pharmacy fraternity were consulted for their opinion on the suitability and representativeness of the questionnaires. It was ensured that the combinations of questions were sufficient to provide valid overall conclusions, a component adding to validity.

1.7 Conclusion

This chapter covered the general overview and rationale of the whole study, including research problem, research purpose and objectives and definitions of the main concepts and research method. The next chapter will discuss the literature review related to this study.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

The purpose of this chapter is to introduce the reader to the nature of the human immunodeficiency virus and how it affects the body, treatment of the virus, concepts of resistance and adherence and treatment guidelines.

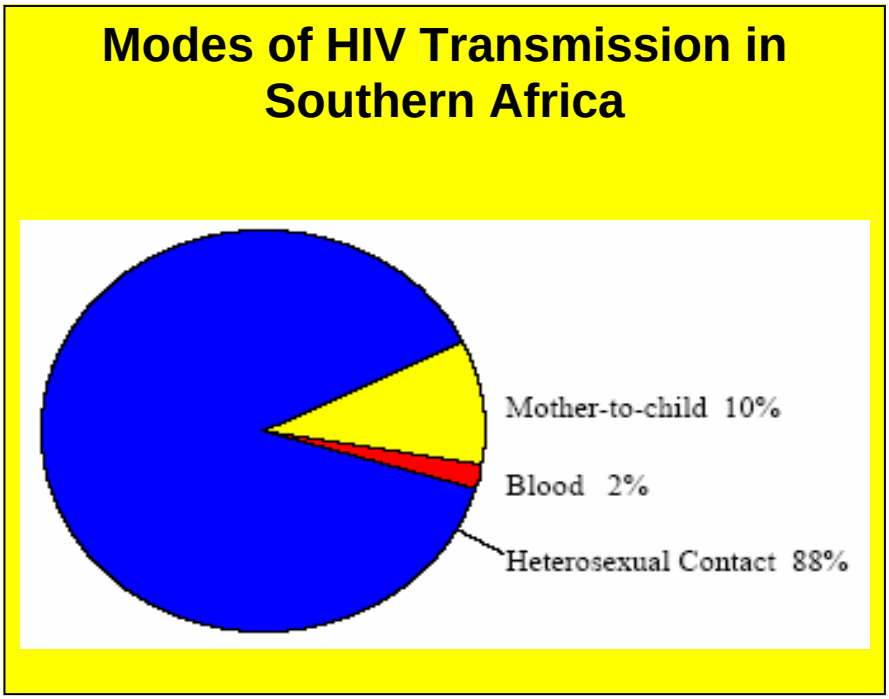
2.2 The Human Immunodeficiency Virus (HIV)

The human immunodeficiency virus is a member of the *Lentivirinae* subfamily of the retroviruses. It is found in body fluids such as semen, cervical secretions, blood and breast milk and therefore exposure to infected body fluids may transmit the virus.

Infection with HIV occurs through three routes: sexual, parenteral (through exposure to contaminated blood such as needle stick injuries or blood products) and from mother to child.

The modes of HIV transmission in AIDS cases reported during recent years vary considerably from region to region. For example, the US Center for Disease Control (CDC) estimated that 88 percent of reported AIDS cases in sub-Saharan Africa have been transmitted through heterosexual activity. (Rational Pharmaceutical Management Plus Programme, 2006). Figure 2 below shows the modes of transmission of HIV in Southern Africa.

Figure 2: Modes of HIV transmission in Southern Africa



(Source: U.S. Center for Disease Control and Prevention (CDC). 2005)

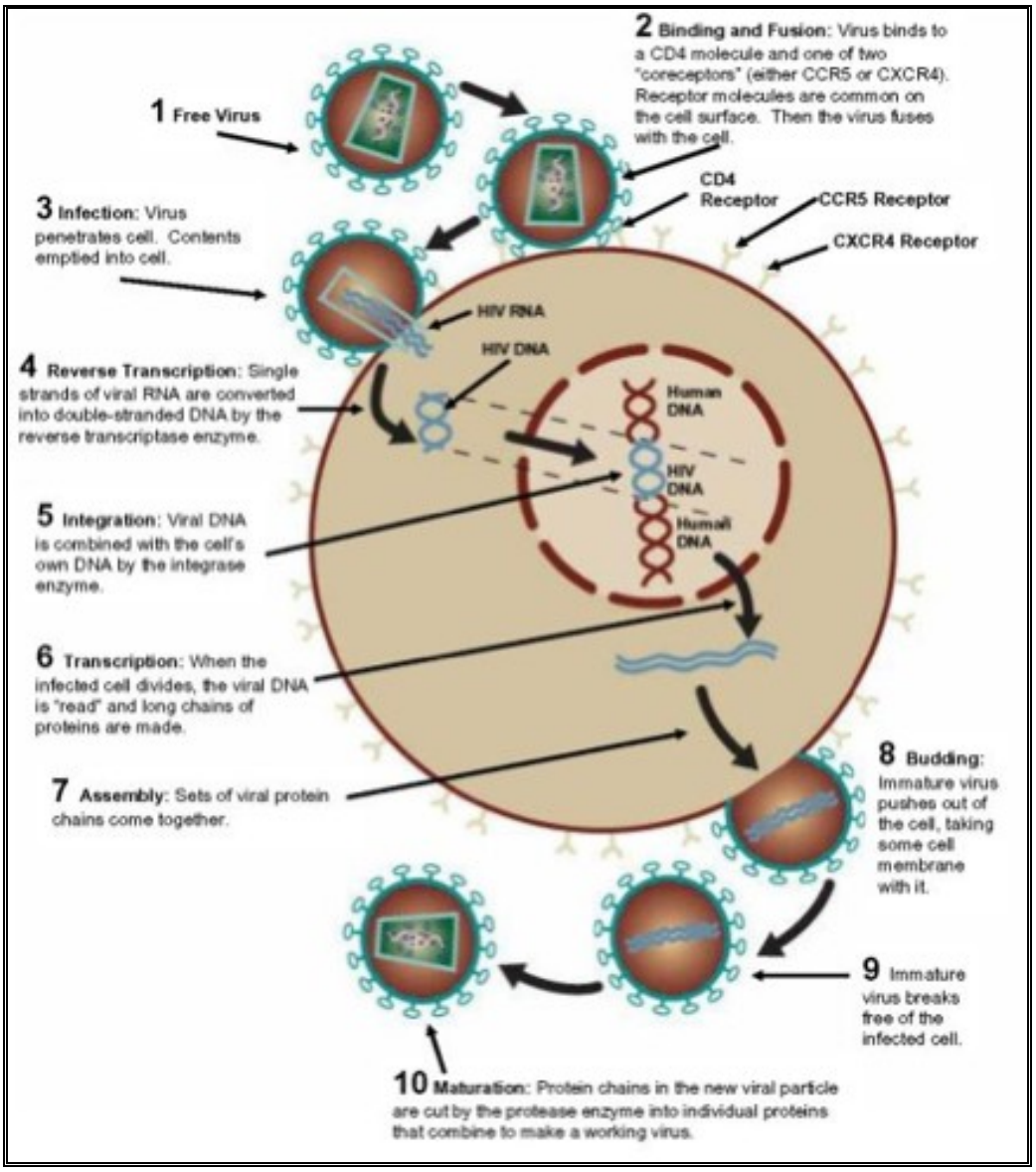
HIV is diagnosed mainly by testing blood for the presence of antibodies to the virus. These antibodies are usually detected 12 weeks after infection. Diagnosis can also be made by establishing the presence of the virus in the blood through detection of P24 antigen (PCR-viral load).

The virus acts primarily by attacking and destroying the CD4 lymphocyte cells. The CD4 cells direct many other cells in the immune network (Tierney, McPhee and Papadakis, 2005, p. 1277). By attacking these cells, the HIV interrupts the entire immune response (Frontline, 2006), resulting in the virus not being destroyed by the CD4 cells and thus it is able to replicate and multiply in the body.

Viruses cannot replicate without the aid of a living cell. HIV like all other retroviruses depends upon the enzyme reverse transcriptase to replicate within the host cells. In order to replicate, the virus has to undergo a series of steps. This process is called the life cycle of the virus. This life cycle is shown in figure 3 below.

There are 6 steps in the life cycle of HIV namely: Binding and Fusion, Reverse Transcription, Integration, Transcription, Cleavage and Viral Assembly and Budding. The figure below shows a schematic description of the life cycle of the virus.

Figure 3: HIV life cycle



(Source: Journal of Young Investigators and mayochub)

Step 1: Binding and Fusion

Once the virus comes into contact with the host cell, it attaches itself to the cell so that it can release its genetic material into the cell. Once the attachment is complete, viral penetration occurs which enables the virus to release its genetic core into the host cell. It is during this stage that the virus fuses to the cell membrane. After fusion, the virus uncoates in preparation for replication.

Step 2: Reverse Transcription

The viral ribonucleic acid (RNA) is then converted to deoxyribonucleic acid (DNA) using the enzyme reverse transcriptase. This new DNA is called a provirus. This is called reverse transcription because in the normal transcription, DNA is converted to RNA and in this case, the reverse occurs.

Step 3: Integration

Reverse transcription is followed by the integration of the viral DNA into the host. The provirus migrates to and enters the host cell nucleus and becomes integrated into the cell DNA with the help of the enzyme integrase.

Step 4: Transcription

The viral DNA then produces all necessary components of a virus. The HIV's genetic material in the host cell directs the cell to produce new virus.

Step 5: Cleavage and Viral assembly

The protease enzymes cut the long protein chain produced in the previous step into individual proteins. The subunits of the virus then assemble to form a new viron.

Step 6: Budding

The final step in the process is budding where a new viral envelope is formed and the new virus pinches off and enters the circulation to start the process again. (Pieribone, 2003, pp.1-8; The Immunodeficiency Clinic; Cain, 2006 and AIDSmeds.com)

2.3 Treatment of HIV

Understanding the life cycle of the virus helps to understand the pharmacodynamics of antiretroviral medicines (ARVs). Antiretroviral medicines are medicines

specifically designed to suppress the replication and growth of the virus. The medicines act by inhibiting the growth and replication of the virus at various stages of its life cycle and thus decrease the progression of the disease (Mayo Foundation for Medical Education and Research, 2004 and Aidsinfo.nih.gov). The medicines do not eradicate the virus.

The first antiretroviral medicine, Zidovudine, was introduced for the management of HIV in March 1987. In the early 1990's other nucleoside analogues were introduced for the management of HIV. In the mid 1990's another class of antiretrovirals, the Protease Inhibitors (PI), was introduced to the management of HIV. In June 1996, another class, the non-nucleoside reverse transcriptase inhibitors (NNRTI), was introduced (Hoffman, 2003).

To date, five classes of antiretroviral drugs (ARVs) have been developed. In Namibia, only the first four classes of ARVs are available. The five classes of ARVs are:

- **Nucleoside Reverse Transcriptase Inhibitors (NRTI)** – these are nucleoside analogues and are inhibitors are both competitive inhibitors of reverse transcriptase and DNA chain terminators. They act as false substrates for reverse transcriptase and terminate the DNA chain. This results in a DNA copy not being, formed thus rendering the viral genome susceptible to destruction by cellular enzymes These include abacavir, didonasine, lamivudine, stavudine, zalcitabine and zidovidine. (South African Medicines Formulary, 2003)

- **Nucleotide Reverse Transcriptase Inhibitors** (NtRTI) – these are chemically different to the nucleoside analogues but also interfere with the replication of reverse transcriptase and thus prevent the virus from inserting its genetic material into the host cell. Examples in this group include tenofovir.
- **Non-Nucleoside Reverse Transcriptase Inhibitors (NNTRI)** – these bind directly to the reverse transcriptase enzyme, resulting in conformational changes at the active site of the enzyme and therefore inhibition of the enzyme activity. These include: Nevirapine and efavirenz
- **Protease Inhibitors (PI)** – The protease inhibitors bind competitively to the substrate site of the viral protease - the enzyme responsible for the post-translational processing and cleavage of a large structural core protein during budding from the infected cell. Inhibition at this stage prevents cleavage of viral polyproteins and results in immature, non-infectious HIV viral particles (South African Medicines Formulary, 2003). Currently available protease inhibitors include: amprenavir, lopinavir, indinavir, nelfinavir, retonavir and saquinavir.
- **Fusion Inhibitors** – these act by preventing the virus from fusing with the membrane of the host CD4 cells (Mayo Foundation for Medical Education and Research, 2004).

The New York State Department of Health AIDS Institute in their Adult HIV Guidelines (2005) define the goals and risks of antiretroviral therapy. The goals are

maximal suppression of viral replication, restoration and preservation of the immune system, reduced HIV-related mortality and morbidity, improved quality of life and the limitations to the likelihood of viral resistance to preserve future treatment options.

The risks associated with antiretroviral therapy (ART) include adverse effects, long term toxicities (including fatal toxicities) and the development of viral resistance to available drugs thus limiting future options.

Deeks (2000) suggests that the best way to achieve the above mentioned goals of antiretroviral therapy is to suppress HIV replication to very low levels indefinitely. HAART uses a combination of at least three drugs which have been found to have a synergistic effect resulting in significant and prolonged viral suppression (Idemyor, 2002, p. 659). HAART is characterised by elevated antiviral potency resulting in suppression of the viral replication and a good level of immune reconstitution (Vella and Palmisano, 2005, p. S239)

Since its inception in the mid 1990's, HAART has produced dramatic decreases in morbidity and mortality of HIV infected people and has made HIV a potentially treatable chronic disease. (Vella and Palmisano, 2005, p. S240). The HAART cocktail usually comprises of drugs from at least two ARV classes. The World Health Organisation (WHO) recommends, as first line, the use of two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) in combination with a Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) in resource limited countries. HAART has been proven to be far superior to monotherapy and dual therapy regimens which

are not recommended owing to the rapid emergence of resistance and treatment failure. (Ministry of Health and Social Services 2003, p. 4)

2.4 Resistance

The biggest obstacle to the success of current HIV therapy (including HAART) is the emergence of viral resistance which is the naturally occurring response of any micro-organism facing the selective pressure of drugs. In the case of HIV, it is the ability of a virus to replicate in the presence of antiretroviral agents. Viral resistance is caused by mutations in the HIV-1 genome coding for structural changes in the target enzymes that can affect the binding or activity of the inhibitors (Idemyor, 2002). This leads to development of variants of the virus with reduced susceptibility to antiretroviral agents.

The development of resistant viral strains is one of the main reasons for failure of antiretroviral therapy. Emergence of resistance can be due to several factors such as: inappropriate regimen, poor adherence to regimen by patients (leading to suboptimal drug levels in the body) and severe immune repression at the start of therapy. Under these circumstances, viral replication is incompletely suppressed allowing for the gradual emergence of resistant strains of the virus.

If there is resistance to several drug classes, the number of alternative treatment regimens is limited and the virological success of subsequent therapies, or so-called salvage regimens, may be only short-lived (Wolf, 2005).

Vella and Palmisano (2005, p. S245) noted that HIV resistance will continue to emerge and spread and that paradoxically, the increased access to HAART is likely to increase HIV resistance. They suggest multiple strategies that are aimed at minimising the magnitude of the problem and these include:

- Selection of drug regimen with high potency. They emphasise that poorly effective drug combinations should be avoided even in resource limited settings.
- Adherence to prescribed regimens should be carefully considered and reinforced. Adherence can be improved by ensuring patient readiness prior to initiating HAART, having a multidisciplinary team to support the patient and monitoring the patient closely.

2.5 Adherence

Adherence can be defined as the extent to which a patient follows a prescribed health care regimen. Jeffrey (2004) describes adherence as important because:

- <95% adherence is associated with increased risk of virologic failure
- Adherence is strongly correlated with viral suppression. The better the adherence, the better the virus will be suppressed.
- Adherence results in better CD4 response to therapy
- Non-adherence is associated with resistance. Some studies have shown that the risk of resistance is highest with good but incomplete adherence (e.g. 80-90%).

- Non-adherence limits future treatment options if it results in resistance
- Non-adherence increases risk of HIV transmission

Adherence to HAART has been noted as one of the most important aspects of HIV care (New York State Department of Health, 2006). It is a key determinant to the degree and duration of virological suppression (Smith, Golin and Reif, 2004). Smith et al further argue that non adherence to medication is a common problem in the treatment of many diseases and has also been frequently observed in HIV studies. They suggest that to reduce the odds of treatment failure and possibly resistance, patients should be assisted with adherence practices.

Jeffrey (2004) also identifies some of the factors affecting adherence being complexity of medication regimen, poor provider-patient relationship and patient's lack of knowledge about HIV and rationale for treatment. These identified factors show the importance of the role of the health care provider in the management of HIV infections and in promoting adherence.

In the *Guidelines for Antiretroviral Therapy 2003*, MoHSS recognises that adherence is the key determinant for the success of HAART. To improve adherence, HIV Clinical Resource (2006) recommends:

- A team approach to achieving adherence should be used. Nurses, pharmacists, peer counsellors, caseworkers, and others who work in outreach, evaluation, and support of adherence should be involved.

- The clinician should assess treatment readiness prior to initiation of treatment, adherence readiness for subsequent regimens, and adherence at every clinical visit.
- Interventions should be intensified in times of decreased adherence.
- Information about patients' beliefs and attitudes should be communicated with all members of the healthcare team so that each provider can consistently address treatment adherence issues within the context of the overall treatment plan.
- If the patient is not fully committed to adhering to therapy, treatment should be delayed, and the clinician should continue to work on abating the patient's concerns. Appropriate referrals should be provided for support groups, mental health, and drug treatment.

2.6 Treatment Guidelines

Clinical guidelines are evidence-based recommendations which provide health care professionals with scientific information about the most appropriate strategy for the management of patients in specific conditions, in order to avoid unnecessary or inappropriate interventions. (Lauria,Vanacore and Casciello, 2001, p.310).

Steinhart (2003, pp. 536-543) noted that the availability of a large number of antiretroviral medications and the need for correct combinations to effectively suppress viral replication has introduced a complex challenge to health care providers in the management of HIV-positive patients. This, therefore, has created a

need for the development of clinical practice guidelines which will ensure uniformity of care for all patients.

UNAIDS in Developing HIV Treatment Guidelines (1999) suggests that guidelines can improve clinical management of patients and outlines some of the benefits as the reduction in cost of treatment by minimizing excessive use of treatments and tests; the training of health workers in diagnosis and management of HIV infection and improving health care by changing prescribing habits.

Guidelines address four key areas namely: When should antiretroviral therapy be started? What regimen(s) should be used for initial therapy? When should therapy be changed? and What should it be changed to?

In 2003 the World Health Organisation (WHO) released its first guidelines on antiretroviral treatment. These guidelines served as a basis for development of national guidelines by different countries and Namibia was no exception.

WHO recommendations

When to start

WHO guidelines recommend that in resource limited settings, decisions to initiate therapy be based on clinical and immunological assessments. The clinical assessment is based on clinical staging and the immunological assessment is based on CD4 counts. (World Health Organization, 2006b, pp. 13-14)

Adolescents and adults should start ARV therapy when they have:

- WHO Stage IV HIV disease (clinical AIDS)
- WHO Stage I, II, or III disease and a CD4 count < 200 cell/ml

Pregnant women

- WHO Stage III or IV disease and a CD4 count < 250 cell/ml

Paediatrics

- WHO Stage III disease
- WHO stage I and II disease and a CD4 percent < 20% cell/ml

What to start with

The recommended first line therapy is the use of two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) in combination with a Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

When to change therapy

WHO recommends that the time for switching therapy should be dictated by treatment failure which is measured by: clinical failure (by disease progression), immunological failure (increases in CD4 counts) and virological failure (increases in viral loads). Another reason for changing therapy is toxicity which is related to the inability to tolerate side-effects of medicines and to the significant organ dysfunction that may occur. (World Health Organization, 2003, p. 21)

What to change to

Changing regimen from first to second line still requires the use of three different medicines with at least one medicine being from a new class (i.e. a class that was not used in first line therapy). The preferred second line regimen are PI based i.e. two NRTIs and in combination with a PI. When the reason for changing therapy is toxicity, only the offending medicine can be replaced with another one without the same side-effect

Namibian guidelines

The first guidelines for antiretroviral therapy in Namibia were published in April 2003 (Ministry of Health and Social Services, 2003). These guidelines constitute the basis for HIV management in Namibia. The table below describes a summary of the key areas in ART therapy as outlined in the guidelines.

Table 1: Summary of Namibia guidelines criteria

Criterion	Concordant with guidelines if
Patient eligibility to start therapy (clinical criteria)	• Adult: WHO stage III, or IV, or CD4 below 200 • Pregnant: WHO stage III, or IV, or CD4 below 250 • Children <18 months: WHO paediatric stage III, or I and II with CD4 percentage <20% (+ve virologic test) WHO paediatric stage III with CD4 % <20% (no virologic test, mother seropositive) • Children >18months but < 8yrs WHO paediatric stage III, or I & II with CD4% of < 20%. • Children > 8yrs CD4 < 200
Patient eligibility to start therapy (social criteria)	Has lived in a fixed address for ≥ 3 months Has a therapy supporter
Appropriateness of combination	2NRTI + 1 NNRTI or 1 boosted PI but exclude: AZT + d4T and d4T + ddI combinations
Appropriateness of first line of therapy	Started with 2NRTIs + NNRTI
Change of therapy from 1st line to 2nd line (and reasons for change)	2NRTIs + PI (exclude d4t/ddi combination)
Reasons for changing therapy	• Treatment failure (clinical, immunological or virological) • Toxicity (inability to tolerate adverse effects)
Clinical Monitoring	Laboratory testing as per guideline schedule NVP based: FBC,ALT, CD4,VL EFV based: ALT,CD4, pregnancy
Adherence Monitoring	Monitoring follow-up, Pill count Validated patient questionnaires
Medication Counselling	• Explain administration schedule for each medication • Provide instructions for use • Assess and explain potential drug interactions • Discuss storage requirements • Discuss potential side-effects and their management • Explain what to do with missed doses • Explain importance of adherence • Mention follow-up appointment (refill appointment)

The guidelines provide both the social and clinical criteria for starting therapy. They also provide guidance on what regimen to start with, when to change and what to change to. Furthermore they provide information on when and how to monitor patients on treatment and how to counsel the patients on their medication. Table 2

below provides regimens that are recommended for both first and second line therapy.

Table 2: Recommended regimens for antiretroviral therapy

Regimen	Comments	Major Toxicities
NVP plus D4T/3TC NVP plus AZT/3TC NVP plus AZT/ddI (NVP plus D4T/ddI) EFV plus d4T/3TC EFV plus AZT/3TC EFV plus AZT/ddI (EFV plus D4T/ddI)	EFV is contra-indicated in pregnant women. Effective contraception should therefore be provided for women with reproductive potential before initiation of EFV therapy	• Zidovudine-related anaemia and neutropaenia • EFV-associated CNS (mood and sleep) disorders • Possible teratogenicity of EFV • Nevirapine-associated hepatotoxicity and severe rash • NRTI-associated metabolic side effects
IDV/r plus D4T/3TC IDV/r plus AZT/3TC IDV/r plus AZT/ddI (IDV/r plus D4T/ddI) LPV/r plus D4T/3TC LPV/r plus AZT/3TC LPV/r plus AZT/ddI (LPV/r plus D4T/ddI)	2 regimes for RTV enhanced Indinavir (IDV/r) IDV 800 mg bd+RTV 100 mg bd ***or*** IDV 400 mg bd+RTV 400 mg bd RTV enhanced Lopinavir (LPV/r) is available as fixed dose combination (33mg+133mg/tabl.)	• AZT-related anaemia • IDV-related nephrolithiasis • PI- and NRTI-related metabolic side effects

(Source: Ministry of Health and Social Services, 2003)

Items in the first row are for first line treatment. The second row is for second line treatment which is advised for patients who cannot take first line therapy.

2.7 The role of doctors and pharmacists in the management of HIV positive patients

The success of HAART lies on the coordinated efforts of different health care providers (doctors, pharmacists, nurses, counsellors and treatment supporters) and the involvement of the patient. The doctor's role is typically clinical history and

examination to stage the patient and determine eligibility for ART, perform screening for TB, writing up prescriptions for ARVs and providing follow-up care.

The pharmacist's role includes ensuring adequate uninterrupted supply of medicines, assessing ARV therapy prescriptions including potential for drug-drug interactions, providing patient education on medication (such as use, side-effects, food effects) and adherence counselling, dispensing of medicines and monitoring of patient adherence. (World Health Organization, 2005, p.13). Fitt, Runn, McManus and Moxham (1989) concluded that that "as the management of HIV and AIDS patients often involves complicated drug therapy, the pharmacist is the most important person to monitor and advise on this important aspect of care."

In their HIV guidelines (2006), the HIV Clinical Resource suggest that the quality of the relationship between the patient and the clinician greatly influences adherence and that the following strategies involving the health care provider should be employed to maximise patient's adherence:

- *The healthcare team should promote active patient involvement in decision-making about initiating and managing ARV regimens.* The patient's opinion of successes and challenges in maintaining adherence should be sought at routine visits.
- *A treatment plan should be negotiated, and active patient participation in the development of the treatment plan should be encouraged.* Patient concerns and questions regarding the regimen should be elicited, and an individualized

schedule should be made based on the patient's lifestyle. A plan should be made for changes in routine (e.g., weekends, holidays, travel).

- *Patient trust should be established* and a strong working relationship should be developed.
- *Questions regarding adherence should be open-ended and should be asked in a non-judgemental manner* with an understanding of the difficulty patients will have in admitting to adherence problems.
- *Members of the healthcare team should be open and accessible.* Ways for patients to reach medical team members 24 hours/day when questions or concerns arise should be made available.
- *Intensive support should be provided to patients beginning medication regimens.* Team members should meet with the patients frequently (or speak by phone) to provide encouragement, assess tolerability, assess adherence, and answer questions.

These strategies further help to define the role of the health care provider in HIV infection management and in improving adherence in particular.

2.8 Conclusion

In this chapter, a literature review on the topic of the research was undertaken and described to create a comprehensive picture of the research topic. The chapter covered: introduction to HIV, antiretroviral medicines and how they work, strategies for HIV disease management in particular HAART, concepts of resistance and adherence, treatment guidelines and finally the role of doctors and pharmacists in the

management of HIV positive patients. The next chapter will explain in detail how the study was carried out.

CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

In the previous chapter, the literature review was presented. In this chapter the researcher will describe the methodology applied during the study. It will describe in full the chosen design, the study population, sample size, research instruments, data collection methods, data analysis and ethical considerations applied in the study.

The purpose of this study was to explore and describe the proportion of private health care providers in Windhoek who comply with Ministry of Health and Social Services' HIV treatment guidelines. The manner in which this was done is explained in the design. The research design selected should enhance the validity and reliability of the study.

3.2 The research design

The study design is the overall approach of the study. It is defined as "a set of guidelines and instructions to be followed in addressing the research problem" (Mouton, 2002, p. 107). The study design is determined by the study aims and objectives i.e. the study design should be the most appropriate method to reach the study objectives.

In this study, a quantitative, exploratory and descriptive approach was used to obtain data through the use of questionnaires. Katzenellenbogen, Joubert and Abdool Karim (2004, p. 46) define a descriptive study as one that sets out to quantify the extent of the problem. The aim of this study was to describe the HIV management practices of private health care providers in Windhoek and explore the proportion who comply with the Namibian HIV treatment guidelines. Therefore the descriptive approach is the most appropriate.

Mouton (2002 p. 107) describes exploratory studies as those that seek to establish facts, gather new data and determine whether there is an interesting pattern in the data (i.e. a study that is undertaken when not much is known about the situation at hand (Sekaran, 2000 p. 123)). An exploratory approach has been selected because there is little knowledge on the practices of private health practitioners in the management of HIV disease in Windhoek, Namibia, and the aim of the researcher is to gather new data and develop new hypotheses to explain these phenomena (Mouton, 2002 pp.102-3).

A quantitative research approach is categorized with descriptive research. It collects numerical data in order to explain, predict and/ or control phenomena of interest and data analysis is mainly statistical (Ouyang, n.d). In this study, a cross sectional survey was used to obtain descriptive information on the characteristics of the private health care providers and their reported HIV management practices.

3.3 Research Methods

3.3.1 Study Setting

The study was conducted among private health care providers (general practitioners and pharmacists) in Windhoek, Namibia. Windhoek is the capital city of Namibia and is situated in the Khomas region. It has a population of 230,000 people and has three private hospitals and approximately eighty three (83) private doctors and thirty (30) private pharmacies.

3.3.2 Study Population

The study population is the group the researcher wants to gather information from and make conclusions about (Katzellenbogen, Joubert and Abdool Karim, 2004, p. 74). In this study the target population was the general practitioners and pharmacists managing HIV-positive patients in the private sector in Windhoek, Namibia. Management of patients in the private sector in Namibia is generally condcuted by doctors – who diagnose and provide disease-related management – and pharmacists – who provide medicines and medication-related patient management. This is the reason why these two categories of health care providers were chosen for the study.

The medical listing in the telephone directory was used to identify general practitioners and pharmacies. Practitioners listed in the book that were not practising or that were practising in the public sector were eliminated from the survey. To identify the pharmacists, each pharmacy was called and the pharmacist identified. The pharmacist (and not the pharmacy) was requested to participate in the study. A

total of 83 general practitioners and 30 pharmacists were identified and these constituted the population of the study.

3.3.3 Sampling

Sampling is the process of selecting participants for a research project (Coetzee 2003). It is selecting a convenient or feasible number of units in the place of a target population and to obtain data that are representative of the whole population (Sarantakos, 2000, p. 139)

Since the target population consisted of only 83 doctors and 30 pharmacists, it was decided not to draw a sample but to use the entire population. The decision was motivated by the fact that target respondents are private practitioners who may not readily avail themselves for the survey; it was therefore clear right from the beginning that there would not be a hundred percent (100%) response rate.

The final responses received were 26 doctors and 16 pharmacists which is a response rate of 31% and 53% for doctors and pharmacists, respectively. This was not surprising as it is documented that the response rate for questionnaires, especially self-reporting questionnaires, ranges between 30% and 50%. (Saunders, Lewis and Thornhill, 2003).

3.4 Data collection procedure

Data were collected using self-administered questionnaires containing both open-ended and close-ended questions. (Copies of questionnaires are found in Annexure 3). The procedure used to develop the questionnaires is discussed in detail in Section 3.4.3 below.

3.4.1 Permission and ethical considerations

After approval to conduct the study was obtained from the University of Namibia (Annexure 1), an introductory letter explaining the purpose of the study and requesting consent to participate in the study was faxed to all identified medical practitioners and pharmacists, hereafter referred to as health care providers. Since every pharmacy is operated by at least one pharmacist, only one letter was sent per pharmacy.

The letter informed the participants that their participation in the study was voluntary and that they can withdraw at any time during the course of the research and they would not be penalised in anyway whatsoever, thus ensuring that the ethical principle of voluntary participation is taken into consideration in the study.

The introductory letter further explained how the study would be conducted; the foreseeable risks to the participants, that confidentiality and anonymity would be maintained and that the actions of the researcher are aimed at benefitting society generally. This was ensuring that the principle of beneficence and non-malevolence (which require that actions of researchers be directed at improving the well being of patients and that the reseacher has an obliogation of doing no harm) are considered in

the study. (Katzenellenbogen, Joubert, and Abdool Karim, 2004, p.29 and Ouyang n.d). Refer to Annexure 2 for a copy of the letter.

The health care providers were then contacted telephonically to determine:

a) If they were willing to participate in the study;
b) Methods of response to questionnaires which they preferred: face-to-face interviews, telephonic interviews or self-administration of the questionnaire.

Most health care providers contacted wanted to see the questionnaire first. The questionnaires were then faxed to all of them.

The questionnaires were also taken to the HIV Clinicians Society's open lecture and passed on to health care providers to complete. The list of attendees of this lecture was collected and these health care providers were not contacted again regarding the study.

3.4.2 Data collection period

In collecting the data a cross-sectional approach of collecting data was chosen. Data were collected between November 2006 and March 2007 (excluding December 2006). Over this period of four months the health care providers were followed-up telephonically and reminded to complete the questionnaires and send them back. Some wished to be paid consultation fees even for self-administration of the questionnaire; such respondents were no longer followed up to complete the questionnaire as the study did not make provision for such consultation fees. In addition, paying respondents could be an ethical dilemma as the paid respondents could be tempted to provide the answers that they expect the reseacher to receive.

3.4.3 Data collection instruments

Research instruments are devices for obtaining information relevant to the research project. In this study, questionnaires were used as research instruments. A questionnaire is a list of questions which are answered by the respondents and which give direct and indirect measures of the variables being investigated (Katzenellnbogen, Jobert and Abdool Karim, 2004, p. 82).

Questionnaires with pre-coded closed and open-ended questions were designed to collect information from health care providers. The questionnaires were divided into two sections; the first section focused on the biographical details of the respondents and the second section on determination of compliance to standards. In determining compliance, four main criteria were measured, namely availability of guidelines, initiation of therapy, choice of treatment and management of patients. Because different health care professionals play different roles in the management of treatment for of HIV patients, separate questionnaires for doctors and pharmacists were used. The questionnaires were developed by the researcher in collaboration with a statistician and experienced researchers to ensure validity.

The following process was followed in developing the questionnaire:

a) Determination of questions

The questions to be asked were determined based on the aims and objectives of the study. A literature review was conducted to see if similar studies had been conducted elsewhere and what questions had been asked. The criteria to be measured were determined and questions that would best address the identified

criteria were thus chosen. Once the questions were determined, the exact type of question and wording for each question were selected. The questions were designed in such a way as to ensure that they were clear, unambiguous, concise, and that ambiguous questions were avoided.

b) Design of the questionnaire

The next stage was to design the lay-out of the questionnaire. Two elements were considered and that is to make sure that the questionnaire was not too long and that the sequence of questions was logical. The questionnaires were divided into sections that would cover the areas the study wishes to explore and describe.

c) Peer review of the questionnaire

The questionnaires were then given to experienced researchers, one senior statistician and colleagues for review. The peer reviewers were expected to review the content of their respective questionnaire, the flow of questions, identify ambiguity in questions and responses. In addition, they were also expected to look at the lay-out, the sequencing of the questions, possibility of multiple answers, can the answers be easily coded and whether or not some questions should be split. Comments received from the peers were used to improve the questionnaires for example, additional questions were added, irrelevant questions were removed, long questions were split into sub-sections of a question.

d) Piloting of the questionnaire

The questionnaires were piloted with four doctors and four pharmacists. The piloting was conducted to detect any flaws in the questions, to determine understandability and ease of completion. During the piloting, some questions were found to be too long and other questions required multiple answers. The participants in the piloting and the results of the pilot study were excluded from the final statistics.

e) Finalisation of the questionnaire

The results from the pilot testing were used to improve and finalize the questionnaires. The questions that were too long were shortened (for example, all of the training section component) and those that required multiple answers were divided into sub-sections of a question (example, question 9 of the doctors' questionnaire). The final questionnaires are attached in Annexure 3 (Questionnaires A and B)

3.5 Data Analysis

Data analysis is the act of transforming data with the aim of extracting useful information and facilitating conclusions (Wikipedia, the free encyclopedia). Completed questionnaires were either faxed back or collected by the researcher from the participants. These were then screened, categorised, coded and analysed with the assistance of a statistician.

A computer statistics software programme, SPSS version 14.0, was used to analyse the data. The first step taken was to generate frequency distributions of all variables. From these, errors of data entry (such as illegitimate codes, missing data) were identified and rectified. Then cross-tabulations were generated for different variables. The aim of cross-tabulation was to determine which variables seemed to be related. Further tests were done on these variables that seem to be related using Chi-square, ANOVA and t-tests; however, in most results of the Chi-square test, it was found there were cells with less than five "Expected" frequency, in which case the Chi-square result tests would not be conclusive. As a result, such Chi-square test results were discarded in favour of other non-parametric tests such as Wilcoxin test and the Spearman's rank correlation. All these tests were aimed at ensuring statistically significant results.

Similarly, ANOVA is based on normality of the sampling units and equality of variances of the populations under study. The equality of variance was difficult to verify. Because the sample size for the doctors was greater than twenty-five (25), normality of distribution can be assumed. However for pharmacists, the respondents were fewer than 25 therefore the reseacher cannot assume normal distribution. The third requirement for ANOVA to be valid is that sampling units must be independent and randomly picked. This can safely be assumed to be the case here since there is no reason to suspect that only doctors and pharmacists with certain characteristics responded while those with certain other characteristics did not. Hence there was no systematic selectivity among the sampling units (i.e. doctors and pharmacists) Therefore, it can be concluded that the responses received were from independent

and randomly picked doctors and pharmacists. But because of the first two conditions, only a few of the ANOVA test results were adopted. For quantitative variables the Pearson's correlation co-efficient followed by the co-efficient of determination were calculated to measure and explain the relationship between variables.

3.6 Strategies to Ensure Validity and Reliability

Validity refers to the instrument or study actually measuring the concept in question and measuring it accurately (de Vos, 2004, pp. 166 -168). Reliability refers to the accuracy or precision of the instrument i.e. the extent to which independent administration of the same instrument yields the same or similar results under comparable conditions (de Vos, 2004, pp.166 -168; Struwig and Stead, 2001, p. 130). To ensure validity, the questionnaire was developed to correspond to the criteria being evaluated and it was ensured that the combinations of questions were sufficient to provide a valid overall conclusion. A list of variables to be measured was developed and questions formulated (to best elicit the information to be measured).

The questionnaires were piloted prior to the collection of data with four doctors and four pharmacists with the aim of determining understandability, ease of completion and improving their quality. The results from the pilot testing were used to improve the questionnaire.

3.7 Conclusion

This chapter described the actual processes that were followed in carrying out the study. The methods for ensuring validity and reliability were also discussed. The next chapter will look at the study result, the interpretation and discussions thereof.

CHAPTER 4: RESEARCH FINDINGS AND DISCUSSIONS

4.1 Introduction

An in-depth description of how the data were analysed is given in Chapter three.

At the end of the data collection period, the total responses received were 26 from doctors and 16 from pharmacists, which is a response rate of 31% for doctors and 53% for pharmacists. These response rates are statistically significant at 17% level of significance for doctors and at 9% level of significance for pharmacists. The meaning of these levels of significance is that we are 83% confident that the results from the 26 doctors that responded are consistent with what could have been found out had we covered all the 83 doctors who are in the private practice. The confidence level increases to 91% in the case of pharmacists. Hence, the findings contained in this report are reliable.

The chapter outline is as follows:

- Part A – Presentation of medical practitioners' results
- Part B – Presentation of pharmacists' results

  Both these presentations of results follow the format background (characteristics of respondents), availability and awareness of guidelines, proportion of respondents complying with guidelines, monitoring of patient adherence, training and challenges in HIV management
- Conclusion

4.2 PART A: Presentation of study results on medical practitioners

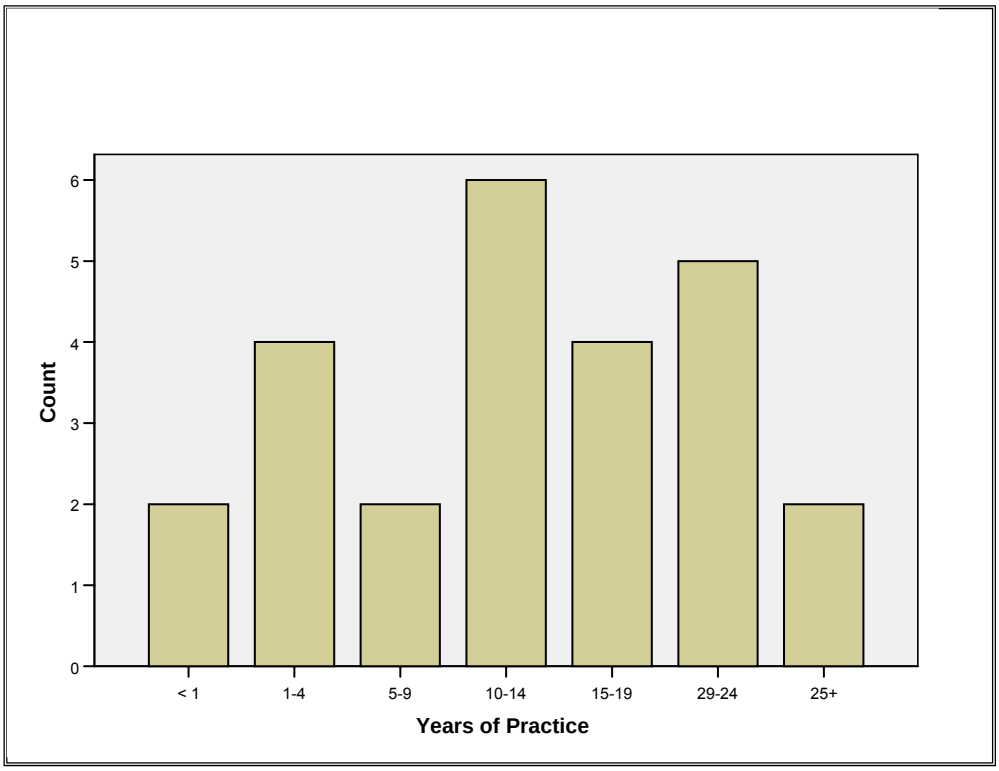
4.2.1 Background Information

Doctors by years of practice

A total of 26 of the 83 doctors who were sent questionnaires responded.

Fifty percent (50%) of the respondents (n=13) reported that they practise alone while the other 50% (n=13) reported working in a combined practice. The years of practice of the respondents ranged from 6 months to 27 years. The chart below shows the years in practice of the respondents.

Figure 4: Private doctors by years of practice



Doctors by professional body

All respondents belong to a professional body with 50% (n=13) belonging to one professional body, 38.5% (n= 10) belonging to two and 11.5% (n=3) belonging to three professional bodies. The HIV Clinicians Society and Medical Association of Namibia are the professional bodies to which most respondents belong. The researcher thought it necessary to determine whether the respondents belonged to a professional body and which one as some professional bodies such as the HIV Clinicians Society conducts regular training sessions for their members on different aspects of HIV management. It is also important to know which professional bodies respondents belong to as these could be possibly used in future to address any HIV management gaps identified. Table 3 shows the distribution within the professional bodies.

Table 3: Professional body to which respondents belong

Doctors by professional body		
Professional body	**Frequency**	**Percentage**
HIV Clinicians Society	16	62%
Medical Association of Namibia	22	85%
South African Medical Association	4	15%

Doctors dispensing own medicines

Fifty eight percent (58%) of the respondents (n=15) reported that they dispense their own medicines. These however did not complete the Pharmacist's Questionnaire and

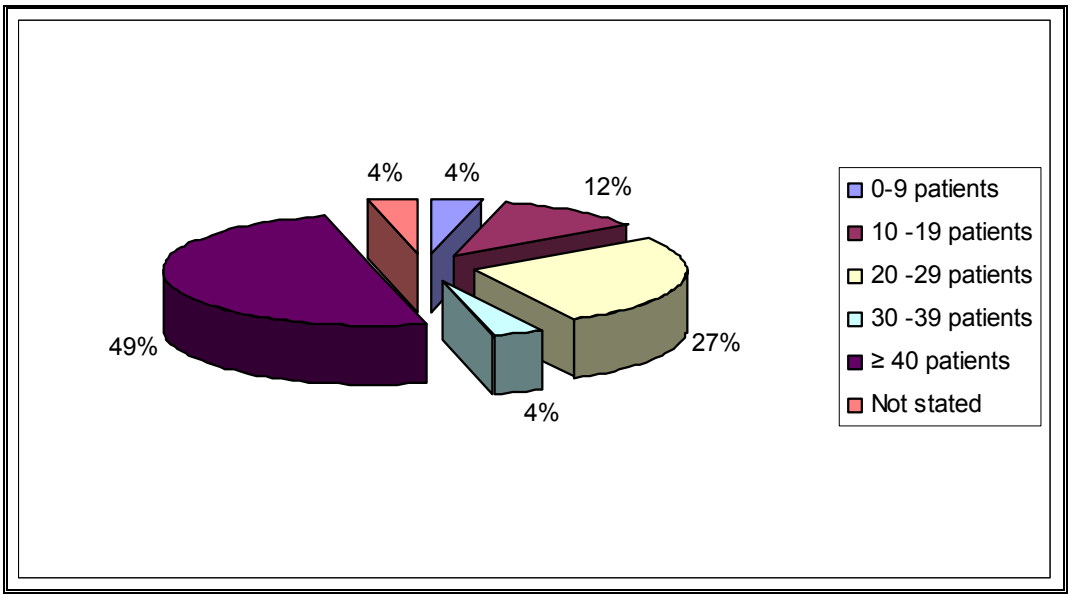
therefore it could not be assessed if their dispensing practices were in accordance with the guidelines' recommendations.

Patients seen per day by doctors

In terms of patients seen per day, the range was from fewer than 24 to between 50 - 74. Fifty four percent (54%) of the respondents (n=14) reported to be seeing 25- 49 patients per day while 38% (n=10) reported to be seeing between 0-24 patients per day. Only 8% (n=2) reported to be seeing between 50 – 74 patients per day.

The total number of HIV positive patients seen per doctor varied from fewer than 9 (for 3.8% of respondents) to more than 40 (for 50% of respondents). The chart below shows the distribution of HIV positive patients per practitioner.

Figure 5: HIV positive patients per practitioner



The Pearson's Correlation Coefficient (R = 0,264) shows that there is a weak positive correlation between the average number of patients per doctor and the HIV positive patients. This means that it cannot be assumed that the higher the patient load, the higher the number of HIV patients the doctor sees.

4.2.2 Awareness and availability of Namibian guidelines

Twenty five (25) of 26 of the respondents (96 %) reported that they were aware of the guidelines and twenty four (92 %) of all the respondents reported that they had a copy of the guidelines. The actual results are presented in table 4

Table 4: Availability and Awareness of Namibian Guidelines

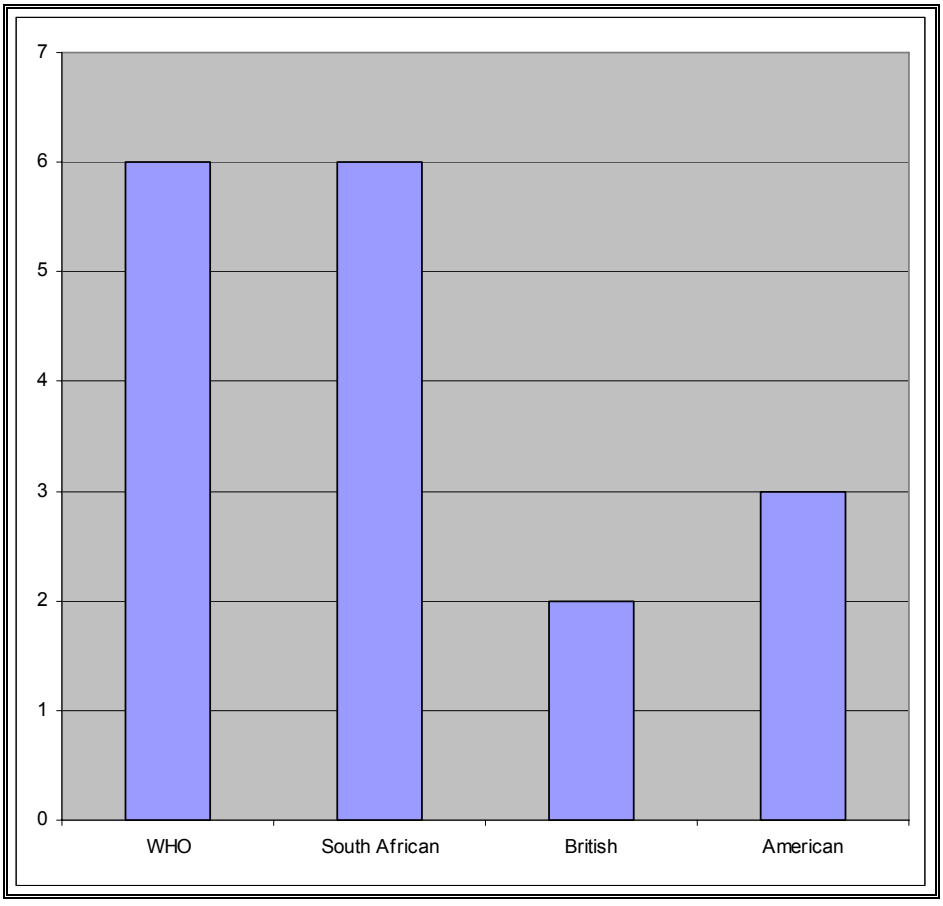
Variable	Response	Frequency	Percentage
Aware of guidelines	Yes	25	96%
	No	1	4%
Have copy of guidelines	Yes	24	92%
	No	2	8%

In the study presented by Cabana, et al (1999) it was found that lack of awareness and lack of familiarity with guidelines were cited among the barriers to compliance by doctors. In the same study, 54% and 57% of respondents cited lack of awareness and lack of familiarity to guidelines respectively as reasons for non-compliance.

Use of other guidelines in the management of HIV

When asked if there were any other guidelines they used in their practice in the management of HIV, 54% of the respondents (n=14) reported using other guidelines to manage HIV positive patients. The graph below shows the "other" guidelines used and the frequency of their use among the respondents.

Figure 6: Other guidelines used in the management of HIV patients



As shown above, the South African and WHO guidelines are the guidelines mostly used by respondents (both used by 23% of respondents). Both these guidelines are similar to the Namibian guidelines in terms of when to start ARV Therapy, what

drugs to start with, when and why to switch therapy and how to monitor patients on therapy.

4.2.3 Proportion of doctors adhering to guidelines

4.2.3.1 When to start ARV Therapy

The Namibian guidelines recommend that patients should be started on treatment if they meet the following criteria:
Adolescents and adults (these categories of patients are grouped together in the guidelines and receive the same treatment) should start antiretroviral therapy (ART) when they have:

- WHO stage IV HIV disease (clinical AIDS), irrespective of CD4 cell count
- WHO stages I, II or III HIV disease, with a CD4 cell count below 200/mm^3
- Pregnant women: CD4<200 or WHO stage IV disease

For paediatric patients

- WHO stage III disease irrespective of CD4 percentage WHO stage I or II disease with CD4 percentage <20%CD4 < 200 cells/mm^3 for children over 8 years

Below is a tabular presentation of the stages at which the respondents in this study reported as starting therapy for each of the groups specified above (i.e. adolescents and adults, paediatrics and pregnat women).

Adults and adolescents

Table 5: Criteria for starting adults and adolescent patients on ART

Stage	Frequency	Percentage
CD4 < 200	10	40%
CD4 < 200 and stage III or IV disease	13	52%
CD4 < 300	1	4%
CD4 < 350	1	4%
Total	**25**	**100%**

For adults, twelve (12) of the respondents (48 %) reported that they use only CD4 cell counts to determine when to start treatment with 40 % (n=10) starting treatment at CD4 count less than 200 cells and 8% (n=2) starting treatment at higher CD4 counts between 350 and 300 cells. Only ten (13) of the respondents (52%) reported that they start treatment when patients are on WHO stage III or IV of the disease or CD4 count lower than 200. One respondent (4%) did not state at what stage he/she starts treatment.

These results show that only 50% of the respondents start treatment as per guidelines' recommendations. Twelve of these (92%) reported that they have a copy of the treatment guidelines. Only one of the respondents who reported not having a copy of the Namibian guidelines started treatment at the correct stage.

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Paediatric patients

Table 6: Criteria for starting Paediatric patients on ART

Stage	Frequency	Percentage
CD4 < 20%	4	23%
CD4 < 20% and stage III	10	59%
CD4 < 30%	1	6%
CD4 < 20% and stage III or Stage IV disease	2	12%
Total	**17**	**100%**

Nine (9) out of 26 respondents (35%) reported that they do not treat paediatric HIV patients. The majority (71%) of the doctors who treat paediatric patients (12 out of 17 who treat paediatric patients) reported that they start treatment in accordance with guidelines.

Five (5) respondents (30%) use only the CD4 count to determine when to start treatment and of these, only one respondent starts treatment at a higher CD4 % (i.e. CD< 30%) and the remaining four (4) start at the recommended CD4 count. These results show that 71% of those treating paediatric patients start treatment as recommended by the guidelines. All twelve (12) of the doctors who reported that they treat according to the guidelines reported that they were aware of the Namibia guidelines and eleven (11) of these (92%) reported that they have a copy of the guidelines. It can therefore be concluded that having the guidelines influenced decision-making in treating the patients.

Pregnant women

Table 7: Stage for starting pregnant women on ART

Stage	Frequency	Percentage
CD4 < 250	3	16%
CD4 < 250 and stage III or IV disease	12	63%
All pregnant women	2	11%
34 weeks (PMTCT)	1	5%
CD4 < 250 and stage III or IV disease and All pregnant women irrespective of CD4 count	1	5%
Total	**19**	**100%**

The Namibian guidelines recommend that for pregnant women, treatment be started at CD4 counts less than 250 or stage III or stage IV disease. Seven of the respondents did not respond to the question. Of those who did respond (n=19) twelve (12) (63 %) reported as starting treatment in accordance with guidelines. Three (3) of the respondents (16%) reported that they treat all pregnant women regardless of CD4 count or disease staging. Another 16% (n=3) use only CD4 count values to determine when to start treatment and one (5%) reported to provide only PMTCT at 34 weeks of pregnancy. These results show that only 63% of respondents treating pregnant women start treatment as recommended by the guidelines. All twelve doctors who use the correct criteria to start treatment reported that they have a copy of the guidelines.

The results presented for starting treatment for all three categories of patients show that some doctors use only CD4 count to determine when to start treatment. Using only CD4 count to determine when to start therapy can disadvantage those patients who are at the advanced stage of the disease (clinically) but have higher CD4 counts. Some doctors also start treatment at higher CD4 counts (these include those who treat all pregnant women irrespective of disease staging and CD4 count). Starting treatment at higher CD4 counts has the disadvantage that long-term medication toxicity is likely to occur to individuals who are living longer, healthier lives with HIV infection. Bradley Hare (2006) argues that it is because of this realisation that the paradigm of HIV treatment underwent revision, and treatment was now recommended primarily for individuals at a more advanced stage of the disease (i.e. starting at lower CD4 counts). The US Department of Health and Human Services (2004) guidelines for use of antiretroviral agents in adults and adolescents identified the potential benefits of delayed therapy to include:

- Avoidance of treatment-related negative effects on quality of life and drug-related toxicities
- Preservation of treatment options
- Delay in development of drug resistance is incomplete viral suppression
- Decreased total time on medication with reduced chance of treatment fatigue

For all three categories of patients, the majority of doctors who start treatment appropriately reported that they have guidelines. This suggests that the possession of guidelines influenced treatment practices. This is in line with the findings of the British HIV Association (2001) presented by Dr. Johnson which showed that 74% of

clinicians who had guidelines reported that they influenced patient care at their practices.

Apart from the clinical criteria to start treatment, the Namibian guidelines also stipulate that each patient should have a treatment supporter. Five respondents (19%) did not respond to the question on whether their patients have treatment supporters or not. Fifty four percent (54%) of respondents (n=14) reported that their patients have treatment supporters and 23% (n=6) reported that their patients do not have treatment supporters. This means that more than 50% of doctors comply with the social criteria requirement for starting treatment.

4.2.3.2 What to start with

WHO (2006b) recommends that a clinical assessment prior to the initiation of ART should include documentation of past medical history, identification of current and past HIV related illnesses, identification of co-existing medical conditions and medications in use that may influence choice of therapy (such as TB or pregnancy) as well as current symptoms and physical signs. Minimum laboratory tests include an HIV antibody test, and (if AZT is part of the regimen) haemoglobin (HB) or hematocrit level. Other tests are white blood cell count and differential, CD4 count, serum alanine, aspartate aminotransferase level (i.e. liver function tests (LFTs)), serum creatinine, blood urea nitrogen, serum glucose, bilirubin, amylase and serum lipids, and pregnancy tests for women.

The Namibian guidelines recommend that treatment-naïve patients starting therapy should be treated with a combination of two NRTIs (first column on the table below) and one NNRTI (middle column on the table below) avoiding the combination stavudine and didonasine.

The table below mentions the individual medicines falling under each class of antiretroviral medicines.

Table 8: Antiretroviral medicines by class

NRTI:	**NNRTI:**	**PI:**
zidovudine (AZT), lamivudine (3TC), didanosine (ddI), stavudine (D4T), abacavir (ABC) emtricitabine (FTC) tenofovir (TDF)	nevirapine (NVP), efavirenz (EFV) delavirdine (DLV)	lopinavir (LPV), indinavir (IDV), nelfinavir (NFV), saquinavir (SQV), ritonavir (RTV),

The regimens of choice reported to be used as first line therapy are presented in the table 9 below.

Table 9: First line treatment regimes used in private sector

Regimen	Frequency	Percentage
AZT/3TC/NVP	4	16%
AZT/3TC/EFV	6	24%
D4T/3TC/NVP	3	12%
D4T/3TC/EFV	4	16%
AZT/3TC/NVP or AZT/3TC/EFV	1	4%
AZT/3TC/NVP or AZT/3TC/EFV or D4T/3TC/NVP or D4T/3TC/EFV	6	24%
AZT/3TC/NVP or AZT/3TC/EFV or D4T/3TC/NVP or D4T/3TC/EFV or TDF/3TC/NVP or TDF/3TC/EFV	1	4%
Total	**25**	**100%**

Only one (1) of the respondents (4%) did not respond to the question on what regimen they start therapy with. The rest of the respondents (96%) start with 2 NRTI's and an NNRTI combination. This is the combination that is recommended in the guidelines. These findings are consistent with the findings by van der Veen and Serfontein (2004) where they found from reviewing medical aid claims that 93% of adults were on the recommended first line treatment.

The guidelines recommend baseline tests including HB, LFT and tests (such as serum lipids, blood glucose, creatinine, RPR for syphilis, pregnancy test) for other medical conditions be conducted prior to starting therapy. The results of these tests have a direct bearing on which medications to choose for therapy. Only 61.5% (n=16) of doctors reported to use the combination of HB, LFT and concomitant disease to decide on therapy, 11.5% (n= 3) use only LFT while another 11.5% use either HB or LFT in combination with other diseases?. The remaining 11.5%

reported using other methods to determine therapy; however, none of these respondents specified which method they used.

Although 96% of doctors choose the recommended regimen, the fact that at least 30% of the doctors do not perform all the required baseline tests before choosing therapy suggests that while on the recommended therapy, some patients could be receiving treatment that is not specific/ tailor-made for them (i.e. empiric treatment).

Another important consideration in treating HIV infected patients is the presence of opportunistic infections. Prophylaxis and maintenance therapy against opportunistic infections are a mainstay of management of HIV-infected patients and can lead to a significant improvement in quality of life and survival. The Namibian guidelines recommend that patients be given prophylaxis to prevent opportunistic infections, in particular Pneumocystis Carinii, Toxoplasmosis and TB. (Ministry of Health and Social Services, 2003, p. 10). For Pneumocystis Carinii and Toxoplasmosis the guidelines recommend the use of co-trimoxazole and for TB the guidelines recommend the use of isoniazid (INH). The results of the study are shown in tables 10 and 11 respectively.

Table 10: Stage at which Cotrimoxazole is given to patients

Stage	Frequency	Percentage
CD4 < 250	3	14%
Prophylactic	1	5%
CD4 < 300 and stage III or IV disease	2	9%
CD4 < 200	10	45%
Stage III disease	2	9%
For everyone	1	5%
CD4 < 300 and Stage IV	1	5%
CD4 < 300 and Post TB	1	5%
Don't know	1	5%
Total	**22**	**100%**

These results show that only 45% (n=10) of doctors provide cotrimoxazole prophylaxis at the recommended CD4 count, and these do not consider patients who are at stage III and IV of the disease with CD4 counts higher than 200. Three of the doctors (14%) considered disease staging as a determinant for giving cotrimoxazole and started prophylactic treatment at higher CD4 counts. This is a cause for concern as it suggests that patients who could be in need of prophylactic treatment are not offered it. During the Fourteenth Conference on Retroviruses and Opportunistic Infections in Los Angeles in February 2007, a study conducted in Malawi comparing the risk of death between patients on ART and cotrimoxazole and patients on cotrimoxazole alone was presented. The findings of this study showed that when antiretroviral therapy was administered with cotrimoxazole prophylaxis, the risk of death during the first six months of treatment was reduced by 41%. (Alcon and Differing, 2007)

Table 11: Stage at which INH is given to patients

Stage	Frequency	Percentage
Any value CD4 count	2	11%
Do not give	1	5%
At start of TB treatment	1	5%
TB contact and all paediatrics	1	5%
When indicated	1	5%
TB contacts	8	42%
CD4 < 200	2	11%
TB contacts with low CD4	1	5%
TB suspects	1	5%
Stage IV disease	1	5%
Total	**19**	**100%**

The guidelines recommend that all HIV positive patients without active TB be put on isoniazid (INH) prophylaxis. The results above do not give an indication as to whether all patients without active TB are given INH. It is however evident that most doctors are not aware when INH prophylaxis should be given to patients.

The AIDS Education and Training Centre Clinical Manual chapter on Latent TB (2006) suggests that persons with HIV or AIDS and latent TB infection (i.e. no active TB) have a much higher risk of developing active TB (estimated at 10% per year) than does the general population (estimated at 10% in a lifetime). The risk of developing active TB can be reduced dramatically with prophylaxis. TB prophylaxis not only reduces the risk of disease for the individual, but also reduces the risk of further TB transmission should the HIV/TB-coinfected person develop active pulmonary TB. In their chapter on Latent TB in resource-limited settings (updated in July 2007), it is stated that “randomized trials in Haiti, Zambia, and Uganda have

demonstrated that a 6-month course of INH reduced the risk of active TB among HIV-infected persons by 60% over 1-5 years of follow-up"

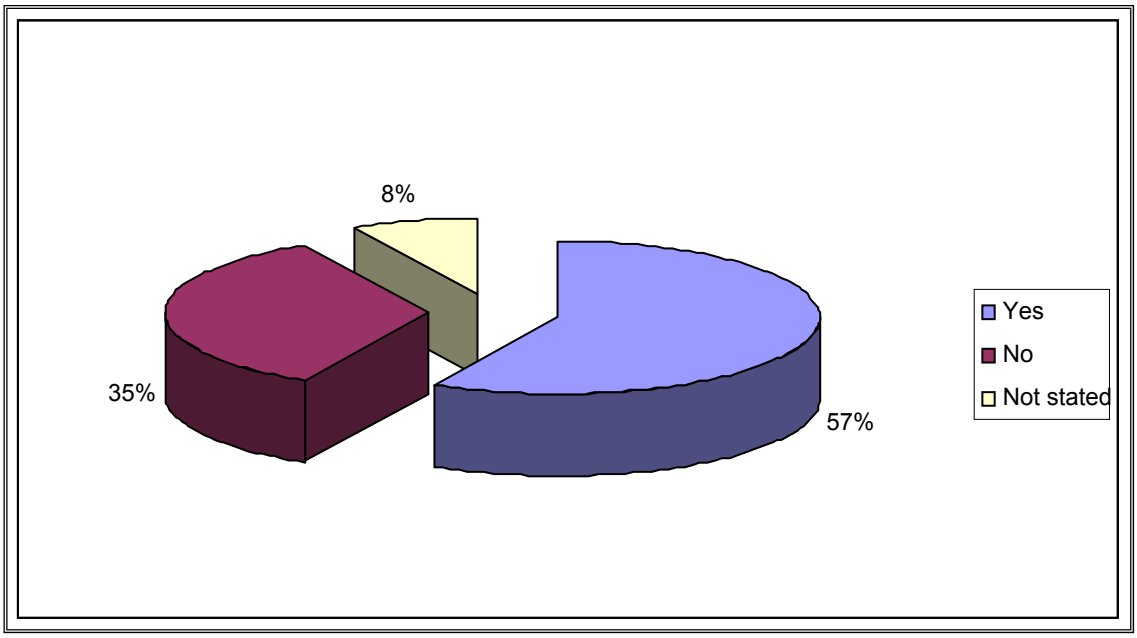
It can therefore be concluded that although 96% (n= 25) of the doctors start ART with the correct regimen, only 45% (n = 10) give cotrimoxazole prophylaxis as recommended and none of them are confident about when to give INH prophylaxis.

4.2.3.3 When to change therapy: Second line treatment

A second line regimen should be chosen to substitute first line regimens when needed either for toxicity or treatment failure. Treatment failure can be measured by clinical failure (progression of the disease), immunological failure (decreases in CD4 cells) and virologic failure (increases in the viral load). When a change in treatment is indicated because of toxicity or resistance (which could be a reason for treatment failure), either an entirely new second line regimen can be prescribed, or, when the toxicity or resistance is related to an identifiable medicine in the regimen, the offending medicine should be replaced.

Fifteen respondents (58%) reported to have patients on 2nd line treatment; two (8%) did not respond to the question while nine (35%) reported not having any patients on 2nd line treatment. Figure 7 below shows a graphic presentation of percentage of respondents with patients on second line therapy.

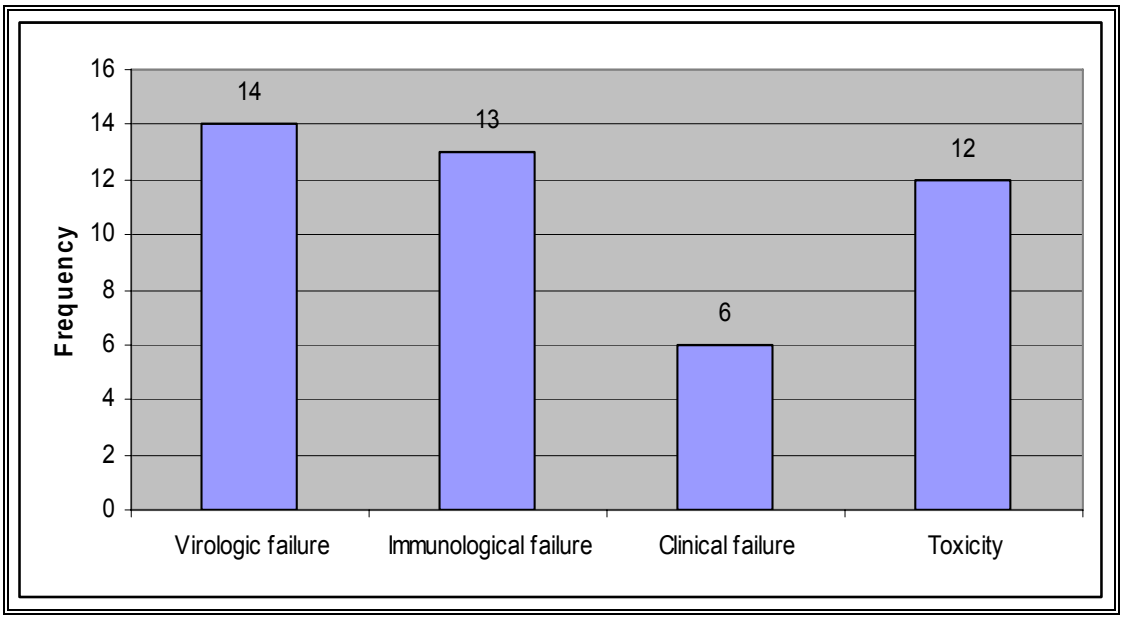
Figure 7: Percentage of respondents with patients on second line treatment



Although the majority of respondents (58%) reported that they have patients on second line therapy, the percentage of patients on second line therapy is not high. A cross-tabulation to determine the percentage of patients on second line therapy estimated that 15.3% of HIV patients from all respondents are on second line therapy.

As depicted in figure 8 below, the reasons given for changing regimen were treatment failure which could either be clinical (23%, n= 6), immunological (50%, n= 13) or virologic (54%, n=14) and toxicity (46%, n=12). In responding to the question on reasons for changing therapy, respondents could give more than one reason; hence the total percentage of responses is more than 100%.

Figure 8: Reasons for starting second line treatment



The results of the study show that patients being placed onto second line therapy are being so placed either due to treatment failure or toxicity (see figure 8). These results are consistent with the results of the question on how the doctors monitor their patients' therapy and progress. To this question, twenty five (96%) said they monitor CD4 counts, twenty four (92%) monitor clinical response (using patient history and relevant laboratory tests) and 78% (n=20) reported to monitor virologic response. Again for this question, respondents could give more than one answer hence the total percentage is higher than one hundred.

4.2.3.4 What to change to: Second line treatment

Namibian guidelines recommend that patients on second line therapy should be given Protease Inhibitor (PI) based regimen – either retonavir boosted indinavir or

lopinavir. Only thirteen (13) respondents (42%) responded to the question on what treatment regimen they give to their patients on second line therapy. Of these, three respondents (27%) reported as giving PI based regimen. However they gave the contraindicated combination of NRTIs (d4t and ddI). The remaining seventy three percent (73%) of respondents (n=8) reported giving the correct second line therapy combination as per the guidelines.

4.2.4 Monitoring of patients' adherence

Adherence monitoring and assessment is generally recognized as a key component of patient monitoring to slow down development of resistance and predict treatment outcomes. (WHO, 2006a, p. 27). There is no gold standard for accurately determining true patient adherence as all available methods have their limitations. The Namibian guidelines mention pill count and validated patient questionnaire (also known as self-reporting forms). The table below gives a representation of the strategies reported to be used in monitoring patients' adherence.

Table 12: Strategies employed for monitoring patients' adherence to treatment

Strategy	Frequency	Percentage
Pill Count	1	4%
Monitor follow-up	17	65%
Pill Count and Follow-up	7	27%
Pill count, follow-up and self-reporting	1	4%
Total	**26**	**100%**

Seventeen of the 26 doctors (65%) reported that they monitor patients' adherence by monitoring the patients' follow-up. Although this provides a good indication of a patient's commitment to therapy, it does not give information on whether the patient takes their medication or not.

Almost twenty seven percent (27%) of doctors (n=7) perform pill counts and monitor follow-up of patients. A combination of these two methods is a better strategy for monitoring adherence when compared to monitoring follow-up alone. Counting the remaining patient's pills can provide a quantitative measure of patient's adherence.. However this method is subject to error and manipulation.

Combining pill count, monitoring follow-up and self-reporting are even better strategies of monitoring adherence. Only one of the doctors (4 %) reported to be doing this. The advantage of this combination is that self-reporting helps to validate the pill count. The Pearson's correlation coefficient is -0.196 for number of patients per practitioner and strategy used to monitor adherence. While it could be expected that time-consuming adherence monitoring strategies such as pill-count and self-reporting should be performed in practices where fewer patients are seen, the correlation coefficient shows that there is no strong relationship between number of patients in a practice and strategy used to monitor adherence. It can, therefore, be concluded that the strategy used is not influenced by patient numbers.

In the Patient Monitoring Guidelines for HIV Care and Antiretroviral Therapy (2006 c), WHO recommends a combination of both pill count and self-reporting as pill count alone tends to underestimate adherence while self-reporting alone tends to

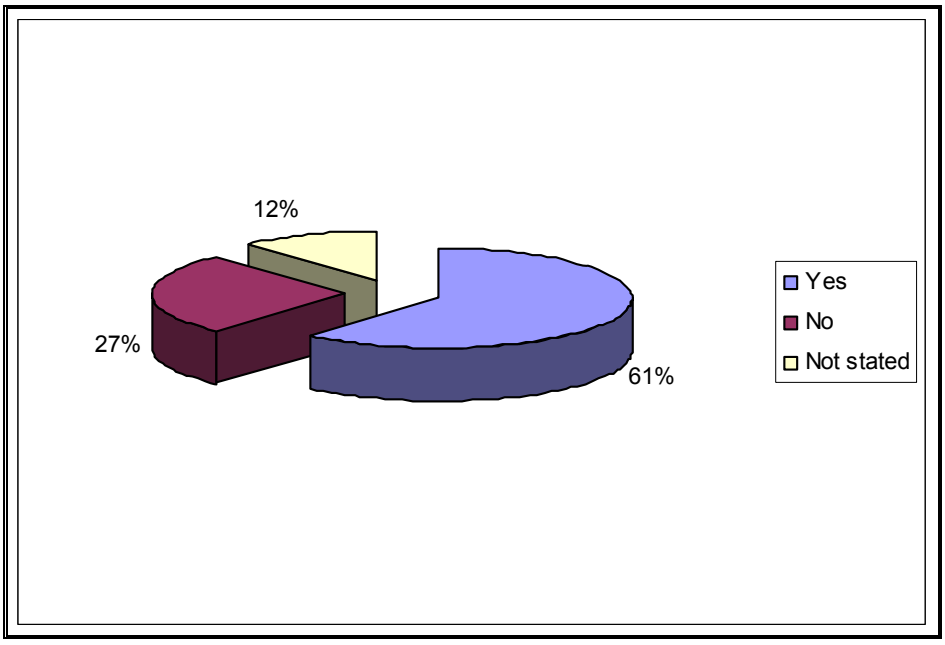
overestimate adherence. Monitoring patient follow-up is also another method of monitoring patient's adherence – patients who miss their follow-up appointments, especially for medicines, are likely not to be taking medication. The Namibian guidelines stipulate that patients who miss two or more consecutive follow-up visits should be discontinued from HAART. (Ministry of Health and Social Services, 2003, p. 7).

4.2.5 Training

Training was not a specific objective of the study. However this component was added in order to determine if the presence or absence of training had a bearing on the results.

Sixty one (61%) percent (n= 16) reported to have received formal training on HIV management while 27% (n=7) reported not to have had any formal training and 12 % (n=3) did not respond to the question. Figure 9 shows the graphic presentation of the doctors who had formal training.

Figure 9: Distribution of doctors by whether or not they had formal training



Only 19% of all respondents (n=5) reported that they have training needs. Twenty of the doctors (77%) did not respond to the question and one (1) (4%) respondent reported not having any training needs. Of the five (5) people who reported having have training needs, two reported having had formal HIV management training while the other three reported as not having had any formal training. This result matches the results obtained from the Pearson's correlation coefficient which showed that there was a weak correlation between previous formal training and need for more training (i.e. the respondents who stated that they had training needs did so regardless of whether they had formal HIV training or not).

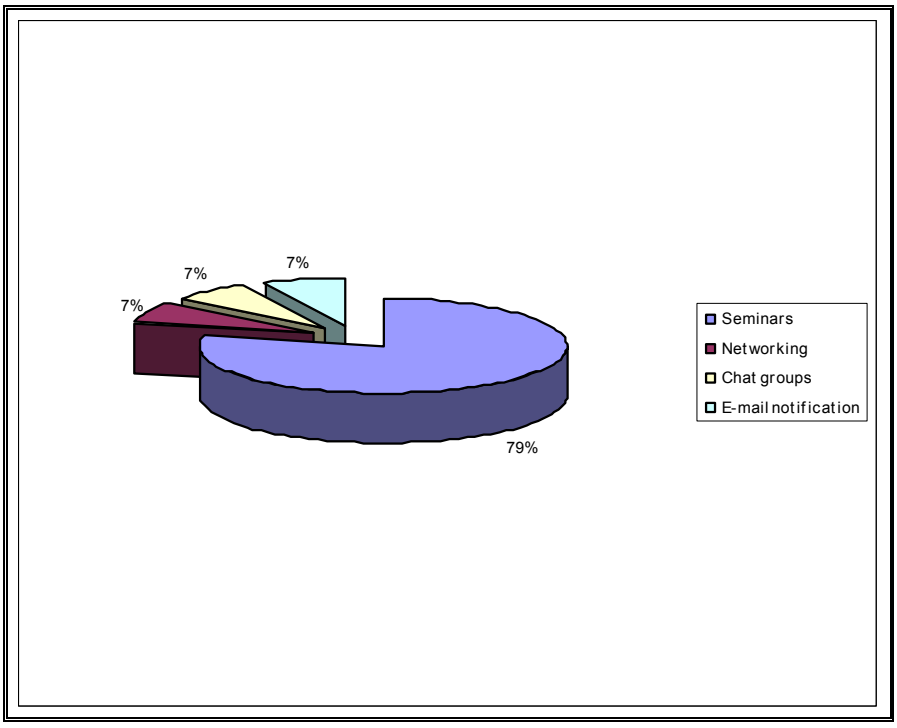
Although only five (5) respondents reported having training needs, nine (35%) respondents indicated areas for which training is required. A wide range of training needs was identified and these were summarised into broader topics. A summary of these topics is presented in table 13 below.

Table 13: Identified training needs in HIV management

Topic	Frequency	Percentage
Update on current trends (including regimen and medicines)	4	44.4%
Drug resistance	1	11.1%
Management of long term side-effects	2	22.2%
Patient counselling	1	11.1%
Management of complicated HIV cases	1	11.1%

The doctors identified the preferred methods for addressing training needs as: seminars (workshops, tutorials and presentations), networking, chat groups and e-mail notifications. Figure 10 below shows a graphic presentation of preferred methods of addressing training needs.

Figure 10: Preferred method of addressing training needs



4.2.6 Challenges facing HIV management in Namibia

The respondents were also requested to mention what they consider to be challenges facing HIV management in Namibia. The perception of doctors on challenges is wide and varied with poverty and adherence-related factors ranking the highest. Although most of the patients in the private sector have medical insurance, cost of treatment ranked the third highest among the challenges facing HIV management.

The challenges are shown in Table 14 below.

Table 14: Identified challenges to HIV management in Namibia

Challenge	Frequency	Percentage
Patient adherence (non-adherence)	6	29%
Poverty	6	29%
Patient follow-up (difficulty in tracing patients)	4	19%
Poor patient education	4	19%
Stigma	2	10%
High cost of treatment	2	10%
Resistance	2	10%
Life style (infidelity, teenagers experimenting with sex)	2	10%
Difficulty in management of side-effects	1	5%
Poor routine patient monitoring	1	5%

It is not surprising that patient adherence ranks highest on the challenges to HIV management. Steel, Nwokike and Joshi (2007) argue that non-adherence is a common problem among patients stating that adherence to ARVs by patients varies between 37 and 83 percent depending on the drug being used.

4.3 PART B. Presentation of study results: Pharmacists

4.3.1 Background Information

The role of pharmacists in the management of HIV/AIDS in Namibia has been detailed by the Ministry of Health as ensuring adequate uninterrupted supply of medicines, assessing ARV therapy prescriptions including potential for drug-drug interactions, providing patient education on medication (such as use, side-effects, food effects) and adherence counselling, dispensing of medicines and monitoring of patient adherence (Ministry of Health and Social Services, 2005, p. 13). These responsibilities of pharmacists in HIV management have also been identified by others such as Zappa (1999, pp 19 -28) and the South African Pharmacy Council (2003). Hill (2006) suggests that "because HIV is a disease for which treatment is entirely drug based, pharmacists play an important role in the multidisciplinary team".

It is because of these identified roles and responsibilities of pharmacists that the study also set out to explore and describe the practices of pharmacists in the management of HIV/AIDS in Namibia.

The characteristics of pharmacists and their pharmacies are discussed and presented below (see tables 15 and 16).

Characteristics of the pharmacists and their pharmacies

A total of sixteen (16) out of the thirty (30) pharmacists who were sent the questionnaire responded to the questions on the type of practice they operate in. Six (6) of the respondents (37.5%) practise in a hospital setting while nine (56%) practice in a retail setting. One of the respondents did not answer this question.

The number of years in practice ranged from one (1) to thirty-five (35); the point of location having the highest frequency (i.e. the mode) being two years of practice. The average (mean) number of years in practice for the pharmacists was 7.56 years while the median was 4.5 years. What the median tells us is that half of the pharmacists were in practice for less than 4.5 years while the other half had been in practice for longer than that. The percentiles tell us that a quarter (25%) of the pharmacists had been in practice for less than two years. At the same time 75% had been in practice for less than nine years (implying that only 25% of the pharmacists had been in practice for longer than nine years), with the longest serving pharmacist having logged 35 years of practice. The data indicate a substantial variation in length of practice from pharmacist to pharmacist, the standard deviation being about 8.7 years.

Table 15: Distribution of Pharmacists by Different Demographic Characteristics

Type of Practice		
	Frequency	**Percentage**
Hospital	6	37.5%
Retail	9	56.25%
Not stated	1	6.25%
Total	**16**	**100.0%**
Number of Years in Practice		
	Frequency	**Percentage**
1 – 5	9	56.25%
6 - 10	4	25.0%
11 - 15	1	6.25%
16 - 20	1	6.25%
> 20	1	6.25%
Total	**16**	**100.0%**
Membership To A Professional Body		
	Frequency	**Percentage**
Belonging to a professional body	12	75.0%
Not belonging to a professional body	3	18.75%
Not stated	1	6.25%
Total	**16**	**100.0%**
Distribution of pharmacists by Professional Body		
	Frequency	**Percentage**
None	3	18.75%
Pharmaceutical Society of Namibia	10	62.5%
HIV Clinicians + Pharmaceutical Society of Namibia	1	6.25%
HIV Clinicians Society	1	6.25%
Not Stated	1	6.25%
Total	**16**	**100.0%**

Seventy five percent (75%) of the pharmacists (n= 12) reported as belonging to a professional body. The majority (n= 11) of the respondents (79%) belonged to the Pharmaceutical Society of Namibia while only 13% (n=2) belonged to the HIV Clinicians Society.

Table 16: Distribution of Pharmacies by Workload and Confidentiality

Ranges of Total New Prescriptions Received Per Day		
	Frequency	**Percentage**
0-24	2	12.5%
25-49	5	31.25%
50-74	5	31.25%
75-99	4	25.0%
Total	**16**	**100.0%**
Ranges of Total Refill Prescriptions Received Per Day		
	Frequency	**Percentage**
0-24	1	6.25%
25-49	13	81.25%
50-74	2	12.5%
Total	**16**	**100.0%**
Ranges of ARV Prescriptions Received Per Day		
	Frequency	**Percentage**
0-9	2	12.5%
10-19	6	37.5%
20-29	6	37.5%
30-39	0	0.0
40+	2	12.5%
Total	**16**	**100.0%**
Number of Dispensers by Pharmacy		
	Frequency	**Percentage**
2.0	6	37.5%
3.0	4	25.0%
3.5	1	6.25%
4.0	2	12.5%
6.0	3	18.75%
Total	**16**	**100.0%**
Place for Confidential Matters by Pharmacy		
	Frequency	**Percentage**
Private place present	9	56.25%
No private place	7	43.75%
Total	**16**	**100.0%**
Availability of treatment supporters		
	Frequency	**Percentage**
Patients have treatment supporters	12	75
Patients do not have treatment supporters	4	25
Total	**16**	**100%**

To estimate the workload of the pharmacy, the total number of prescriptions and the number of dispensers per pharmacy were used.

The number of ARV prescriptions received per day in their respective pharmacies as reported by the pharmacists ranged from under ten (12.5%) respondents to over forty (12.5%) respondents with seventy five percent (75%) of respondents reporting to receive between ten (10) and thirty nine (39) prescriptions per day.

In summary, the pharmacies in which the 16 pharmacists who responded work, receive on average 20.75 ARV prescriptions per day. The median is 19.5, which means that half of the pharmacies receive less than 19.5 ARV prescriptions per day while the rest receive more than that. The upper quartile tells us that three-quarters of the pharmacies receive less than 24.5 ARV prescriptions per day while 25% receive more than that.

The data in the foregoing paragraphs throw light on the workload facing pharmacists. It is clear that pharmacists have other responsibilitiess besides dispensing to HIV patient on HAART since they have to cater for clients with other ailments as well. The figures indicate how much time the pharmacists would have to counsel the patient, monitor drug-use and re-fills, discuss side-effects and drug interactions and perform other dispensing duties required to ensure adequate patient understanding.

The number of dispensers reported in each pharmacy ranged from two (2) to six (6). The pharmacies with high volumes of prescriptions reported having a high number of dispensers.

Confidentiality was determined by the presence or absence of a private place to counsel patients confidentially (the assumption being that if there is a confidential place to discuss private matters, it will be used when counseling patirents). Fifty six percent (56%) of the pharmacists (n=9) reported that their pharmacies have a private area to discuss confidential matters while forty four percent (44%, n=7) reported not having such a private area.

With regrads to treatment supporters, seventy five percent (75%) of the respondents(n=12), reported to that their patients have treatment supporters while the remaining twenty five percent (25%) (n=4) reported that their patients did not have treatment supporters.

4.3.2 Awareness and availability of guidelines

As shown in table 18 below, eighty one percent (81%) of the respondents (n=13) reported to be aware of the Namibia Guidelines for ARV therapy while only fifty percent (50%, n=8) reported having a copy of the guidelines. Fifty percent (50%) of the respondents (n=8) reported using other guidelines in their management of HIV patients and the guidelines used are the South African (44% of those using other guidelines) and British guidelines (33% of those using other guidelines).

Table 17: Awareness and availability of guidelines by Pharmacists

	Response	Frequency	Percentage
Aware of guidelines	Yes	13	81%
	No	3	19%
Have copy of guidelines	Yes	8	50%
	No	8	50%

Anderson (2002, pp. 391 - 404) defines pharmacy as a health profession that has the responsibility of ensuring the safe, effective and rational use of medicine. Rational use of medicine is defined as ensuring that the correct medicine is given to the appropriate patient in the appropriate dosage at the right time for the appropriate indication. It also encompasses correct dispensing which includes providing of appropriate information to the patient regarding their medicine. (Management Sciences for Health). The fact that 50% of the pharmacists do not have a copy of the guidelines may suggest that it is impossible for them to ensure appropriateness of patient's prescription in accordance with the national guidelines.

4.3.3 Dispensing Practices

The pharmacist is often the last member of the health care team to have contact with the patient and therefore has the responsibility of ensuring that the patient has the correct medication (with all prescription errors eliminated), the patient understands his or her therapy (i.e. how to take the medication and when), understands the need for strict adherence to the therapy, understands appropriate storage of the medicine

and understands what foods and medicines to avoid while taking the medicines. In order to assess the dispensing practices of the pharmacist, the researcher identified twenty two (22) actions (or dispensing practices) that should be performed during dispensing to ensure patients' understanding which will in turn yield better compliance by the patient and therefore better treatment outcomes. The responses to these actions are presented in tables 18 to 19 are discussed below.

Table 18: Distribution of pharmacists by how they interact with new patients

Modus operandi	Always	Most of the time	Some-times	Rarely	Never	Not stated	Total
Do you explain how HIV medication works?	14 (87.5%)	-	-	2 (12.5%)	-	-	16 (100%)
Do you explain administration schedule for each medication?	5 (31.3%)	6 (37.5%)	5 (31.3%)	-	-	-	16 (100%)
Do you explain food requirements for each medication?	4 (25.0%)	7 (43.8%)	5 (31.3%)	-	-	-	16 (100%)
Do you help patients plan administration time of medicines?	4 (25.0%)	7 (43.8%)	5 (31.3%)	-	-	-	16 (100%)
Do you ask patients to repeat administration and storage instructions?	2 (12.5%)	10 (62.5%)	3 (18.8%)	1 (6.3%)	-	-	16 (100%)
Do you explain potential drug interactions?	1 (6.3%)	8 (50.0%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	1 (6.3%)	16 (100%)
Do you explain storage requirements?	8 (50.0%)	6 (37.5%)	2 (12.5%)	-	-	-	16 (100%)
Do you discuss potential side-effects and how to manage them?	11 (68.8%)	4 (25.0)	1 (6.3%)	-	-	-	16 (100%)
Do you discuss resistance?	4 (25.0%	4 (25.0%)	6 (37.5%)	2 (12.5%)	-	-	16 (100%)
Do you discuss consequences of non-adherence?	12 (75.0%)	4 (25.0%)	-	-	-	-	16 (100%)
Do you explain what to do if a dose is missed?	8 (50.0%)	4 (25.0%)	4 (25.0%)	-	-	-	16 (100%)
Do you tell patients when refill is due?	10 (62.5%)	6 (37.5%)	-	-	-	-	16 (100%)
Do you ask patients of all other medicines, over-the-counter (OTCs) and herbal supplements?	3 (18.8%)	3 (18.8%)	7 (43.8%)	1 (6.3%)	2 (12.5%)	-	16 (100%)
Do you check for documented interactions?	7 (43.8%)	4 (25.0%)	5 (31.3%)	-	-	-	16 (100%)
Do you inform patients of potential interaction and how to manage them?	5 (31.3%)	6 (37.5%)	5 (31.3%)	-	-	-	16 (100%)
Once interaction is identified, do you refer the patient to the doctor?	15 (93.8%)	-	-	-	-	1 (6.3%)	16 (100%)

The above results show that only fourteen (14) of the pharmacists (87.5%) reported as always explaining how the medication works. All pharmacists reported explaining how the medicine should be administered although only 31% (n=5) reported performing this action always. Twenty-five percent 25% (n=4) of the respondents

reported always informing the patients of food requirements for HIV medication. Again, twenty-five 25% (n=4) reported always helping their patients plan administration times for medication. All pharmacists reported to asking patients to repeat administration instructions; however, only 12.5 % (n=2) reported that they always perform this action.

Adequate patient counselling and education on the goal of therapy and how the medication should be taken are essential in ensuring patients' understanding of their medicine. Hill (2006) suggests that appropriate counselling is fundamental to ensuring compliance and ultimately best patient outcomes. The Namibian guidelines also state that educating the patient on the goal of therapy, pills and food effects is one of the methods that should be employed to achieve patients' readiness for HAART and also maintaining adherence. (Ministry of Health and Social Services, 2003, p. 7). The findings of the study show that except for explaining how the medication works, most pharmacist do not always ensure adequate patient understanding on how to take the medicines.

Medicines are chemicals that react to external stimulants such as heat, moisture, light and dust. In many cases, such reaction leads only to superficial changes, such as discoloration. In many other cases, the reaction may affect the drug more seriously, leading to reduction or elimination of its efficacy and/or potency. There are cases of drugs that, thus affected, not only exert no healing effect but also cause adverse effects on the patient's health (Ganguluy, n.d.). It is therefore very important that patients are advised how to store their medicines.The above results show that only

50% of the pharmacists reported that they always explain how the medicines should be stored.

The Namibian guidelines suggest that one of the methods that should be used to improve patient's adherence to medication is educating the patient about the possible side-effects and how they should be managed. The New York State Department of Health (2006) suggest that the patients should be informed of drug related toxicities, in order to avoid premature discontinuation of HAART by the patients. Sixty nine percent (69%) of respondents (n=11) reported that they always discuss potential side-effects and their management with their patients.

Concerning adherence, the results of the study show that 75% (n= 12) of pharmacists reported that they always discuss the importance of adherence; 50% (n=8) explain what to do in case of missed doses and only 25% (n=4) discuss resistance.

Drug interactions pose a great challenge in the management of HIV. There are many significant interactions between ARVs themselves and ARVs and other medication that patients could be taking. Drug interaction can either result in sub-therapeutic levels of the drug in the body (which predisposes to development of resistance) or development of toxicities owing to too much of the drug? in the body. It is important that the pharmacists inform patients about potential drug interactions and also assess and manage possible interactions for each patient.

The results show that only one (1) (6%) of the respondents reported to always informing the patients of possible interactions while 50% reported to do this most of the time. Only 19% (n=3) pharmacists reported asking patients about other medicines

that they are using including over-the-counter medicines and herbal supplements. Forty four percent (n=7) reported performing this action sometimes. Surprisingly, only 44 % respondents (n=7) reported to actually always checking for documented interactions. Ninety four percent (94%) of the respondents (n = 15) reported that in the event that an interaction is detected they refer the patient to the doctor.

The Namibian guidelines recommend that a review of drug interactions should be conducted with each patient and that medicines that are likely to cause significant interactions be avoided. The fact that only 19 % of pharmacists always ask for other medicines that the patients are using suggests that most patients on ART could be using other medicines that interact with their ARVs. This compromises the quality of care to the patient.

Refill visits are important not only because the patients get to obtain their medication but also because they provide an opportunity to monitor patients' adherence. The Namibian guidelines recommend that to maintain adherence, providers must ensure that patients collect their medication refills from the pharmacy. (MoHSS, 2003, p 7). New York State Department of Health (2006) recommends that patients be encouraged to refill all ARV prescriptions at the same time as this has been shown to reduce number of missed doses and thus to improve adherence.

For new patients, 62.5% (n= 10) of the respondents reported always telling their patients when their refills are due. For patients coming for refill visits, only 44% (n=7) respondents reported informing patients of their next refill date.

Table 19: Distribution of pharmacists by how they dispense to refill patients

Modus operandi	Always	Most of the time	Some-times	Rarely	Never	Not stated	Total
Do you ask how medication was taken?	4 (25.0%)	8 (50.0%)	2 (12.5%)	1 (6.3%)	1 (6.3%)	-	16 (100%)
Do you ask whether the patient experienced side-effects?	6 (37.5%)	6 (37.5%)	4 (25.0%)	-	-	-	16 (100%)
Do you ask if problems were experienced with medication?	8 (50.0%)	2 (12.5%)	6 (37.5%)	-	-	-	16 (100%)
Do you review administration instructions?	7 (43.8%)	5 (31.3%)	4 (25.0%)	-	-	-	16 (100%)
Do you ask patients to repeat administration and storage instructions?	4 (25.0%)	4 (25.0%)	5 (31.3%)	2 (12.5%)	1 (6.3%)	-	16 (100%)
Do you tell patients when refill/follow-up is due?	7 (43.8%)	9 (56.3%)	-	-	-	-	16 (100%)

Reviewing administration instructions re-enforces the patients' understanding of their medication. However only forty four percent (44%) of respondents (n=7) reported always reviewing medication administration instructions. Five (31%) reported reviewing medication instructions most of the time while the remaining 25% (n=4) reported reviewing only sometimes.

Only six (6) of respondents (37.5%) reported asking the patients if they experienced any side-effects. In most cases patients see the pharmacist more than they see their doctor, therefore it is important that the pharmacists ascertain that the patients are not suffering from side effects and if they are, to advise on how these should be treated.

With respect to adherence, only 25% (n=4) of respondents reported that they always ask the patient how the medication was taken. Asking how the medication was taken provides the pharmacist with the opportunity to determine if the patient understood

how to take their medication and if they are taking it as directed. If patients are not compliant, an intervention by the pharmacist at this stage could improve the patient's adherence and treatment outcomes. Eight (8) of the respondents (50%) reported that they always ask their refill patients if they had any problems with their medication. Addressing problems encountered with medication reduces the chances of patients being non-adherent.

4.3.4 Monitoring Adherence

Adherence monitoring and assessment is generally recognized as a key component of patient monitoring to slow down development of resistance and predict treatment outcomes. (World Health Organization, 2006a: p. 27). There is no gold standard for accurately determining true patient adherence as all available methods have their limitations. The Namibian guidelines mention pill count and validated patient questionnaires (also known as self-reporting forms). The table below shows the strategies employed in monitoring adherence as reported by the respondents.

Table 20: Strategies used by pharmacists to monitor adherence

Strategy	Frequency	Percentage
Pill Count	2	12.5%
Monitor refills	10	62.5%
Pill Count and monitor refills	2	12.5%
Pill count, monitor refills and self-reporting	2	12.5%
Total	**16**	**100%**

While it could be expected that time-consuming adherence monitoring strategies such as pill-count and self-reporting, should be performed in practices where fewer patients are seen or where there are more dispensers, the cross-tabulations that compare adherence method used with either the number of patients or number of dispensers per pharmacy showed that there was no association between these variables. (See tables 21a and 21b). Therefore it can be concluded that neither the workload nor the number of dispensers influenced the method of adherence monitoring.

Table 21a: Effect of workload on monitoring adherence

	How do you monitor patient's adherence				Total
ARV Prescriptions received per day	Pill Count	Monitor refill	Pill Count and monitor refill	Pill count, self-evaluation questionnaire, monitor refills	
0-9	0 (0%)	2 (20%)	0 (0%)	0 (0%)	2 (12.5%)
10-19	2 (100%)	2 (20%)	2 (20%)	0 (0%)	6 (37.5%)
20-29	0 (0%)	6 (60%)	0 (0%)	0 (0%)	6 (37.5%)
40+	0 (0%)	0 (0%)	0 (0%)	2 (100%)	2 (12.5%)
TOTAL	2 (100%)	10 (100%)	2 (100%)	2 (100%)	16 (100%)

Table 21b: Effects of number of dispensers on adherence monitoring

	How do you monitor patient's adherence				Total
Dispenser working in the pharmacy	Pill Count	Monitor refill	Pill Count and monitor refill	Pill count, self-evaluation questionnaire, monitor refills	
2.0	0 (0%)	4 (40%)	0 (0%)	2 (100%)	6 (37.5%)
3.0	0 (0%)	3 (30%)	1 (50%)	0 (50%)	4 (25%)
3.5	0 (0%)	0 (0%)	1 (50%)	0 (0%)	1 (6%)
4.0	2 (100%)	0 (0%)	0 (0%)	0 (0%)	2 (12.5%)
6.0	0 (0%)	3 (30%)	0 (0%)	0 (0%)	3 (19%)
TOTAL	2 (100%)	10 (100%)	2 (100%)	2 (100%)	16 (100%)

Both tables 21a and 21b show that the preferred method of monitoring adherence was monitoring refills. Ten out of the 16 respondents (i.e. 62.5%) reported to be using this method to monitor adherence. Out of those ten respondents 60% had 20-29 patients on ARVs; 20% had 10-19 such patients and the remaining 20% had 0-9 patients on ARVs. It would seem that pharmacies with higher numbers of patients on ARVs are the ones that preferred to use monitoring of refills as a way of checking for adherence.

The other time-consuming method of checking for adherence is pill counting. This method was used by two (12.5%) out of the 16 respondents and both of them had 10-19 patients on ARVs. Thus, it is not obvious that the number of patients on ARVs is the guiding factor on whether or not to use pill count to monitor adherence.

As far as number of dispensers in the pharmacy is concerned, out of the ten pharmacies that use monitoring of refills to monitor adherence, four (40%) had two dispensers each; three (30%) had three dispensers each; and the remaining three (30%) had six dispensers each. It would seem, therefore, that the fewer the number of dispensers the more this method is preferred for monitoring adherence.

With respect to counting pills as a way of monitoring adherence, the two pharmacies that use this method had four dispensers each.

From the above data, it is not absolutely conclusive that it is the number of patients on ARVs or the number of dispensers in the pharmacy that are the deciding factors in how to check for adherence. In fact the results of the ANOVA (Analysis of variance) tests are not statistically significant. The P-value is 0.133 (for "Number of patients on ARVs) and 0.591 (for "Number of dispensers). This means that there is not enough evidence to conclude that those two factors influence the choice of method of monitoring adherence.

In the Patient Monitoring Guidelines for HIV Care and Antiretroviral Therapy (2006), WHO recommends a combination of both pill count and self-reporting, as pill count alone tends to underestimate adherence while self-reporting alone tends to overestimate adherence. Only 2 respondents (12.5%) were using both methods. Monitoring patient follow-up is also another method of monitoring patient's adherence – patients who miss their follow-up appointments (especially for medicines) are likely not to be taking medication. The Namibian guidelines stipulate

that patients who miss two or more consecutive follow-up visits should be discontinued from HAART. (Ministry of Health and Social Services, 2003, p. 7).

External factors that can affect patients' adherence include lack of availability of medicines and lack of availability of funds to purchase medicines. All pharmacists (100%) reported not to have had any stock-outs of any medicine in the previous six months preceding the survey. When asked what action they take in case of stock-outs of one or more medicines, only 7 (44%) of the respondents responded to the question (possibly because none had experienced stock-outs) and of these, 57% of the respondents (n=4) said they would refer the patient elsewhere, 28.5% (n=2) said they would order the medicines and deliver later to the patient and 16% (n=1) said they contact the doctor for a substitution. These findings suggest that there is an uninterrupted supply of ARVs in the private sector pharmacies. They also suggest that in the event that stock-outs are experienced, appropriate measures are taken by all pharmacists to ensure that the patients do not go without treatment.

On the question of whether there had been any patients who were ever turned away because of exhausted medical aid funds (therefore inability to pay for treatment), 25% (n=4) of the pharmacists reported to have turned away patients while the remaining 75% (n=12) reported not to have turned patients away. Of those who reported having experienced patients with exhausted funds, three (75%) reported sending the patients to state hospitals, while one (25%) reported advising the patients to contact their medical aid scheme. One of the respondents from the group that reported not having turned patients away, reported advising patients whose medical

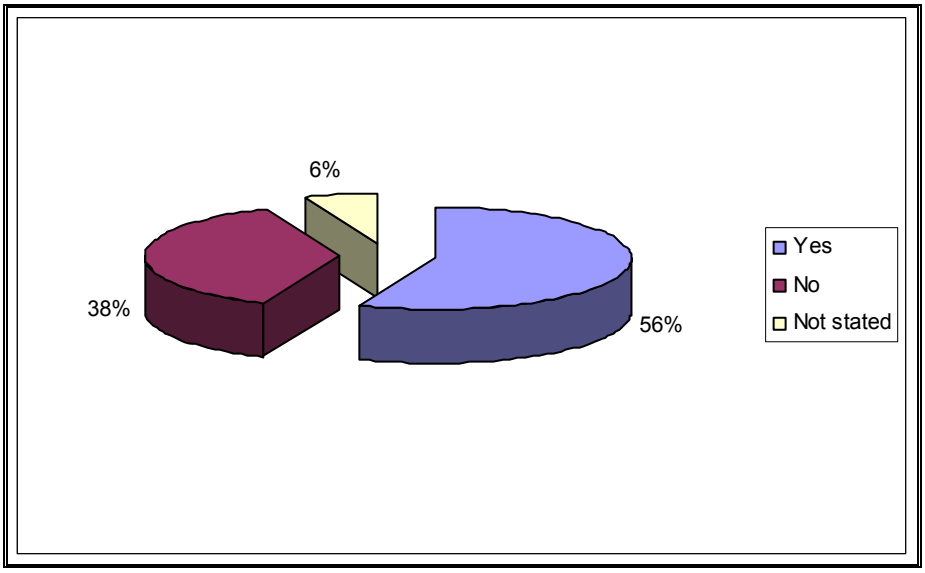
funds are exhausted, to pay cash for their treatment. These results suggest that although not large, a problem of medical funds being exhausted and affecting the patient's ability to get medication does exist. At least 75% of patients whose funds run out are advised to get medicines from state hospitals. This ensures that patients' treatment is not interrupted.

4.3.5 Training

As already mentioned, training was not a specific objective of the study. However this component was added in order to determine if the presence or absence of training had a bearing on the results.

Nine (9) of the respondents (56%) reported that they require training in HIV management while 38% (n=6) reported not to require training. One respondent (6%) did not respond to the question. A graphic presentation of the need for training by pharmacists is presented below.

Figure 11: Need for training by pharmacists



The areas of training identified by the respondents are tabulated below. The need for training on drug interaction came out top. This finding is in line with the findings of the dispensing practices where in general the respondents reported performing poorly when it comes to management of drug interactions.

Table 22: Training needs as identified by pharmacists

Topic	Frequency	Percentage
Drug interactions	3	33%
Paediatric Counselling and Monitoring	2	22%
TB and HIV	2	22%
Opportunistic Infections	1	11%
PMTCT	1	11%
	9	**100%**

All nine respondents requiring training identified seminars (workshops, lectures) as the preferred method of addressing the training needs. Among them, some

recommended other methods as well such as: information brochures, guidelines, on-the-job training and exchanging experiences with other colleagues.

These results show that there is a great need for training among the pharmacists with knowledge about drug interactions being the main area of training identified. This result is consistent with the findings on dispensing actions which showed that drug interactions activities were the ones least performed by pharmacists.

4.3.6 Challenges to HIV management in Namibia

The respondents were also requested to mention what they consider as challenges facing HIV management in Namibia. To this question, only ten (10) pharmacists (62.5%) responded (some gave multiple responses). The challenges are shown in Table 23 below.

Table 23: Identified challenges to HIV management in Namibia: Pharmacists

Challenge	Frequency	Percentage
Stigma	4	25%
Monitoring patient's adherence	3	18.75%
Patient adherence	2	12.5%
Poverty	2	12.5%
Exhausted funds	2	12.5%
Patient counselling and education	1	6.25%
Lack of privacy for counselling	1	6.25%
Lack of HIV management training	1	6.25%

The perceptions of pharmacists on challenges is wide and varied with stigma ranking the highest, followed by monitoring patient's adherence, which was attributed to be due to patients using different pharmacies for their medication. Adherence by patients ranked third highest. Note that stigma, follow-up of patients and adherence by patients are the same top three challenges identified by doctors. Only one respondent (6.25%) reported lack of training on HIV management as a challenge. Lack of a private counselling area was cited by only one respondent (10%) as a challenge. This is consistent with the results of the demographics as the majority of the respondents (56%) reported that they do have a private counselling area.

CHAPTER 5: CONCLUSION, LIMITATIONS AND RECOMMENDATIONS

5.1 Introduction

The study set out to assess the practices of private health care providers (doctors and pharmacists) in Windhoek in the management of HIV positive patients, in particular those who are on antiretroviral therapy. The practices were compared to the recommendations of the first edition of the *Guidelines for Antiretroviral Therapy in Namibia*, 2003. The purpose of this study was to explore and describe the proportion of private health care providers in Windhoek who comply with Ministry of Health and Social Services' HIV treatment guidelines.

The specific objectives of this study were to:

- determine availability of "*Guidelines for antiretroviral therapy in Namibia*" in the private sector
- determine the proportion of private health care providers who adhere to ART guidelines in the treatment and care of patients on ART.
- determine how patient adherence is being monitored in the private sector.

The findings of the study were presented in the previous chapter. This section will give a conclusive summary of the findings in relation to the objectives that the study sought to accomplish and also give some recommendations as deduced from the study findings.

5.2 Conclusions

This study has uncovered a wide diversity of practice in the different aspects of HIV management and significant deviations from the Namibia guidelines for antiretroviral therapy, first edition.

5.2.1. Objective 1: Availability of guidelines

It was revealed by the results of the study that there was a great general awareness of Namibian ART guidelines for both doctors and pharmacists. The possession of a copy of the guidelines was somewhat lower than the awareness. For both awareness and availability of guidelines, it was shown that the proportion of pharmacists knowing and owning the guidelines was lower than that of doctors.

This objective has been met.

5.2.2. Objective 2: Proportion of health care providers adhering to guidelines

Adherence to guidelines was assessed for doctors by looking at: when to start therapy, what to start with, when to change regimen and what to change to; and for pharmacists by evaluating the dispensing practices.

5.2.2.1 When to start therapy

The study findings show that at least 50% of medical doctors start treatment at the clinical stages recommended by the guidelines. The level of adherence was the highest with the paediatrics and lowest with adults. The majority of the doctors, who start at the correct clinical stage, are also the ones who reported to have a copy of the guidelines. It can therefore be deduced that possession of the guidelines influences decision making among the doctors treating persons with HIV.

The study also reveals that there is poor adherence to the social criteria for starting treatment among the doctors.

5.2.2.2 What to start with

The results of the study show that there is a high proportion of doctors that start patient on antiretroviral therapy using the correct combinations of medicines as recommended by the guidelines. However, the results also reveal that at least 30% of doctors do not perform all the required baseline tests before choosing therapy. It was also further revealed that there is poor adherence to the prevention of prophylaxis for opportunistic infections among the doctors.

5.2.2.3 Second line therapy

For all the patients who have been put on second line therapy, the results of the study show that the therapy was changed in accordance with the reasons stipulated in the guidelines i.e. treatment failure and/or toxicity. Furthermore, the study revealed that there was a high proportion of compliance (73%) to guidelines when it comes to choice of second line therapy.

5.2.2.4 Dispensing practices

Majority of the dispensing practice behaviours or actions that should be performed to ensure better patient understanding of the medicines and therefore improve patients' adherence to therapy were not always performed by the majority of the pharmacists. The actions that were always performed by more than 50% of the respondents were counselling on how medication works, side-effects and adherence for new patients.

The actions that the pharmacists performed poorly were:

- drug interaction management,
- adherence counselling for refill patients
- advice on food requirements for taking medication
- Determination and management of side effects experienced by patients on medicines (refill patients).
- Advice on appropriate storage of medicines

This objective has been met.

5.2.3. Objective 3: Monitoring of patient's adherence

The most common method of monitoring adherence by both doctors and pharmacists was shown to be monitoring follow-up (or patient refills). Very few health care providers use a combination of methods to monitor patients' adherence to treatment. For both categories of health care providers, patient adherence and monitoring patient's adherence (follow-up) were rated among the top three challenges facing HIV management in Namibia.

This objective too has been met.

5.2.4 Training

The majority of the doctors have received formal HIV training. However, the study findings reveal that there is poor adherence to guidelines, especially regarding baseline tests prior to starting therapy and prevention of opportunistic infections.
The findings of the study reveal a need for training for pharmacists, especially in the area of drug interactions.

5.3 Limitations of the study

The study had several important limitations.
The response rate to the study was poor meaning that the findings of the study cannot be generalized to all private health care practitioners

The second limitation is that the data were derived from self-reports meaning that the responses may be biased by the desire of respondents to provide socially desirable answers. Further studies should be conducted in such a way that means of verifying the reported data such as reviewing patient records and analysing prescriptions are part of the study.

The third limitation was that the telephone directory was used to identify participants. This automatically excluded health care providers who were not listed at the time of the study.

5.4 Recommendations

The results of this study should be disseminated to the private health care providers through the professional bodies. It is a reflection of their practice. Feeding the results of practice studies back to the practitioners is likely to improve adherence of the practitioners to the guidelines.

Awareness and availability of guidelines should be increased by disseminating the guidelines through professional bodies and medical insurance schemes. The medical insurance companies send statements on a monthly basis to all health care providers claiming from them. The guidelines could be given to the insurance schemes to mail to health care providers with their statements.

A national multi-method tool for monitoring adherence should be adopted by the Ministry of Health and Social Services. This method should then be introduced to all health care providers.

Nationwide training to address areas that the study found to be weak in the management of HIV (i.e. baseline tests, management of opportunistic infections, adherence monitoring, drug interactions and other dispensing practices) should be conducted for all health care providers.

Further studies should be planned and implemented to identify the reasons why adherence to other aspects of the guidelines is as this study discovered. Intervention programmes based on the reasons for non-adherence should be put into operation to improve adherence.

Private health care providers should be encouraged to advise their patients who run out of funds for medication to collect their medicines from the state hospitals. This will ensure that patients' treatment is not interrupted. In order for this reccomendation to be effective, it is important that treatment between the private and the public sector be harmonized.

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ANEXURE 1: STUDY APPROVAL LETTER

UNIVERSITY OF NAMIBIA

Private Bag 13301, 340 Mandume Ndemufayo Avenue, Pionierspark, Windhoek, Namibia

FACULTY OF MEDICAL AND HEALTH SCIENCES

Letter of permission:
Post graduate students

Date: 5.9.2006

Dear Student: D Pereto

The post graduate studies committee has approved your research proposal.

Title: Assessment of compliance of private health care providers to guidelines for antiretroviral therapy in Windhoek Namibia

You may now proceed with your study and data collection.

It may be required that you need to apply for additional permission to utilize your target population. If so, please submit this letter to the relevant organizations involved. It is stressed that you should not proceed with data collection and fieldwork before you have received this letter and got permission from the other institutions to conduct the study. It may also be expected that these organizations may require additional information from you.

Please contact your supervisors on a regular basis.

UNAM
FACULTY OF MEDICAL AND
HEALTH SCIENCES
P/Bag 13301 WINDHOEK
Date 6.9.2007

Faculty representative on Post graduate committee

Prof A van Dyk

ANEXURE 2: LETTER TO PARTICIPANTS

Letter of Consent for Participation in the study to assess the management of HIV patients in the private sector of Namibia

Dear _____.

I am a final year Master of Public Health student at the University of Namibia. In partial fulfilment of my MPH, I am conducting a research to assess the management of HIV patients in the Namibia Private Sector using the Namibia Guidelines to Antiretroviral Therapy as a standard (A copy of the study approval is attached).

I wish to request for your participation in this study.

Your participation will involve responding to a two page questionnaire. The questionnaire can be completed either through a face to face interview, telephonic interview or individually completing the questionnaire which will be dropped off and collected at your practice by a member of the research team (the reseacher's secretary). The interview will take at most 12 minutes. Your participation in this study is voluntary. You can choose not to participate or to withdraw from the study at any time. I assure you that the information you provide will be anonymous but the results may be published.

There are no foreseeable risks or discomforts if you agree to participate in this study.

Although there may be no direct benefit to you, the study is envisaged to avail information on local practices in the management of HIV in Namibia.

A member of the research team will contact you telephonically. If you are willing to participate in the study, please inform her which method you choose to give the information.

If you have any questions concerning this research study, please call me at (061) 228616/ 0812934754 or e-mail: dpereko@msh.org.na

Sincerely,

Dawn Pereko

* * * * * * *

I give my consent to participate in the above study.

_____ (signature) _____
(date)

ANEXURE 3: THE RESEARCH INSTRUMENTS

Questionnaire A: Management of HIV Patients by Doctors

A: Demographic Information

1. Type of practice
   □alone □combined

2. Number of years in practice? _____

3. a) Do you belong to a professional body? □Yes □No

   b) If so, which one
   □HIV Clinicians Society
   □Medical Association of Namibia
   □Other (state) _____

4. Does your practice dispense medicines?
   □Yes □No

5. On average how many patients do you see per day per day? (If in a combined practice, you as an individual doctor)
   □0-24 □25-49 □50-74 □75-99 □100+

6. On average how many HIV positive patients do you have in your practice?
   □0-9 □10-19 □20-29 □30-39 □40+

B: Awareness and Availability of guidelines

7. Are you aware of the Namibia Guidelines for Antiretroviral Therapy?
   □Yes □No

8. Do you have a copy of the Namibia Guidelines for Antiretroviral Therapy?
   □Yes □No

9. a) Are there any other guidelines that you use for management of HIV positive patients? □Yes □No

   b) If yes, please state which ones

   _____

C: Starting Treatment

10. At what stage do you start patients on ARV treatment? *(Tick appropriate box/es. If other, provide information)*
    i) Adults and adolescents

□CD4≤200 □Stage III or IV disease □Other _____

ii) Pediatrics

□ CD % < 20% □Stage III disease □Other _____

iii) Pregnant women

□ CD4 ≤250 □Stage III or IV disease □Other _____

11. Do you perform TB and STI screening at the start of therapy?

□Yes □No

12. Do your patients have treatment supporters? □ Yes □ No

13. What is your usual first line therapy for an ARV naïve patient?

□ AZT/3TC/NVP
□ AZT/3TC/EFV
□ D4T/3TC/NVP
□ D4T/3TC/EFV
□ Other (specify) _____

14. What informs your choice of medicine/regimen?

□ HB
□ LFT
□ Concomitant Disease
□ Other

15. At what point do you give your patients?

i) INH

_____

ii) Co-trimoxazole

_____

16. Do you have any patients on second line treatment? □ Yes □ No

i) How many _____

ii) What treatment

_____

_____

_____

iii) What are the reasons for starting second line treatment?

□ Virologic failure irrespective of immunologic failure
□ Immunologic failure
□ Clinical Failure
□ Toxicity

D: Monitoring of Therapy and Adherence

17. How do you monitor your patients' therapy and progress?
    - □ CD4 response and clinical response
    - □ CD4, clinical and virologic response
    - □ Clinical response only

18. What laboratory tests do you do for patients on Nevirapine based regimens?

_____

_____

_____

19. What laboratory tests do you do for patients on Efavirenz based regimens?

_____

_____

_____

20. How do you monitor your patient's adherence?
    - □ Pill Count
    - □ Monitor Follow-up
    - □ Other (please specify) _____

E: Training and Challenges

21. Training
    i) Have you had any formal training on HIV patient management?
       □Yes □No
    ii) Do you have any training needs in your management of HIV patients?
       □Yes □No
    iii) If yes, in what areas?

_____

_____

    iv) How do you think these training needs should be addressed?

_____

_____

_____

22. What do you consider to be challenges to the management of HIV positive patients in Namibia?

_____

_____

_____

_____

Questionnaire B: Management of HIV patients by Pharmacist

A. Demographic Information

1. Type of practice
   □hospital □retail □medical centre

2. Number of years in practice? _____

3. a) Do you belong to a professional body? □Y □N

   b) If so, which one
   □HIV Clinicians Society
   □Pharmaceutical Society of Namibia
   □Other (state) _____

4. On average how many new prescriptions do you receive per day?
   □0-24 □25-49 □50-74 □75-99 □100+

5. On average how many refill prescriptions do you receive per day?
   □0-24 □25-49 □50-74 □75-99 □100+

6. Of your total prescriptions per day, how many are for antiretrovirals?
   □0-9 □10-19 □20-29 □30-39 □40+

7. How many dispensers are working in the pharmacy? _____

8. Do you have a private place where confidential information can be discussed?
   □Yes □No

9. Are you aware of the Namibia Guidelines for Antiretroviral Therapy?
   □Yes □No

10. Do you have a copy of the Namibia Guidelines for Antiretroviral Therapy?
    □Yes □No

11. a) Are there any other guidelines that you use for management of HIV positive patients? □Yes □No

    b) If yes, please state which ones

    _____

B. Dispensing to new patients

12. Do your patients have treatment supporters? □Yes □No

13. What actions do you perform when dispensing an ARV script for the first time patient?
    Note: For questions 13 -15 use the code A=Always, M=Most of the time, S= Sometimes, R=Rarely, N=Never)

	A	**M**	**S**	**R**	**N**
a. Do you explain how the HIV medication works?					
b. Do you explain administration schedule for each medication?					
c. Do you explain food requirements for each medication?					
d. Do you help patients plan administration time of medicines to suit their routine?					
e. Do you explain potential drug interactions?					
f. Do you explain storage requirements?					
g. Do you discuss potential side-effects and how to manage them?					
h. Do you discuss resistance?					
i. Do you discuss consequences of non-adherence?					
j. Do you explain what to do if a dose is missed?					
k. Do you ask patient to repeat administration and storage instructions?					
l. Do you tell patient when s/he is due back for refill (follow-up)?					

14. What approach do you use to determine and manage drug interactions?

	A	**M**	**S**	**R**	**N**
a. Do you ask patients of all other medicines including OTCs and herbal supplements?					
b. Do you check for documented interactions?					
c. Do you inform patient of potential interaction and how to manage them (e.g. food spacing)?					
d. Once interaction has been identified, do you refer to the doctor?					

C. Dispensing to refill/follow-up patients

15. What actions do you perform when dispensing an ARV repeat script for a patient?

	A	**M**	**S**	**R**	**N**
a. Do you ask how medication was taken?					
b. Do you ask whether patient experienced side-effects?					
c. Do you ask if any problems were experienced with taking medication?					
d. Do you review administration instruction?					
e. Do you ask patient to repeat administration and storage					

instructions?					
f. Do you tell patient when s/he is due back for refill (follow-up)?					

D: Monitoring of Adherence

16. How do you monitor your patient's adherence?
    - □ Pill Count
    - □ Self-evaluation Questionnaires
    - □ Monitor refills (i.e. does the patient collect refills on the expected date)
    - □ Other (please specify) _____

17. a) Have you experienced any stock-outs of any ARVs in the last 6 months?
    □Yes □ No
    b) If so, which one? _____

    b) What do you do with the patients in a case where one of the ARVs is not in stock?

_____

_____

_____

18. a) Have you had to turn any HIV patients on ARVs away because their funds were exhausted? □Yes □No

    c) If yes, where do you refer such patients?

_____

_____

_____

E: Training and Challenges

19. Training
    i. Do you have any training needs in your management of HIV patients?
    □Yes □No
    ii. If yes, in which areas? _____

    _____

    iii. How do you think these training needs could be addressed?

    _____

    _____

_____

20. What do you consider to be challenges to the management of HIV positive patients in Namibia?

_____

_____

_____

_____

_____