EVALUATION OF THE CLINICAL AND DRUG MANAGEMENT OF HIV/AIDS PATIENTS IN THE PRIVATE HEALTH CARE SECTOR OF THE ETHEKWINI METRO OF KWA- ZULU NATAL. SHARING MODELS AND LESSONS FOR APPLICATION IN THE PUBLIC HEALTH CARE SECTOR

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Declaration

This research is the original work of P.Naidoo and has not been submitted in any form to any other University. The data was collected by fieldworkers working under the supervision of the author.

Where use has been made of the work of others, it has been duly acknowledged.

P.Naidoo

Dedication

This thesis is dedicated to my parents, husband and sons**.**

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Conference presentations

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2. **Poster Presentation:**

   Private Sector Doctor Involvement in HIV and AIDS management: *2nd SA AIDS Conference,* ICC, Durban, 7-10th June 2005

   Private Sector Specialist Involvement in the Management of HIV and AIDS and a Comparison of their Management to that of General Practitioner in the eThekwini Region: *3rd SA AIDS Conference,* ICC Durban, 5-8th June, 2007.

   Factors influencing HAART adherence amongst South African private sector patients; A pilot study: *3rd SA AIDS Conference,* ICC Durban, 5-8th June, 2007

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Abstract:

Introduction:

South Africa is currently experiencing one of the most severe AIDS epidemics in the world with South Africa‘s public sector under great stress and under-resourced whilst there exists a vibrant private healthcare sector. Private healthcare sector doctors have a pivotal role to play in the management of HIV and AIDS infection. However not much is known about the extent of private healthcare sector doctor involvement in the management of HIV and AIDS patients. In addition these doctors need to have an accurate knowledge of the management of the infection, and a positive attitude towards the treatment of persons with HIV and AIDS. With the availability of antiretroviral drugs only since around 1996, many of the doctors who were trained prior to 1996 would not have received any formal training in the management of HIV and AIDS patients, further it is very important that these doctors constantly update their knowledge and obtain information in order to practise high-quality medicine. Although private sector doctors are the backbone of treatment service in many countries, caring for patients with HIV brings a whole new set of challenges and difficulties. The few studies done on the quality of care of HIV patients, in the private sector in developing countries, have highlighted some problems with management thus it becomes important to ascertain these doctors‘ training needs together with where these doctors source information on HIV/AIDS to stay updated. In South Africa two thirds of the doctors work in the private sector. To address some of the resource and personnel shortages facing the public sector in South Africa,

partnerships between the public and private sectors are slowly being forged. However, little is known about the willingness on the part of private sector doctors in the eThekwini Metro of KwaZulu-Natal, to manage public sector HIV and AIDS patients. Though many studies have been undertaken on HIV/AIDS, fewer have been done in the private sector in terms of the management of this disease which includes doctors' adherence monitoring practices, their training needs and sources of information and their willingness to manage public sector patients. A study was therefore undertaken to assess the involvement of private sector doctors in the management of HIV, their training needs and sources of HIV information, the quality of HIV clinical management that they provided, together with their strategies for improving adherence in patients. Further the study assessed factors that affect adherence in patients attending private healthcare, and finally investigated whether private sector doctors are willing to manage public sector HIV infected patients. A literature review of the barriers that prevent doctors from managing HIV/AIDS patients was also undertaken.

Method:

A descriptive cross sectional study was undertaken using structured self reported questionnaires. All private sector doctors practising in the eThekwini Metro were included in the study. The study was divided into different phases. After exclusions a valid sample of 931 participants was obtained in Phase 1. However only 235 of these doctors indicated that they managed HIV infected patients, of which only 190 consented to be part of Phase 2 of the study. In Phase 2 the questionnaires were administered by trained field workers to the doctors after confirming doctors' consent. The questionnaires

were thereafter collected, the data captured and analysed using SP55 version 15.

Results:

Although 235 (71.6%) doctors managed HIV and AIDS patients, 93 (28.4%) doctors did not, and of the latter 48 (51.61%) had not encountered HIV and AIDS patients, twenty five (26.88%) referred such patients to specialists, six (6.45%) cited cost factors as reasons for not treating such patients, whilst twelve (12.90%) doctors, though they indicated that there were other reasons for not managing HIV infected patients, did not specify their reasons. Two doctors (2.15%) indicated that due to inadequate knowledge they did not manage HIV and AIDS patients. Significantly younger (recently qualified) doctors rather than older (qualified for more years) doctors treated HIV/AIDS patients ($p<0.001$). Most doctors (76.3%) expressed a need for more training/knowledge on the management of HIV patients.

Eighty five doctors (54.5%) always measured the CD4 count and viral load levels at diagnosis. Both CD4 counts and viral load were always used by 76 doctors (61.8%) to initiate therapy. Of the doctors 134 (78.5%) initiated therapy at CD4 count

< 200cells/mm^3. The majority of doctors prescribed triple therapy regimens using the 2 NRTI +1 NNRTI combination. Doctors who used CD4 counts tended to also use viral load (VL) to assess effectiveness and change therapy ($p<0.001$). At initiation of treatment 68.5% of the doctors saw their patients monthly and 64.3% saw them 3-6 monthly when stable.

The majority of the doctors (92.4%) obtained information on HIV and AIDS from journals. Continuing Medical Education (CME), textbooks, pharmaceutical

representatives, workshops, colleagues and conferences were identified as other sources of information, while only 35.7% of doctors were found to use the internet for information. GPs and specialists differed significantly with regard to their reliance on colleagues (52.9% versus 72.7%; $p < 0.05$) and conferences (48.6% versus 78.8%; $p < 0.05$) as sources of HIV information.

Of the respondents, 78.9% indicated that they monitor for adherence. Comparison of GPs and specialists found that 82.6% of the GPs monitor for adherence compared to 63.6% of the specialists. ($p=0.016$). Doctors used several approaches with 60.6% reporting the use of patient self reports and 18.3% pill counts. Doctors (68.7%) indicated that their adherence monitoring is reliable, whilst 19.7% stated they did not test the reliability of their monitoring tool. The most common strategy used to improve adherence of their patients was by counseling. Other strategies included alarm clocks, SMS, telephoning the patient, encouraging family support and the use of medical aid programmes.

One hundred and thirty three (77.8%) doctors were willing to manage public sector HIV and AIDS patients, with 105 (78.9%) reporting adequate knowledge, 99 (74.4%) adequate time, and 83 (62.4%) adequate infrastructure. Of the 38 (22.2%) that were unwilling to manage these patients, more than 80% cited a lack of time, knowledge and infrastructure to manage them. Another reason cited by five doctors (3.8%) who were unwilling was the distance from public sector facilities. Of the 33 specialist doctors, 14 (42.4%) indicated that they would not be willing to manage public sector HIV and AIDS patients, compared with only 24 (17.4%) of the 138 GPs ($p < 0.01$).

There was no statistical difference between adherence to treatment and demographics of the respondent patient such as age, gender and marital status. In this study 89.1% of patients were classified as non-adherent and reasons for non-adherence included difficulty in swallowing medicines (67.3%) ($p = 0.01$); side effects (61.8%) ($p = 0.03$); forgetting to take medication (58.2%) ($p = 0.003$); and not wanting to reveal their HIV status (41.8%) ($p = 0.03$). Common side effects experienced were nausea, dizziness, insomnia, tiredness or weakness.

Reasons for taking their medicines included that tablets would save their lives (83.6%); they understood how to take the medication (81.8%); tablets would help them feel better (80.0%); and that they were educated about their illness (78.2%). All participants that were on a regimen that comprised protease inhibitors and two NRTIs were found to be non-adherent.

Conclusion:

All doctors in the private healthcare sector were not involved in the management of HIV/AIDS patients. Doctors indicated that they required more training in the management of HIV/AIDS patients. However private sector doctors in the eThekwini Metro do obtain information on HIV from reliable sources in order to have up-to-date knowledge on the management of HIV-infected patients, with the majority of private sector doctors being compliant with the current guidelines, hence maintaining an acceptable quality of clinical health care. These doctors do monitor for adherence and employ strategies to improve adherence in their patients who do have problems adhering to their treatment due to various factors. Many private sector doctors are willing to

manage public sector HIV and AIDS patients in the eThekwini Metro, potentially removing some of the current burden on the public health sector.

CHAPTER 1:

Introduction:

1.1 Background:

The history of the Human Immunodeficiency Virus (HIV) infection epidemic in Southern African dates back to 1982 when the first South African Acquired Immune Deficiency Syndrome (AIDS) cases were reported among the homosexual population. Until 1987, HIV-1 diagnosis was almost completely limited to the male portion of the population, but by 1992 the reported cases in women approximated those in men. The rapid evolution of HIV-1 is well documented with clade C being the most prevalent within the southern region of Africa.[1]

1.1.1 The Human Immunodeficiency Virus (HIV):

Human Immunodeficiency Virus (HIV) is a retrovirus (belonging to the lentovirus group of retroviruses) so named because it is a single stranded RNA (Ribonucleic Acid), virus, which contains a pol gene that codes for a reverse transcriptase, which allows a DNA copy to be made from viral RNA thus going against what is considered the normal flow of genetic information. Almost all organisms, including most viruses, store their genetic material on long strands of DNA. Retroviruses are the exception because their genes are composed of RNA. RNA has a very similar structure to DNA. HIV genetic material exists both as genomic RNA inside viral particles and as proviral DNA in the

nucleus of infected cells. Both forms are infectious and the latter allows HIV to persist in long-lived reservoirs. Like all viruses, HIV cannot grow or reproduce on its own. In order to make new copies of itself it must infect the cells of a living organism. It replicates primarily in human CD4+ T cells and macrophages.[2]

HIV is divided into two distinct types, HIV-1 and HIV-2, which display biological and clinical distinctions. HIV-2 is more closely related to the simian immunodeficiency virus; it is present in fewer and isolated geographic locations and is considered less cytopathic than HIV-1. HIV-1 is further divided into three groups: major (M), outlier (O), and new (N). Most HIV-1 isolates to date belong to the M group. Groups O and N are confined to more restricted geographical areas. Group M isolates have diversified during their spread and therefore are grouped according to their genomic sequences into ten distinct clades (subtypes) designated A-J. HIV-1 clade C accounts for 48% of worldwide- and 51% of African-HIV type 1.[3]

1.1.1.1 Brief overview of the HIV transmission cycle in humans:

The HI virus enters the human T-cell, by attaching itself to chemokine receptors that are found on the cell surface called CCR5 or CXCR4. On the surface of the HI virus are two proteins called gp 41 and gp120, which allow the virus to attach itself to the T-cell and begin the process of inserting itself into the cell. Protein gp41 connects to one of the receptors on the T cell surface whilst gp120 connects to the CD4 receptor on the T cell. After attachment is completed, viral penetration occurs. Penetration allows the nucleocapsid (genetic core) of the virus to be injected directly into the cell‘s cytoplasm.

Gp120 contains three sugar-coated proteins (glycoproteins) and, once gp120 attaches itself to CD4, these three proteins spread apart. This allows the gp41 protein, which is normally hidden by the gp120 proteins, to become exposed and bind to the chemokine receptor. Once this has occurred, the viral envelope and the cell membrane are brought into direct contact and essentially melt into each other. Once inside the cell the virus releases its own genetic material (RNA) and enzymes. The HIV RNA has to be converted to DNA in order to produce more viruses. The conversion process depends on the HIV enzyme called reverse transcriptase. Once converted to DNA, the copied DNA is then integrated into the genetic material of the CD4 cell with the help of another HIV enzyme called the integrase enzyme. After successful integration of the viral DNA, the host cell is now latently infected with HIV. This viral DNA is referred to as provirus. From this viral DNA two strands of RNA are constructed and transported out of the nucleus. One strand is translated into subunits of HIV such as protease, reverse transcriptase, integrase, and structural proteins. The other strand becomes the genetic material for the new viruses. Once the various viral subunits have been produced and processed, they must be separated for the final assembly into new virus. This separation, or cleavage, is accomplished by the viral protease enzyme. If cleavage is successfully completed, the HIV subunits combine to make up the content of the new virions. In the next step of the viral life cycle, the structural subunits of HIV mesh with the cell's membrane and begin to deform a section of the membrane. This allows the nucleocapsid to take shape and viral RNA is wound tightly to fit inside the nucleocapsid. The final step of the viral life cycle is called budding. In this process, the genetic material enclosed in the nucleocapsid

merges with the deformed cell membrane to form the new viral envelope. With its genetic material tucked away in its nucleocapsid and a new outer coat made from the host cell's membrane, the newly formed HIV pinches off and enters into circulation, ready to start the whole process again.[4,5,6,7]

1.1.2 The HIV/AIDS Epidemic: Global, African and South African perspectives:

The HIV/AIDS epidemic is a major catastrophe that affects millions of people worldwide.

As of early 2008, 27 years after the recognition of AIDS approximately 33 million people were estimated to be living with HIV/AIDS[8] and more than 35 million had died since the beginning of the epidemic.[9] Each day nearly 7000 people become newly infected with HIV with increasing numbers among young adults, women and children.[9]

The AIDS epidemic is undermining the social fabric of many societies in developing countries. The demographics, economy, cultures and political structures of many countries have been dramatically affected by the spread of HIV and AIDS.[9] The global percent of people living with HIV has stabilized since 2000, however it has stabilized at an unacceptably high level.[10]

Sub-Saharan Africa remains the most affected region in the AIDS epidemic with over 68% of the people HIV infected. It is also the region where more than three quarters of all AIDS deaths have occurred. Nearly 90% of all HIV positive children live in Sub Saharan Africa and the majority (61%) of people living with HIV in this region are women.[11] The annual number of new infections had declined from three million in 2001 to 2.7 million

in 2007 and in Sub Saharan Africa most of the national epidemics had stabilized or begun to decline.[10]

South Africa is experiencing one of the most severe AIDS epidemics in the world. By the end of 2005, there were approximately 5.7 million people living with HIV in South Africa, and almost one thousand AIDS deaths occurring every day.[10] It is thought that almost half of all deaths in South Africa, and a staggering 71% of deaths among those aged between 15 and 49, are caused by AIDS, with over half of fifteen year olds not expected to reach the age of sixty.[12] Caring for HIV/AIDS patients is placing a huge burden on the hospitals that are struggling to cope, with a leading researcher estimating that HIV-positive patients would soon account for 60-70% of medical expenditure in South African hospitals.[13] The education sector is also bearing the burden of the epidemic since in 2006 21% of teachers in South Africa were living with HIV.[14]

It is clear that AIDS is having a devastating impact on South Africa. There are many possible reasons why South Africa has been so badly affected by AIDS, including its history resulting in poverty and social instability and a lack of government action.

The Study Site: The Province of KwaZulu-Natal (KZN).

The most recent report on HIV prevalence amongst antenatal clinic attendees indicates that the province of KwaZulu-Natal remains the epi-centre of the epidemic with a prevalence of 38.7%.[15]

A study done in KwaZulu-Natal Province to determine the management of sexually transmitted diseases (STD), revealed that there was inadequate treatment of STD in the private health care sector and a continuing medical education program for the doctors and their staff was subsequently created to improve the private sector treatment of STD in KZN.[16] There is considerable geographical variation in the distribution of HIV infection , within South Africa, being highest along the east coast and lowest in the west coast of South Africa.[17] Antenatal HIV prevalence increased from 1.6% in 1990 to 37.5% in 2003 in KZN compared to 0.06% to 13.1 % in the Western Cape during the same period. While the overall doubling time at the start of the epidemic in South Africa was 13.8 months, the doubling time at a provincial level varied from 9.2 months in the Northern province of South Africa to 14.1 months in KwaZulu-Natal.[17] The province of KwaZulu-Natal has the second largest population in South Africa with 10 449 300 people according to mid 2009 estimates by Statistics South Africa. This is 21,2% of the total population of 49 320 500 people living in the country.[18] Slightly more than 50% of South Africa‘s population live in urban areas, due to migration from rural to urban and also because much of the open space is dry and arid.

The most rural province in South Africa is Limpopo, Gauteng is almost entirely urban with eThekwini Metro in KZN also having a high urban concentration.[18] The eThekwini Metro has a population of 3,090,126. Most of the eThekwini Metro is urban (central) and suburban (south, north and west) with a small rural constituency (inner west and further south). eThekwini‘s population includes 51.9% (1 605 080) females whilst 48.1% (1 485 046) are males.[19]

1.1.3 Stigma and discrimination in South Africa:

Prejudice towards people living with HIV due to misinformation of the disease condition has prevented efforts to increased access to treatment and has also created a climate of confusion. In South Africa due to the correlation between extreme poverty and high prevalence of HIV, HIV is sometimes seen as a disease of the poor, although it is prevalent across all sectors of society.[20] Even though Deputy President Thabo Mbeki made the Declaration of Partnership Against AIDS, in which he called for an end to discrimination against people living with HIV[21] stigmatization of the condition remained deeply rooted. A study in 2002 revealed that only one third of respondents who had revealed their HIV-positive status were met with a positive response in their communities. One in ten said that they had been met with outright hostility and rejection.[22]

1.1.4 The role of government policy on HIV and AIDS:

South Africa has had a turbulent past, and its history is relevant to the explosive spread of HIV in the country. The most rapid increase in South Africa‘s HIV prevalence took place between 1993 and 2000, during which time the country was focused on transforming the apartheid policy of South Africa, thus allowing this epidemic to go unchecked. There was the possibility that the severity of the epidemic could have been lessened by prompt and timeous action.[23] The South African government was hesitant about providing antiretroviral treatment to HIV-positive people and after much debate and controversy the

government eventually approved plans to provide public access to the drugs in November 2003, in the form of the Operational Plan for Comprehensive Care and Treatment for People Living With HIV and AIDS. However the distribution of antiretroviral drugs in the South Africa had been relatively slow, and was below the global average for low and middle income countries, i.e. less than 31% of both adults and children were receiving treatment at the end of 2007.[24]

1.1.5 Treatment regimes in public and private healthcare sectors:

1.1.5.1 Antiretroviral (ARV) drugs:

There are four classes of antiretroviral drugs, based on their mechanism of action[4]:

They are the Reverse Transcriptase Inhibitors (RTI), which includes the Nucleoside Reverse Transcriptase Inhibitors (NRTI) / Nucleotide Reverse Transcriptase Inhibitors (NtRTI) and the Non Nucleoside Reverse Transcriptase Inhibitors (NNRTI),

the Protease Inhibitors (PI), the Entry and Fusion inhibitors and the Integrase Inhibitors:

Reverse Transcriptase Inhibitors:

These drugs interfere with the viral enzyme reverse transcriptase, (that copies viral RNA into DNA in the newly infected cell) in order to prevent HIV from replicating. There are different types of drugs in this class:

a. Nucleoside Reverse Transcriptase Inhibitors (NRTI) / Nucleotide Reverse Transcriptase Inhibitors (NtRTI)

These are structurally similar to the naturally occurring building blocks of DNA, the purine nucleosides adenosine and guanine, and the pyrimidine nucleosides thymidine and cytidine. NRTI/NtRTI function by inhibiting the synthesis of DNA by reverse transcriptase (RT). The RT enzyme cannot distinguish phosphorylated NRTI from their natural counterparts and therefore attempt to incorporate both forms in the synthesis of viral DNA. As the RT enzyme tries to lengthen the growing DNA chain, NRTIs take the place of the naturally occurring purines and pyrimidines. NRTIs are thus incorporated into a strand of synthesized DNA, preventing the addition of further nucleotides and terminating viral DNA replication.

b. Non Nucleoside Reverse Transcriptase Inhibitors (NNRTI)

These drugs bind directly to the reverse transcriptase enzyme, thereby altering its structure, so that it is unable to function properly. The binding stops the ability of the reverse transcriptase to add new nucleotides to the growing DNA chain.

Protease Inhibitors (PI)

Protease is a viral enzyme that breaks up the proteins made by mRNA. These proteins are essential for the final assembly and maturation of new virus particles as they leave the host cell and infect other cells. By binding to the active site of the viral protease enzyme, PIs prevent the processing of viral proteins into functional forms. Viral particles are still produced when the protease is inhibited, but these particles are unable to infect new cells.

Entry and Fusion inhibitors:

These drugs prevent the binding of gp41 and the chemokine receptor, thereby inhibiting HIV from entering a host cell. With no attachment, HIV cannot insert viral RNA into the cell, and is thus unable to replicate.[7,25]

Integrase Inhibitors:

These drugs interfere with HIV's integrase enzyme, which is an HIV-1 encoded enzyme required for viral replication. Inhibition of this enzyme prevents covalent insertion of unintegrated, linear HIV-1 DNA into the host cell genome, thereby preventing the formation of HIV-1 provirus.[7,25]

Experimental Drugs:

a. Assembly and Budding Inhibitors:

These experimental HIV drugs are designed to interfere with the final assembly of new virus particles. They also prevent the so called budding of the new viruses out of the CD4 cell.

There are no drugs of this type yet, but several candidates are being studied.[26]

b. Zinc Finger Inhibitors:

Researchers are also looking at drugs called zinc finger inhibitors, which interfere with the packaging of the viral RNA into the nucleocapsid.[6]

1.1.5.2 Combination therapy and ARV treatment guidelines:

Until 1995, treatment for HIV-1 infection consisted mainly of single-drug and dual-drug therapy regimens that provided limited success. With the introduction of protease inhibitors (PIs), there was a dramatic decline in viral loads and AIDS-associated diseases. The national guidelines for the treatment of HIV disease, was revised, recommending the

use of antiretroviral agents for HIV-infected adults and adolescents and the use of PIs in particular. At present, combination therapy involving agents from three classes of antiretroviral agents—nucleoside reverse transcriptase inhibitors (NRTIs), non-NRTIs (NNRTIs), and PIs—form the basis of potent anti-HIV regimens known as HAART (highly active antiretroviral therapy).[26] HAART regimens have dramatically changed the way that individuals with HIV-1 infection and AIDS are treated.[27]

In 2004 the South African Department of Health (NDOH) published guidelines to help clinicians in the public sector to manage HIV and AIDS patients on antiretroviral drugs.[28] The approach that was adopted was based on the continuum of care, and holistically managing patients in an integrated health care system.

The medical criteria that were recommended to initiate ARV therapy were CD4 cell counts of equal or less than 200cells/mm^3 irrespective of World Health Organisation (WHO) stage, or WHO stage 4 AIDS defining illness irrespective of CD4 count and where the patient expresses willingness and readiness to take ARV adherently.

1.1.6 Medical Aid in relation to HIV/AIDS:

According to AIDS for AIDS (AFA), currently 6.83 million people are beneficiaries of health insurance, with an unknown number of people accessing private care without health insurance. There are about 60000 people on ARV through health insurance plans. A total of 31344 AFA patients had been enrolled by over 4000 private sector doctors. AFA has approved the use of HAART for 23049 patients.[29] However there are factors that threaten sustainability of funded HIV care, such as denial, fear of disclosure, stigma and tolerance and few HIV positive people being aware of their HIV status. Only about

25% of HIV positive beneficiaries seek care, whilst less than 50% of the people present with a CD4 count of < 200cells/mm^3. The funds are therefore still facing high hospitalization costs. The high rate of drug side-effects and less than ideal adherence also make the management of this condition costly and difficult.

AFA believes that cost-effective management of HIV/AIDS remains a comprehensive programme based on education and support, the use of evidence-based protocols, a greater use of electronic solutions to process data and communicate with patients to enhance adherence and monitor progress, and that there should be greater collaboration between public and private sectors, as well as donor funders and corporates.[29]

1.1.7 Private Healthcare Sector

South Africa‘s healthcare sector consists of a large public sector and a smaller growing private sector. The private sector spends about 66 billion rands to service seven million people whilst the rest of the population depends on 59 billion spent through the public health sector.[30]

The (ARV) drugs have been in the private sector since around 1996. With antiretroviral drug treatment, HIV-positive people can maintain their health and often lead relatively normal lives. Few people in South Africa had access to this treatment prior 2004 as the South African government was initially hesitant about providing antiretroviral treatment to HIV-positive people. While the richer countries were using the combination of ARV drugs to effectively treat HIV in 1996, only a small minority of South Africans who could afford to pay for private healthcare had these drugs available to them and were managed by private healthcare sector doctors.

Most of the patients in this sector pay cash or via a medical aid. These patients are classed as private patients as they are managed by the private health care sector. The definition of private health care sector being where government does not pay for the cost of medical care and people fund their own medical costs either by paying from their own resources or being subsidized by the medical aid industry. These patients are in turn managed by private sector doctors that are not employed by the Department of Health of South Africa.[29]

1.2 Problem Statement:

1.2.1 HIV management by Private Sector Doctors:

Private sector doctors are the backbone of treatment service in many countries however caring for patients with HIV brings a whole new set of challenges and difficulties.[31] There have been few studies done in Africa on the quality of AIDS care in the private sector in developing countries, and these studies highlighted some problems in private sector management.[32]

In Brazil, even though the Brazilian HIV/AIDS NGOs had been instrumental to the success of the National HIV/AIDS Program and was an important partner in the country‘s response to the epidemic, the quality of the services and activities delivered by the NGOs was largely unknown. [32a] In an Indian study it was concluded that private practitioners were actively involved in diagnosing and managing patients with HIV/AIDS but that some of their management practices were inappropriate and needed to be remedied.[33] Anecdotal evidence from doctors in Lesotho suggested that the problem of

poor management was widespread with six of the 24 patients who were managed by private sector doctors taking either mono or dual therapy and another patient was prescribed just ten doses of nevirapine which should have been in combination with other drugs and taken for life.[32] Possible reasons cited were affordability in that the doctor had prescribed what the patient could afford but another reason was the lack of knowledge on the part of the doctors .[32] In a study done in Harare a decade ago, to gather data to help formulate treatment guidelines there appeared to be therapeutic anarchy in the private sector in the way that anti-retrovirals were

used.[34] The monitoring practices were also of concern in Uganda where a survey of twenty one private medical facilities reported that only four of seventeen facilities which prescribed antiretroviral drugs had received CD4 and viral load results in the previous two months, for only 38 of the 340 patients they were monitoring.[35]

Since HIV/AIDS is a chronic disease it needs life-long care and treatment.[31] Even though the cost of AIDS treatment decreased many private sector doctors may lack specific AIDS training, or prescribe incorrect drug regimens. They also may fail to monitor patients‘ side effects and their counseling on adherence maybe inadequate.[32] Research is constantly bringing new drugs to the market, that are not without side effects and drug interactions, therefore doctors need to be kept up to date so that they can manage their patients optimally.[31]

1.2.2 Role and clinical contribution of doctors in the HIV epidemic:

AIDS has emerged as a critical public health problem in the developing world, and involvement of both the public and private health care sectors in its management is

essential. South Africa's epidemic has now reached the stage where increasing numbers of people are dying of AIDS.[36] Therefore all doctors, irrespective of where they practise, have a pivotal role to play in the prevention and management of HIV infection and AIDS; this requires an accurate knowledge of the management of this disease, and positive attitudes towards persons infected.[37] Knowledge about appropriate management of HIV and the infections associated with it is an important prerequisite for quality of care at all levels of the health care system. If training is lacking then effective management is not applied, as the treatment is complex with many parameters needing to be monitored. Therefore it is important to be knowledgeable about HIV management and to continue to update knowledge as the complexity of the ARV treatment requires additional skills and current information.[31] Studies done in other countries including Barbados amongst private sector doctors have highlighted problems in the doctors' management of HIV infected patients,[32, 33,34,35,37a] however in South Africa, little is known about the practices of private sector doctors and whether private sector doctors manage their HIV/AIDS patients appropriately, according to national and international guidelines.[28,38] In addition about 17000 registered doctors who qualified before 1990 were working in South Africa but most doctors were not exposed to HIV/AIDS in their original training, and the average doctor therefore may not have the skills or background to manage the disease.[39] Making a correct diagnosis and providing effective medical treatment by health professionals are essential to a patient's survival and quality of life, however, of vital importance to treatment is patient adherence to prescribed medication in order to obtain full therapeutic benefits.[40]

1.2.3 Adherence to ARV treatment and its impact on the management of HIV infected patients:

Adherence to ARV treatment is associated with the characteristics of the patient, the regimen, the clinical setting, and the strength of the provider/patient relationship[41]. The information provided and the patient‘s understanding about HIV infection and the specific antiretroviral regimen is critical. For most patients, near-perfect (>95%) adherence is necessary to achieve full and durable viral suppression. In practice, this degree of adherence requires a patient on a twice-daily regimen not to miss or substantially delay more than three doses of antiretroviral medications per month.[42] Many factors such as low levels of literacy, certain age-related challenges (e.g., vision loss, cognitive impairment), psychosocial issues (e.g., depression, homelessness, lower social support, stressful life events, dementia, or psychosis), active (but not history of) substance abuse particularly for patients who have experienced recent relapse, stigma, difficulty with taking medication (e.g., trouble swallowing pills, daily schedule issues), complex regimens (e.g., pill burden, dosing frequency, food requirements), adverse drug effects, and treatment fatigue, influence compliance and identifying these factors may assist in the design of strategies to enhance adherence to such demanding regimens.[43,44,45,46,47] In communication with private healthcare sector doctors, there appears to be non adherence to treatment amongst their patients. The doctors maintained that they followed the guidelines prescribed for optimum care of these patients but the desired therapeutic outcome was not evident in the majority of their patients.

If the barriers that impede medication adherence go unrecognized and unresolved, then the management of HIV and AIDS patients would be compromised with disastrous results in terms of resistance emerging. Resistance to anti-retroviral drugs is a concern with HIV and AIDS treatment, because once it occurs, it affects patients‘ clinical outcome and it reduces patients‘ treatment options. While this is clearly a bad situation for the individual, from a public health perspective it is also alarming to have multiple drug-resistant strains of HIV that can be transmitted to non-infected people.[48] Therefore it is important for healthcare providers to explore these barriers to adherence and to foster a trusting relationship before offering therapy so that the success of treatment may be maximized. Patient education about the multifaceted aspects of antiretroviral therapy is a crucial component of care.[49] A trilogy of information, motivation and behavioral skills is essential to ensure adherence to Highly Active Antiretroviral Therapy (HAART).[50] Thus improving adherence is arguably the single most important means of optimizing overall therapeutic outcomes. A study done amongst primary care public sector patients in SA demonstrated that with a standard approach of preparing patients and strategies to enhance adherence, patients on antiretroviral medication can be retained in a resource limited setting.[51] The average rate of adherence varies by the method used to assess it and the group studied, but appears to be approximately 70%.[52] Therefore understanding the adherence monitoring practices of private sector doctors could assist in developing interventions to improve adherence in HIV infected patients, but information about such practices is limited or not available at all in the province of KwaZulu-Natal or South Africa.

1.2.4 Critical factors in the appropriate care and management of patients in the private healthcare sector

Medical knowledge increases fourfold during a professional's lifetime, doctors need to constantly update their knowledge and obtain information to help them with particular patients if they want to practice high quality medicine.[53] The central responsibility of doctors is to meet the needs of patients by drawing on the evidence base of scientific and clinical knowledge accumulated by the medical and scientific research over 5000 years.[53] Medicine is considered a knowledge based / evidence based profession, with experienced doctors using about two million pieces of information to manage their patients. Most of the information doctors use when seeing patients is embedded in what has been called "a constantly expanding and reinterpreted database".[53] This information is obtained from many sources including print, colleagues, meetings, lectures, the Internet, and others.[54] It is already widely established where doctors source their general medical knowledge but little is known about where doctors source information on HIV/AIDS. Antiretroviral drugs (ARVs), which significantly delay the progression of HIV to AIDS and allow people living with HIV to live relatively normal, healthy lives, have been available only in the private healthcare sector of South Africa since 1996. As a result many of the doctors that trained prior to 1996 would not have received any formal training in the drug management of HIV and AIDS patients. They have to rely on continuing education, workshops, journals, advice from colleagues etc., in order to help them manage their HIV and AIDS patients. Studies in Vietnam have shown that younger physicians tended to be better informed,[55] and were more up to date with specialist thinking on HIV than older

associates.[56] For doctors in developing countries of Africa and Asia, finding the latest information on HIV and AIDS is difficult because of sluggish and unreliable Internet connections.[57] thus posing great challenges for the doctors in these countries to effectively manage HIV infected patients on current knowledge and practices. Therefore knowing the sources of information that private sector doctors' access can assist in the in-service training of private sector doctors and facilitate their access to such knowledge.

1.2.5 Barriers that prevent doctors from managing HIV/AIDS patients:

It is also important to recognize barriers that prevent doctors from providing care to HIV infected patients and attempts to overcome the barriers should be prioritized.

Barriers to treating HIV infected patients is frequently reported in many countries and by identifying these barriers constructive interventions and strategies can be developed to address these barriers, thereby improving the quality of patient care.

1.2.6 Interface between public and private health care sectors:

In the developing world the health systems are in a crisis.[58] There are inadequate numbers of clinicians to assist in the management of the large number of HIV and AIDS patients, (resulting in high mortality and morbidity rates, with major social consequences),[59] inadequate finance and poor quality of service, together with poor infrastructure, which includes a lack of reliable water, sanitation and electricity.[58] Without adequate infrastructure doctors and nurses cannot provide quality care even when they are available. The HIV /AIDS/TB epidemic has severely affected South Africa and although the country has the largest public sector anti-retroviral programme in the world it is unable to meet the needs of the high number of people infected.[60] The unequal

distribution of resources between the public and private health sectors, results in half the nurses and two/thirds of doctors working in the private sector.[61] In 2008 it was reported that there were >4 000 doctor posts vacant in state hospitals.[62] Therefore there is a need to scale up access and use all available doctors both in the public and private sector to manage this epidemic. Many countries are now engaging the private sector in partnerships with the public sector as a means of rebuilding their infrastructure and improving access to services.[58] To address some of the resource and personnel shortages facing the public health sector in South Africa, partnerships between the public and private health sectors are slowly being forged. In May 2006 the Minister of Health launched the National Consultative Health Forum to discuss key strategic health issues, including tuberculosis, HIV and AIDS, recruitment and retention of health professionals, and transformation of the health sector.[30] South Africa has an extensive antiretroviral treatment programme, with 371,731 patients initiated on antiretroviral treatment by 2007, and about 77003 patients initiated by medical schemes, private sector and development partners.[63] Governments and donors are increasingly considering the private sector as a potential partner in addressing the growing demand for sustaining HIV and AIDS treatment. Given the weaknesses and strengths of both sectors, partnership between the public and private sectors has became a policy option since neither the public nor the private sector alone can best deliver competent, accessible and affordable health care.[64] However, little is known about the willingness on the part of private sector doctors to manage public sector HIV and AIDS patients. In addition if private sector doctors do

become involved in the management of public sector HIV patients then models and lessons could be shared between the sectors.

1.3 Rationale of the study:

Though many other studies have been undertaken on HIV/AIDS in South Africa, there appears to be limited data on the care of patients in the private healthcare sector. There appears to be concern that there is no mechanism in place to oversee the quality of care provided by the private sector doctors in South Africa.[65] This study will therefore be able to provide the framework that will be necessary to create such mechanisms, especially on the management of HIV/AIDS both by doctors and their patients, in particular KwaZulu-Natal, the province with the highest HIV and AIDS prevalence rates.

1.4 Aims and Objectives:

This study therefore aimed at evaluating the clinical and drug management of HIV/AIDS patients in the private health care sector of the eThekwini Metro of KwaZulu-Natal, the possibility of a public private partnership thereby sharing models and lessons for application in the public sector hospital and HIV/AIDS patients‘ adherence behavior and reasons thereof.

The following were the objectives in order to meet the aim:

To examine the level of involvement of private sector doctors in the management of HIV-infected patients.

To assess the doctors‘ training needs for the comprehensive management of HIV-infected patients.

To review the literature on barriers that prevent doctors from managing HIV infected patients.

To investigate private sector doctors HIV/AIDS drug and clinical management in the eThekwini Metro of KwaZulu-Natal.

To investigate where private sector doctors from the eThekwini Metro of KwaZulu-Natal, obtain information on HIV and AIDS for patient management.

To identify strategies that private sector doctors use to improve adherence of their patients in the eThekwini Metro of KwaZulu-Natal.

To establish the willingness of private sector doctors to manage public sector HIV /AIDS patients, with a view to form public private partnerships (PPP) in the eThekwini Metro of KwaZulu-Natal thus sharing models and lessons in the management of HIV and AIDS patients.

To identify factors that impact on the adherence of HIV infected patients who visit private sector doctors in the eThekwini Metro of KwaZulu-Natal.

1.5 Method:

Study design, study area and sample population

This descriptive, cross-sectional study was conducted amongst private general practitioners (GPs) , specialists and HIV patients in KwaZulu-Natal, South Africa. This province was chosen because it has the highest prevalence of HIV, as indicated by the

data of attendees at antenatal clinics.[31] The study focused on the eThekwini Metro of KwaZulu-Natal. Most of the eThekwini Metro is urban (central) and suburban (south, north and west) with a small rural constituency (inner west). The study was conducted in different phases.

Study sample

A comprehensive list of 1 255 GPs and specialists practising in the eThekwini Metro was obtained from the Medpages Directory; the KwaZulu-Natal Managed Care Coalition (KZNMCC), which is a private doctors' grouping: the private doctors' guilds; the Lancet Clinic Courier database; and the Southern African HIV Clinicians Society. The various directories were consulted in order to obtain a representative sample.

The researcher addressed the various doctor guilds after obtaining permission from the chairman of the guild. A brief explanation of the study together with the objectives was given to the doctors. This session also helped to get feedback from doctors on the study. At these sessions doctors were given the questionnaires which was accompanied by a brief introductory letter to the study together with a consent form. A further way of distribution was done via the Lancet Clinic Courier system for doctors that were on their database and who did not belong to any of the doctor grouping. Here again the introductory letter together with the consent form was given.

The completed questionnaires were either collected, posted, faxed, emailed or sent via the Lancet courier system depending on doctor preference. The data was captured and analysed using the SPSS version 11.5 data programme.

One of the questions in phase 1, asked doctors to respond their intention of participating

in phase 2 of the study if they managed HIV infected patients. The doctors were also asked in this phase whether they would allow their patients‘ history file to be examined after obtaining patient consent. The patient had to give a written consent to allow for their files to be examined and to participate in the study which was Phase 3. All questionnaires for both doctors and patients were coded, to ensure anonymity. However, even though doctors had to give their practice code and name in phase 1 if they wanted to participate, so that they could be contacted, their names were not included in the analysis. The following specialist doctors were excluded after explanations that their contact with HIV/AIDS patients was minimal, and that they felt that it was inappropriate for them to participate. These were specialist doctors such as gynaecologists, surgeons, occupational health doctors, psychiatrists, cardiologists, anaesthetists, ophthalmologists, plastic surgeons, critical care, and doctors working in the trauma unit of private hospitals. A total of 200 doctors were thereby excluded giving a sample size of 1055 doctors. Of the 1055 questionnaires administered, 74 (7.4%) questionnaires were returned marked as deceased, emigrated, retired, left address, semi-retired specialist, sick or on holiday and not available. A valid sample of 931 doctors was then established.

Phase 1:

In this phase the involvement of private sector doctors in HIV management and their training needs were assessed.

331 questionnaires were returned. Three doctors did not complete the questionnaire. Two hundred and thirty five doctors indicated that they managed HIV infected patients with 93 doctors stating that they do not manage HIV infected patients and cited reasons

for such. Of the 235 doctors who managed HIV and AIDS patients 190 agreed to participate in phase 2 of the study.

Phase 2:

These Doctors were contacted by telephone to ensure their availability and confirm their consent once again. Trained field workers delivered questionnaires to the doctors‘ rooms and these were collected when the doctors had completed them. In addition where requested some of the questionnaires were faxed or emailed to the doctors, who also returned them by fax or email. The questionnaires were coded so that no names or contact details of participating doctors were recorded. In this phase the following objectives were met:

a. Evaluation of private sector doctors HIV/AIDS drug and clinical management in the eThekwini Metro of KwaZulu-Natal,
b. Identification of the sources from where these doctors obtain information on HIV and AIDS for patient management,
c. Strategies that private sector doctors use to improve adherence of their patients in the eThekwini Metro of KwaZulu-Natal,
d. The willingness of private sector doctors to manage public sector HIV /AIDS patients, with a view to forming public private partnerships (PPP) in the eThekwini Metro of KwaZulu-Natal ,thus sharing models and lessons in the management of HIV and AIDS patients.

The Department of Health and Human Services and the South African National Department of Health HIV guidelines were used to evaluate private sectors' clinical management of HIV infected patients.

The data were captured and analysed using SPSS version 15. A p value of < 0.05 was considered statistically significant. Chi-square testing was used for categorical data and the Fischer Exact test for small numbers. The Independent Samples T test was used for continuous data, to test associations.

Phase 3:

In this phase the participants were the patients of the participating doctors. The objective of this phase was to identify factors that impact on the adherence of HIV infected patients who visit private sector doctors in the eThekwini Metro of KwaZulu-Natal.

The field workers arranged suitable times with the doctors and collected the data whilst the patients were visiting the doctors rooms and after obtaining their written consent.

In this phase due to the concerns of doctors working in a suburb of the eThekwini Metro, who stated that their patients were non adherent. An in depth study was undertaken in this suburb. The doctors stated that they follow the guidelines prescribed for optimum care but they still were unable to obtain the desired therapeutic outcome for their patients. These doctors were also part of the study sample in phase 1 and phase 2.

All doctor questionnaires were pilot tested, amended before administration by doctors not practising in the private sector of the eThekwini Metro during a local doctor meeting. The patient questionnaires were pilot tested by HIV patients attending a para-statal hospital.

Ethical approval for the study was obtained from the Ethics Committee of the Nelson R Mandela School of Medicine, University of KwaZulu-Natal. [Ethics No. HI138/03]

Study Framework:

The overall objective of the study was to evaluate the clinical management and drug management of HIV/AIDS patients by private health care sector doctors working in the eThekwini Metro of KwaZulu-Natal. Sharing models and lessons for application in the Public Health Care Sector.

In order to start the study it was important to ascertain the number of doctors that manage the HIV infected patients in the Metro, their training needs and some reasons why they do not manage if applicable. The first paper found in Chapter 2 describes the results obtained including their training needs. This phase also provided the sample for phase 2 and subsequently phase 3. The second paper was a literature review highlighting reasons why doctors in other parts of the world do not manage HIV infected patients.

The main body of the study where an evaluation of how the doctors practice in the private sector can be found in papers published appearing under Chapters 4 and 5, where the drug management and practices they employ to obtain positive outcomes are highlighted. In order to practice quality medicine, doctors need to constantly update their knowledge, whilst those who do not have the necessary skills do need to obtain the specific training in order that all doctors can assist in containing the epidemic. In the absence of proper training doctors cannot provide the care that is expected of them in managing HOV infected patients. Chapter 6 describes the results obtained. If a partnership is going to be

formed between the public and private sector in order to help the crisis that is fast looming in the public sector, with regards to HIV management, then the willingness of the private sector to manage public sector HIV patients needs to be known. This could further assist in both the sectors sharing their models of care and lessons learnt in managing HIV patients. Chapter 7 contains the paper published describing the results obtained. Finally doctors may provide a quality medical care to their patients, following the guidelines as published, but if the desired outcome is still not achieved, then the role of the patient becomes important. The last paper found in Chapter 8, which was part of phase 3, highlights the problem of adherence in patients visiting private sector doctors and some of the positives in terms of why they take their medicines.

The resulting seven articles were all published in peer reviewed journals.

CHAPTER 2

Role and contribution of private healthcare sector doctors in the management of HIV- infected patients in the eThekwini Metropolitan area of KwaZulu-Natal.

An important first step in this study was to ascertain whether and how many private sector doctors were actually involved in the management of HIV/AIDS patients in the eThekwini Metro and if there were any further training needs that were required. This survey which was conducted during the first phase also provided the sampling for phases 2 and 3. Private healthcare sector doctors are pivotal in the management of HIV/AIDS patients, however other studies have shown that not all doctors are involved in the management due to barriers that prevent them from managing HIV infected patients. This study although it did not undertake a detailed examination of why doctors in the eThekwini Metro were not managing HIV infected patients resulted in some reasons being cited by the doctors for not managing HIV infected patients in this study.

The findings of Phase 1 of the study relating to the role and contribution of private healthcare sectors doctors and a literature review of the barriers that prevent doctors from managing HIV infected patients are presented can be found in this Chapter and Chapter 3 respectively.

CHAPTER 3

Barriers to HIV Care and Treatment by Doctors:

A review of the literature.

CHAPTER 4

Evaluation of the Clinical Management of HIV infected patients by Private Sector Doctors in the eThekwini Metro of KwaZulu-Natal.

One of the barriers noted in studies undertaken to ascertain why doctors do not manage HIV infected patients was the lack of knowledge and training by doctors to manage this disease. In South Africa many doctors had qualified prior to 1996 when the antiretroviral drugs were first introduced into the private sector. Two thirds of the doctors in South Africa work in the private sector. Most doctors were not exposed to HIV/AIDS in their original training. The average doctor therefore does not have the skills or background to manage the disease. Knowledge about appropriate management of HIV and the infections associated with it is an important prerequisite for quality of care at all levels of the health care system. If training is lacking then effective management will not be applied, as the treatment is complex with many parameters needing to be monitored. Therefore it is important to be knowledgeable in the area in order to maximise management. With the lack of data on how these doctors manage HIV/AIDS patients and whether they have the necessary knowledge and skills to manage these patients it was important to conduct a survey to evaluate private sector doctor management of HIV infected patients in the eThekwini Metro. The DHHS and the NDOH HIV guidelines were used to compare the treatment of HIV/AIDS patients by these doctors. The findings are presented in this Chapter 4

CHAPTER 5

Identification of sources for seeking HIV and AIDS information amongst private sector doctors.

Although doctors may have the necessary clinical training and knowledge to manage HIV infected patients, they need to constantly update their knowledge in order to keep abreast of developments in the management of HIV/AIDS patients. Those doctors that did not get formal training in the management of HIV infected patients need to also obtain the necessary skills and information in order to manage HIV infected patients, especially in a country where the HIV prevalence is so high.

This study thus also assessed where these private sector doctors obtain their information on HIV and AIDS.

Chapter 5 presents a paper that was published titled _Identification of sources from which doctors in the private sector obtain information on HIV and AIDS‘.

CHAPTER 6

Adherence Monitoring practices of private healthcare sector Doctors managing HIV and AIDS patients in the eThekwini Metro of KwaZulu-Natal.

Doctors in the private healthcare sector may have the knowledge, skills and update these knowledge and skills in order to provide treatment to their patients, however if they do not monitor for patients‘ adherence to treatment, then positive therapeutic outcomes will not be achievable. Therefore it is vitally important for these doctors to monitor adherence of their patients, this study further evaluated private sector doctors management of HIV/AIDS patients by assessing what monitoring tools do these doctors have to monitor adherence of their patients. The findings can be found in this Chapter 6.

CHAPTER 7

Private sector doctors' willingness to manage public sector HIV and AIDS patients in the eThekwini Metro of KwaZulu-Natal.

Antiretroviral drug combinations have revolutionised HIV treatment since 1996, transforming the virus from a death sentence to a manageable chronic condition. The management of chronic conditions needs to be sustained effectively in order to obtain positive outcomes relating to the disease condition. Sustainability of any treatment is dependent upon many factors amongst which is the availability of trained, skilled medical personnel. South Africa presently is experiencing a great shortage of these personnels in the overburdened public healthcare sector, to the point where partnerships are slowly being forged between the public and private healthcare sectors. The private sector has been identified as a potential partner in addressing the growing demand for sustaining HIV and AIDS treatment. It has also been identified that both sectors have weaknesses and strengths ,thus partnerships between these two sectors has become a policy option since neither sector alone can best deliver competent, accessible and affordable healthcare. However there is no data that demonstrates whether the private healthcare sector would be willing to manage public sector HIV patients, this study further explored this and the results have been published in a journal found in Chapter 7.

CHAPTER 8

Factors influencing HAART adherence among private health care sector patients in a suburb of the Ethekwini Metro.

In order to obtain full therapeutic benefits, an important aspect of HIV management is the role of the patient. Changes to therapy should therefore not be based only on laboratory results, but also on factors such as adherence. It is important to ascertain why patients are not adhering to therapy. It has been suggested that a 20% reduction in adherence to treatment may result in an 80% reduction in efficacy. If the correct regimen is not prescribed and if patients do not adhere to therapy then the possibility of the emergence of resistant strains is high. Studies have shown that non adherence causes 125,000 deaths annually in the United States, leads to 10-25% of hospital and nursing home admissions, [66] and is becoming an international epidemic. Important statistics on medicine taking demonstrates that one third of patients, take all their medicine, one third takes some, and one-third do not take any medicines at all, whilst 50% of all prescriptions filled are taken incorrectly.[66] Therefore it was important to investigate whether adherence is a major problem with HIV/AIDS patients in the Metro and their reasons for non compliance, so that strategies or interventions could be implemented to improve adherence. An analysis of whether private sector patients are adherent and reasons why they take or do not take their medicines was undertaken and published, and the contents of which are to be found in this Chapter.

CHAPTER 9

Discussion:

This is one of the first studies to contribute new information to the body of knowledge relating to the private healthcare sector‘s practices of managing the HIV epidemic in South Africa. Though confined to the eThekwini Metro of KZN, important information has emanated from this study that could assist in further research and answers relating to private sector management of patients in the country and more specifically regarding HIV and AIDS.

This study investigated three dimensions of the private healthcare sector in relation to the HIV epidemic.

The first related to the role and contribution of private sector doctors to the HIV epidemic in terms of the number of doctors that were involved in the management of HIV infected patients, their training needs, and an identification of their sources of knowledge together with their exposure to continuing medical education. The study also investigated their compliance with accepted national and international guidelines for the treatment of HIV/AIDS patients, their clinical and drug including drug treatment and adherence monitoring practices. Another dimension related to the potential role the private sector doctor could play in relieving the overburdened public sector with regard to HIV management, whilst the third dimension considered the adherence to treatment of patients visiting private sector doctors.

In a province that records the highest HIV prevalence rate, [15] all doctors whether in public or private sector care should be involved in helping to curb the epidemic. This study however confirmed that not all private sector doctors were managing HIV and AIDS patients in the eThekwini Metro of KZN. Many studies have highlighted the factors preventing doctors caring for HIV patients which ranged from a fear of becoming infected, unwillingness to care, homophobia,[67] lack of knowledge, competency and training,[37,68] financial risk or lack of insurance,[69,70] to the lack of time [37,68,71] and infrastructure.[72] This study confirmed that inadequate knowledge was a barrier for doctors not wanting to manage private sector HIV and AIDS patients, whilst inadequate knowledge, time and infrastructure were cited by private sector doctors managing HIV and AIDS patients as reasons for not willing to manage public sector patients. Additional training maybe required if these doctors need to manage an increased load of public sector patients as studies have shown that those with lower levels of knowledge saw fewer patients.[73] Doctors that were managing HIV patients indicated that they needed further training, with over 62% indicating a willingness to participate in a postgraduate diploma in HIV/AIDS management. The training needs of the doctors differed depending on the number of patients they treated and the number of years since they had qualified. There is therefore a need to provide further training and information in order to empower doctors to manage HIV/AIDS patients optimally and to remove the barriers that prevent doctors from managing such patients. Urgent educational interventions should be provided in order to improve the knowledge base of private sector doctors to HIV and AIDS management. Structured Continuing Medical Education (CME) programs and

workshops should be conducted in order to facilitate the broadening of HIV and AIDS management amongst private sector doctors. Understanding and reducing these barriers could assist all private sector doctors in the Metro to become involved in HIV management. This study further illustrated that younger doctors (as determined by the number of years qualified) were more involved in HIV management than the older doctors. A possible reason could be that these doctors had HIV training in their University years and were more confident about managing HIV infected patients, and were keeping up to date with HIV information. Studies have shown that younger physicians were found to be more up to date with regard to information on HIV.[55,74]

In order to practise high quality medicine, all doctors need to continue to update their knowledge as the complexity of the ARV treatment requires additional skills and current information.[53] In this study the majority of the doctors were found to access peer reviewed and/or accredited journals and textbooks, followed by attendance at continuing medical education (CME), workshops and conferences. Medical journals normally carry current information relating to the epidemic and many research findings are also found in such journals. More than 90% of doctors reported that CME courses contributed to their better management of HIV infected patients. The doctors also used their colleagues and pharmaceutical representatives to seek information about HIV, however, information from the internet appeared to be the least accessed. These findings are consistent with other studies, which showed that the least frequently used source of information was the internet, with textbooks, journals and colleagues preferred as common sources of HIV information.[53] However, doctors should be encouraged to use the internet as electronic

information is becoming increasingly more easily accessible with many journals now available online. The methods of obtaining information that were reported indicate that these doctors were keeping up to date with HIV information and were continuously educating themselves about its management.

Guidelines for treatment are normally helpful in assisting doctors to practise good quality evidence based medicine. In this study adherence to the guidelines was investigated by comparing empirical data with the guidelines in order to determine the extent of compliance with the guidelines. The majority of the doctors in the private sector complied with the national [National Department of Health (NDOH)] and international [Department of Health and Human Services(DHSS)] guidelines recommendations in treating with 3 drugs combination therapy, consisting of either 2 NRTI/NtRTI with 1NNRTI or 1 boosted or unboosted PI and with the entry level to treatment of a CD4 count of 200 cells/mm^3 and below [28,38] The most common regimen prescribed by doctors in this study was the triple therapy regimen, however, the use of 3NRTI combination even though not recommended as second line regimen by the NDOH, but recommended by the DHSS for use only when the first and second line regimens have failed, and only with specific drugs in the combinations, was used by a fifth of the doctors. A concern however, was that no single doctor used the recommended drugs for this combination and this could comprise the quality of care provided. These doctors need to update their knowledge by attending CME sessions or provide evidence of efficacy of the regimen used as a second line treatment. However, there was compliance with the guidelines by the majority of the doctors in respect of the investigative and monitoring procedures

adopted. The NDOH recommendation that patients be referred to specialists if there was drug failure was adhered to by over 40% of the doctors in the study. Thus there appeared to be overall compliance with the HIV management guidelines published by the NDOH and DHSS. However, with the introduction of the new World Health Organisation (WHO) ART guidelines (2009),[75] which have been adopted by South Africa, doctors need to ensure that they are well equipped to follow these guidelines. The WHO guidelines recommend that all adults and adolescents including pregnant women start treatment when their CD4 count is 350cells/mm^3, irrespective of the clinical symptoms. It further recommends greater access to CD4 testing and viral load monitoring, though stating at the same time that access to ART must not be denied if these monitoring tests are not available. Thus more people will be on ARVs earlier and will be on treatment for a longer period, chronically. For doctors who follow the NDOH guidelines there are financial implications for their patients and the medical aid societies. The question is whether the system within the private healthcare sector can be sustained or are these patients going to join the over burdened public healthcare sector? As important is that if this guideline is not followed then more sick patients may need specialist care or be hospitalized, which can increase hospital costs and have similar financial implications for the private healthcare system, as the major cost drivers in the private sector are private hospitals and specialists.[65]

The new guidelines further specify which drugs should be in first and second line regimens, with the recommendation that Stavudine not be used as first line regimen due to its long term irreversible side effects and drug toxicity. It is important for doctors to

have a thorough understanding of the drugs‘ side effects and also drug interactions, as poor clinical outcomes and drug toxicities can be a direct result of drug interactions. Studies have shown that more than 50% of the world‘s population uses complementary and alternative medicines mostly in combination with conventional medication.[76] In addition there are an estimated 200 000 traditional healers in South Africa compared with 25000 doctors of modern medicine, and up to 80% of black South Africans consult these traditional healers.[77] Owing to this large proportion of South Africans that are seeking alternative forms of therapy, the National Drug Policy aims to encourage traditional healers to work more closely with the formal health sector particularly in programmes such as AIDS management.[78] The factors influencing an individual‘s choice in traditional healing may be attributed to the freedom of choice of a patient to select a treatment modality, availability and easy access of traditional medicine, the cultural beliefs and preponderance of alternative medicines.[79]

Therefore a proper drug history should be taken and doctors need to become knowledgeable in this area in order to recognize any untoward effects from these medicines, but more importantly any drug interactions that reduces the efficacy of ARV treatment or causes toxicity should be noted and acted upon. Perhaps the new guidelines should make reference to the availability of information sources regarding complementary and traditional medicines.

Good clinical practices were also evident in this study such as monitoring for adherence, counseling on various topics and involving patients in therapeutic decision making. However, in terms of monitoring for adherence, though the respondents in this study used

many strategies, just over two thirds considered their monitoring tool to be reliable. Extensive counseling especially for patients who are non adherent can be very time consuming, but over 93% of doctors stated that it was not time consuming to counsel. This allows for questions to be raised on the quality of the counseling sessions as time constraints are commonly cited by doctors not willing to manage HIV infected patients in the developed world.[37,71] However, if counseling is time consuming then perhaps this role could be delegated to another health care professional working in the team, such as a nurse. Doctors also need to employ other strategies to improve the adherence of their patients to ARVs such as the monitoring of pharmacy claims to medical aids for patient refills. Pharmacy claims' monitoring has been shown to be a valuable tool for monitoring adherence in the private sector in South Africa and Southern Africa.[80,81] By adopting a multidisciplinary approach to the management of HIV patients, the quality of care could improve with resultant positive clinical outcomes as nurse led and pharmacist led programmes have been shown to improve virological response and adherence levels respectively, in people receiving HAART.[82]

South Africa's health system faces many challenges amongst them being the human resource challenge. This has worsened due to several factors ranging from poor skills to migration of health professionals from public sector to private sector or to other countries.[65] The situation regarding shortages of doctors in the public sector is serious as the percentage that worked in the private sector rose from 40% in 1980 to 79% in 2007.[65] In addition the number of doctors that graduated from medical schools prior to 2005 increased at an insufficient rate to meet the needs of the country in the medium term.[65]

Thus in a country where there is a shortage and maldistribution of doctors, partnerships between the private and public healthcare sector is essential. However, a successful partnership requires constructive engagement between the two sectors, [83] harmonization of the sectors with regard to using the same drug regimen, similar investigative procedures and compliance with guidelines and an optimal and relevant regulatory mechanism that would ensure a sustainable health system in the near future.[83] There are various models that Public Private Partnerships (PPP) can adopt. One such model could be where the public sector pays the private sector doctor for the management of public sector HIV/AIDS patients, whereby these patients are diverted from hospitals to accredited private sector doctors and paid for per capita. The second model could entail the private sector doctor working for a specified number of hours in a public sector facility and being paid.[84]

In addition the financial cost of addressing the HIV epidemic is enormous and if the health budget continues at its present level, then 47% of the budget will be required to provide first and second line ARV treatment for all eligible persons in the country.[85]

The development of the National Health Insurance (NHI) system to address the inequity present within the healthcare system and to enhance the quality of care will require that both sectors are involved in the management of HIV infected patients. The CEO of KZNMCC (a private doctor grouping in KZN) stated that ‗Private practitioners and private health care generally are resource-rich and can help ensure the seamless implementation of a NHI programme'.[83]

This study demonstrated the willingness amongst many private sector doctors that manage HIV and AIDS patients to also include the management of public sector HIV and AIDS patients. However those that were not willing who comprised about 25% of doctors stated reasons such as inadequate knowledge, poor infrastructure or lack of time, barriers that are commonly cited by doctors globally for not wanting to manage HIV patients. Only 46% of doctors willing to manage HIV and AIDS patients had all three requirements components i.e. adequate time, knowledge and infrastructure to manage public sector patients. There is an urgent need to address these deficiencies in the private health sector if a meaningful partnership is to be established. There is clearly a willingness in the private sector to help government manage the HIV infected population in South Africa, and it now depends on the government to explore this possibility further, and establish a well regulated partnership with the private sector to share resources in the management of HIV and AIDS patients, and to provide a framework of incentives, both financial and non financial.

Equally important is the role that patients visiting private sector doctors can play in the management of the HIV epidemic. Adherence to antiretroviral therapy is a crucial determinant of treatment success. Many factors influence adherence and identifying these factors may assist in the design of strategies to enhance adherence to the demanding regimens of HIV/AIDS. Studies done amongst public sector patients showed the main reason for missing doses was being away from home, difficulty with the dosing schedules and running out of tablets.[86] Stigma also played a role in decreasing adherence. In this study, these factors were also cited in addition to other factors such as side effects, not

being part of decision making, and importantly, a factor directly related to the pharmaceutical formulation where patients had difficulty in swallowing tablets due to tablet size. Of interest, 74.6% of patients took their medicines because they were influenced by the information provided by their health care provider (they understood how to take their medicines, were educated about their illness, and received information from the health care provider), with over 83% stating that they took their medicines because the tablets will save their lives. Being empowered with such knowledge, doctors can explain and motivate their patients to improve adherence.

Limitations:

Generalisability and Validity:

Caution must be exercised with regard to the generalisability of these findings due to the limited response rate. This being a self reported study the reliability of self reporting is difficult to substantiate as information was collected and analysed based on what the doctors reported. Also being a cross sectional study the direction of the association may not be causal.

These results however were consistent with findings in other similar studies in other countries, as previously discussed, thereby making the study and its recommendations valid. In addition these findings provide important information to utilize at this stage of the HIV and AIDS epidemic in SA. Although not a large representative sample relative to the number of doctors registered in SA, it covered doctors serving a wide and diverse geographical area in respect of the social and economic strata of potential patients. The doctors who participated in the study practised throughout the eThekwini Metro which is the largest city in KZN, which is the province with highest HIV prevalence in South Africa. It is the first study of this type to be done with this population.

CHAPTER 10:

Conclusion and Recommendations:

Conclusion:

The following conclusions were drawn from this study:

1. Most doctors in the private healthcare sector in eThekwini are currently involved in the management of HIV and AIDS patients in the Metro of KZN. There are barriers that prevent all doctors from managing HIV and AIDS patients.

2. Younger doctors are predominantly involved in the management, with the _older' doctors being less involved with HIV care.

3. There is a need for further information and training, as indicated by doctors with some even supporting a postgraduate diploma in HIV and AIDS management.

4. The majority of the doctors were managing their patients within the recommended national and international guidelines at the time. However there were some doctors that used drug combinations which were not recommended as second line regimens to treat their patients and these doctors ran the risk of not providing quality healthcare to their patients.

5. That private healthcare sector doctors in the eThekwini Metro obtained their information from reliable sources in order to have an up to date knowledge on the overall management of HIV infected patients, however electronic sources were accessed the least.

6. Private sector doctors who manage HIV and AIDS patients monitored for adherence using different monitoring tools, but the reliability of the tools were not assessed by all the doctors. The doctors have strategies to improve patient adherence to ARV therapy but need to do more in this area.

7. There is a willingness on the part of the private sector doctors to help in the management of public sector HIV and AIDS patients thereby sharing their models and lessons and helping the government to manage the HIV-infected population of South Africa. However, there are barriers that prevent doctors wanting to manage public sector HIV patients which need to be addressed.

8. Adherence to antiretroviral therapy is a problem amongst private healthcare sector patients in KwaZulu-Natal, and barriers to adherence do exist. These barriers to adherence are similar to those cited amongst public sector patients. In this study reasons for patients taking medicines and being adherent related to being adequately informed by the doctor.

Recommendations:

These are grouped into general recommendations and further studies:

General Recommendations:

1. Education on drug interactions and the prevention or management of side effects should be included in doctors training of HIV/AIDS patients and doctors encouraged to take a comprehensive drug history of their HIV infected patients. A HIV and AIDS centre for easily accessible HIV information on management can be set up at tertiary institutions that could help with doctor queries on HIV patient management. The use of the internet should also be encouraged as much information on HIV and AIDS can be sourced via this route and many HIV journals are also available online

2. Other barriers that prevent doctors from managing HIV infected patients should be identified and if possible removed so that more doctors become involved in HIV care in the private healthcare sector.

3. Public Private Partnerships should be established to integrate private health care with the public sector to make private healthcare more accessible and both private and public healthcare sustainable. The proposed NHI policy could be the mechanism through which the PPP could be established.

4. A combination of methods appropriate to the patient and clinical setting should be used to improve adherence. Adherence interventions should comprise dedicated educational sessions with every patient and include a programme of providing the necessary support in an open and non judgmental manner throughout the life-course of treatment. In addition ‘Motivational Interviewing‘, developed by clinical psychologists which is counseling used to change behavior, may also be considered.

5. A multidisciplinary team approach involving the nurse and pharmacist should be encouraged whereby intense counseling and pharmacy refills could be used as tools to improve and monitor adherence to treatment of HIV and AIDS patients.

6. The pharmaceutical formulation of certain antiretroviral drugs should be re-visited in order to facilitate the swallowing of these medications or where possible extemporaneous preparations made and dispensed to patients experiencing such problems in the short term. Dosage forms should be prescribed according to individual preferences, however, when not available then breaking the tablets carefully into smaller sizes if they are scored should be encouraged and counseled on, so that the entire dose is taken. The pharmaceutical industry should be engaged to discuss pharmaceutical formulation as a factor that impacts on adherence.

Further research areas that are identified include:

7. Identification of the possible barriers that prevent private healthcare sector doctors from playing an active role in the management of HIV and AIDS patients in KwaZulu-Natal. Given the high HIV prevalence rate in KwaZulu-Natal, interventions to address possible barriers to treatment of HIV-infected persons by private sector doctors is essential.

8. A further study on the clinical and drug management of HIV infected patients in the private healthcare sector is required based on the revised guidelines. This study however should in addition include other areas in KZN, rather than be confined to the Metro to extend the generalisability of the results.

9. Factors affecting adherence to treatment of HIV infected patients in the private healthcare sector should be investigated with a larger sample size and using patients‘ medical charts to validate the authenticity of the participants‘ responses. The clinical outcome of the patients may be used as an indicator.

10. A study to obtain further information on private sector doctors‘ adherence management which could address the following questions:

    a) The reliability of the doctors‘ adherence monitoring tool by using viral load data of the patient as a comparison.

b) Quality of counseling sessions, by determining the time taken by doctors to counsel on adherence at the first visit and subsequent visits and the counseling topics.

11. A study to investigate the cost of HIV care in the private healthcare sector (including all costs related to doctor visits, blood tests, laboratory, and drug), but excluding hospital costs.

12. A study to document ART regimens with associated clinical outcomes. Clinical outcomes could be determined by clinical indicators such as weight loss/gain, side effects experienced and managed by doctor, presence of opportunistic infections, CD4 counts, and viral load data. A comparison of the different treatment regimens could be done based on data obtained.

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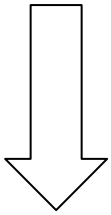
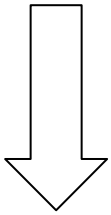
APPENDICES:

Flow Chart:

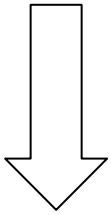
1255 [Sample from eThekwini Metro]: Phase 1



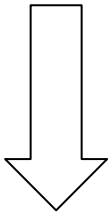
1055 [Sample from eThekwini Metro after exclusion]



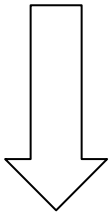
931 [Valid Sample from eThekwini Metro after further exclusions]



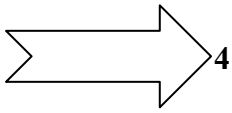
331 [Sample that responded from eThekwini Metro]



235 [Sample that manage HIV infected patient from eThekwini Metro]



Phase 2 and 3
190 [Consented Sample –Metro]



Phase 2 and 3
4 [Sample-Suburb of Metro]

Questionnaires:

Phase 1---Doctors : Introductory letter, consent form and questionnaire

Phase 2---Doctors: Questionnaire

Phase 3---Patients Introductory letter, consent form , questionnaires and history profile.

PHASE 1: Introductory Letter:

Dear Doctor,
I am undertaking research in the field of HIV/AIDS. My topic is as follows: –Evaluation of the Clinical and Drug Management of HIV/AIDS patients in the Private Health Care Sector of the Ethekwini Metro of KwaZulu-Natal. Sharing model and lessons for application in the Public Health Care Sector"

The objectives of the study are as follows:

- To examine the current practice in the treatment and care of HIV/AIDS patients in the private health care sector of the Ethekwini Metro of KwaZulu-Natal.
- To document antiretroviral treatment regimen and associated outcomes of this treatment among a random sample of private health care practitioners in the Ethekwini Metro of KwaZulu-Natal.
- To assess the level of adherence to therapy and problems experienced by HIV/AIDS patients treated in the private health care sector of the Ethekwini Metro of KwaZulu-Natal.
- Based on the above findings to develop and evaluate a model of care to manage HIV/AIDS patients.
- To make recommendations to the relevant role players for the provision of effective management according to the continuum of care strategy for HIV/AIDS patients.

The data obtained will be totally confidential and the participants anonymous, no doctor will identified by the results. The practice number is required in order to contact doctors that give consent to be part of the study. However in phase two of the study where a more comprehensive and detailed questionnaire will be administered, a coding system will be used and no identification whatsoever will appear on the questionnaire thereby rendering the questionnaire totally anonymous.

To this end could you please take a few minutes to fill out this questionnaire in order to assist me undertake research in this area of HIV/AIDS.

I thank you.

Mrs.P.Naidoo (Vassie)

PS :The questionnaire is divided into 2 sections: General and Specific.

PHASE 1: Consent Form & Questionnaire

I , (name)----------, hereby consent to participate in the study. The study has been explained to me in a language that I understand and I do not have any objections to filling in the questionnaire. I understand all information will be confidential. I am also aware that if at any stage I withdraw from the study there will be no penalties for my action and that I could withdraw from the study if I choose not to continue.

Signed

Dated:

Dear Doctor

Please tick the correct box where relevant:

GENERAL QUESTIONS:

1.Do you feel you require more training/knowledge on the management of HIV/AIDS?

☐ Yes ☐ No ☐ Unsure

2. What aspects would you like more information on?

☐ Drugs ☐ Monitoring ☐ Drug Therapy ☐ Other

3. If other please specify:

4.Would you be willing to participate in a Diploma in HIV medicine?

☐ Yes ☐ No

5. Number of years in practice:

---

6. Apart from clinical aspects, are there any other aspects of the management of HIV/AIDS patients that you need information on?

7.Do you manage HIV/AIDS patients?

☐ Yes ☐ No

SPECIFIC RESEARCH RELATED QUESTIONS:

If **YES:**

8. Practice Code and details: (needed to contact you-if consent to be part of study)

---

9. The number of HIV/AIDS patients you see on average/month?

---

10. Would you be willing to be part of the research and share some of your experiences and lessons confidentially?.

☐ Yes ☐ No

If **YES:**

11. Would you be willing to allow an analysis of your HIV/AIDS patient scripts.

☐ Yes ☐ No

12. Would you allow an exit interview of your HIV/AIDS patients (patient questionnaire)

☐ Yes ☐ No

Thank you for your time.

PHASE 2: Questionnaire

Dear Doctor,
Thank you for agreeing to be part of the study.

The purpose of this questionnaire is to understand:
1. Your demographics.
2. The characteristics of your HIV and AIDS patients and .
3. To do an assessment of your clinical management of HIV and AIDS patients.

I would greatly appreciate it if you could please complete this questionnaire. Thank you.

SECTION 1:
In this section we wish to survey your demographic characteristics:

1. How many years have you been practicing as a doctor?

PLEASE INDICATE WITH A TICK IN THE APPROPRIATE COLUMN.

2. Area of practice: (Tick all those that apply if more than 1 practice)

Township	Suburbs	City Centre	Rural	Other—please specify

3. Please indicate how you would classify your practice: (Tick all those that apply)

General Practice	
Specialist Practice	
Manage HIV and AIDS Patients as well	
HIV and AIDS Specialist only	
HIV and AIDS General practitioner Only	

4. Do you interact with the following organizations? (Tick all those that apply)

	Yes	No
Hospice		
Treatment Action Campaign		
HIV/AIDS NGO		
Other-please specify		

5. Where do you get your HIV and AIDS information from: (Tick all those that apply)

	Tick
Pharmaceutical Representatives	
Internet	
Journals	
Conferences	
Workshops	
CME Courses	
Fellow Colleagues	
Textbooks	
Other-please specify below	

6. IF Journals please name them below: (Tick all those that apply)

	Tick
SAMJ	
AIDS Care Journal	
SA Journal of HIV medicine	
BMJ	
JAMA	
Lancet	
Journal of Acquired Infectious Diseases	
AIDS	
AIDS Patient care	
New England Journal	
Clinical Infectious Disease	
Other-please specify below	

7. If from Conferences please indicate the following:

Name of Conference /s attended.	Year attended	Duration of conference

8. If from HIV and AIDS Workshops and CME please indicate number of Workshops and/or CME Courses attended from 2003 till end of 2004.

	1	2-4	5-8	9-12	More than 12	Total No.of hours spent
Workshop						
CME						

9. Do you think that HIV and AIDS Conferences, Workshops and CME Courses contribute to better management of HIV and AIDS patients? (Tick all those that apply)

	Yes	No
Conference		
Workshop		
CME Courses		

10. Are you a member of the SA.HIV Clinicians Society?

Yes	No

11. Do you feel adequately re-numerated by Medical Aids for the management of HIV and AIDS patients presently?

Yes	No

12. Would you be willing to manage public sector HIV and AIDS patients.

Yes	No

13. If YES do you feel you have the following to manage public sector HIV and AIDS patients. (Tick all those that apply)

	YES	NO
Time		
Skills		
Infrastructure		

14. If NO is it because of the following:

Lack of time	Inadequate Infrastructure	Lack of knowledge	Distance from public sector facility	Other-please specify

15. Do you think that the following has a role to play in HIV and AIDS management.

	Yes	No
Complementary medicines/homeopathic		
Traditional African Medicines		
Ayurvedic medicines		
Any other—please state		

16. Do you think that Traditional Healers have a role to play in HIV and AIDS management ?

Yes	No

SECTION 2:
In this section we wish to survey the profile of your patients:

17. How many HIV and AIDS patients you currently care for in a month?

1-5	6-20	21-50	51-100	100-200	>200

18. What proportion of your patients are of: (Tick all those that apply if more than 1 practice)

	Example (%)	Township	Suburb	City Centre	Rural	Other
African origin	20					
Indian origin	35					
Coloured Origin	15					
European origin	30					
Total	100					

19. What percentage of your HIV and AIDS patients are on a medical aid?.

None	About 25%	About 50%	Majority	100%	Not Sure

19a. What is the average household income of your patients:

Under R1000	R1000-R2000	R2001-R3000	R3001-R5000	R5000-R10000	Over R10000

SECTION 3:
In this section we wish to survey your clinical management of HIV and AIDS patients:

20. Do you follow any published guidelines to treatment when managing your HIV and AIDS patients?

	Name of guideline	Unsure of name
Yes		
No		
Sometimes		

21. Do you measure the following at the time of *diagnosis* of HIV and AIDS patients?.

	Always	Often	Sometimes	Rarely	Never
CD4					
Viral Load					

22. Do you do the following evaluation before *initiating ARV therapy*?

	Always	Often	Sometimes	Rarely	Never
Complete History and Physical (Clinical Assessment)					
Complete blood count					
Complete chemistry profile					
CD4 lymphocyte count					
Plasma HIV RNA measurement					

22a. If Clinical Assessment is used for evaluation before initiating ARV therapy, please state what indicator is used. (tick all those that apply)

Weight Loss/Slim disease	Opportunistic Infections	Fever	Other—Please State

22b. If CD4 Count, is used for evaluation before initiating ARV therapy at what level of the CD4 count do you initiate ARV therapy?

>500	<500	<350	<200	<100.	Any CD4 if pregnant	Any CD4 if patient requests therapy	Other-please specify

22c. If Viral Load is used for evaluation before initiating ARV therapy, please state at what level do you initiate ARV therapy?:

<3000	<10000	<50000	50000-100000	>100000	>500000	Any level if patient requests therapy	Other-Please specify

If in question 22 you never or rarely do the following evaluation before *initiating ARV therapy*?

22d Please indicate WHY: (tick all those that apply)

	Too costly for patient	Inadequate Lab. Facilities	No Access to lab.	Inadequate training	Other
Complete blood count					
Complete chemistry profile					
CD4					
Plasma HIV RNA measurement					

22e. If other please specify:

---

23. What drug/s do you prescribe as initial therapy?

ARV Tx	Single therapy	Dual therapy	Triple therapy	Four drug therapy	Prophylaxis only
ddi					
3TC					
d4T					
Abacavir					
Tenofovir					
ddc					
AZT					
Efavirenz					
Nevirapine					
Saquinavir					
Ritonavir					
Lopinavir					
Atazanavir					
Indinavir					
Nelfinavir					
Prophylaxis					
Other					

23a If other drug/s are used please state name of drug .

---

24. What clinical indicators do you use to assess the effectiveness of ARV therapy (tick all that apply).

Clinical Assessment	CD4 count	HIV RNA Levels	None	Other-Please specify

24a. If clinical assessment is used , please state what indicator is used. (tick all those that apply)

Weight Loss	Opportunistic infections	Other-please specify

24b. If you use the CD4 count as a clinical indicator when do you monitor the CD4 count?

	8-12 weeks	3-6 months	8-11 months	12 months	Not done	Describe Other
Every						
At						

24c. If you use the HIV RNA Levels as an indicator when do you monitor the viral load?

	8-12 weeks	3-4 months	6-8 months	12 monthly	Not done	Describe other
Every						
At						

25. What clinical indicators do you use when you want to change the ARV therapy? (tick all those that apply)

Clinical assessment	CD4 count	Viral Load	Resistance Testing	Other-please state

25a. If clinical assessment is used , please state what indicator is used. (tick all those that apply)

Weight Loss	Opportunistic infections	Other-please specify

25b. If CD4 count is used to change ARV regimen, please state at what CD4 values this happens.

<350	<300	<250	<200	<100	Depends on degree of change from previous CD4 count	Other-specify

25c. If viral load values are used to change ARV regimen, please state at what level of HIV RNA levels.

Any detectable Viral Load	>1000	>5000	>10000	50000	Other-specify	Depends on degree of change from previous level

26. Do you monitor for adherence in HIV and AIDS patients?

Yes	No

26a. If yes to above then how do you monitor for adherence? (tick all those that apply)

CD4 Count	Viral load	Refills	Pill count	Doctor‘s estimate	Side effect-tolerance	Patient self report

26b. How reliable do you think your adherence monitoring is?

Very Reliable	Reliable	Not Reliable	Have not tested reliability

26c. What if any interventions do you do to improve adherence.

Adherence education talks	SMS on cell phone	Set time on alarm clock of patients	Other—please indicate intervention.

27. How often do you see your HIV and AIDS patients for a check up?

Every month	Every 2 months	Every 3 months	Every 4-6 months	Every 6-12 months	At patient request	Depends on patient's clinical status	Other-Please specify.

28. What period of time do you prescribe/ dispense HIV and AIDS medications for:

30 days	60 days	90 days	>90 days	Only when patient requests	Only when patient visits	Other-Please state.

29. Do you (or via interpreter) / nurse/ peer counselor , counsel your HIV and AIDS patients on the following?

	Always	Often	Sometimes	Rarely	Never
Disease state					
How to take their drugs					
Side effect of the drugs					
Interaction (food or drug)					
Adherence					
Complementary medicines					
Nutrition.					
Alcohol use					
Other Drug/s abuse					
Condom use					
ABC of management					
Sexuality					
Risk behaviours					
Immunisation					
Other Lifestyle promotion-in prevention					
Disclosure					
Support systems eg hospice					
Support systems eg. Grants					

29a. If you have answered rarely or never in any or all in question 29 above please indicate **WHY:**

Time Consuming	Poor Renumeration for Time spent	Refer to other health professionals eg pharmacists ,social workers etc	Language Barrier	Uncomfortable to discuss issue with patient

30. How often do you involve your HIV and AIDS patient in any therapeutic decision making concerning their management?

Always	Often	Sometimes	Rarely	Never

31. Do you screen for the following?

	Yes	No
TB		
STI		
Hepatitis A,B,C		
Toxoplasmosis		
Substance use disorder		
CMV		
Other-Please Specify Below		

31a. If other please specify what you screen for:

---

32. Do you give prophylaxis for the following conditions?

	Yes---Please state name of drug/s used	No
PCP		
TB		
MAC		
Toxoplasmosis		
Other-please specify below		

32a. If other please specify condition and what drug/s is used.

---

33. Do you refer HIV and AIDS patients to the next level of care?

Yes	No

34. If yes at what point do you refer. (Tick all those that apply)

CD4-specify level	Viral Load-specify level	Very ill patients	Patients request	Drug failure	Other-specify

35. To whom do you refer HIV and AIDS patients to? (Tick all those that apply)

Specialists	McCords Hospital	Public Health Facility	Other-specify	

36. Do you have sufficient time to counsel HIV and AIDS patients?

Yes	No	Sometimes

OPTIONAL INFORMATION ON DEMOGRAPHICS:

37. Age :

30-40 yrs	41-50yrs	51-60 yrs	61-70 yrs	Over 70 yrs

38. How do you describe yourself?

SA of African origin	SA of Indian origin	SA of Coloured origin	SA of European Origin	Other—please specify

39. Gender?.

Male	
Female	
Transgender	

Thank you Doctor for your time in filling out this questionnaire and for your contribution to science.

Do you have any questions or comments relating to the study?

Mrs P.(Vassie) Naidoo
Research undertaken at the Department of Community Health
Nelson R.Mandela School of Medicine
UKZN.

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Fax: 031-4013072/ 2607792
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Cell: 0839645429

PHASE 3:

Dear Doctor,

Thank you for agreeing to participate in phase 3 of my research titled –Evaluation of the Clinical and Drug Management of HIV/AIDS patients in the Private Health Care Sector of the Ethekwini Metro of KwaZulu-Natal. Sharing model and lessons for application in the Public Health Care Sector".

The data collectors who are either 5th year medical students or final year pharmacy students will be contacting you for this phase of the research which will be filling of the patient questionnaire and a history taking of patient's clinical and drug profile after obtaining consent from patient. Please be so kind as to assist in this phase so that the objectives of the study will be realized.

I thank you.

NB: All data obtained will be totally confidential and will be done anonymously, no patient or doctor will be identified by the results. In order to ensure anonymity the researcher is not personally involved with the data collection and therefore have employed medical and pharmacy students.

The students have signed an undertaking acknowledging the confidentiality and anonymity of the data collected.

Mrs. P.Naidoo
Telephone: 031-2607487/ 4014356:
Cell: 0839645429
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Email: naidoopj@ukzn.ac.za

PHASE 3: Introductory Letter:

Dear Patient,
I am currently doing a study to help manage HIV/AIDS patients. The study involves doing research. Most people with HIV/AIDS have many different pills to take at different times during the day with different instructions. Many people find it hard to always remember taking their pills.

This study needs to understand how people actually handle the taking of pills and the difficulty surrounding them in keeping themselves healthy and well.

Please tell me what you are actually doing not what you think I really want to hear. I need to find out how you feel when you take these pills, what are the reasons that prevent you from taking the pills. There are no right or wrong answers. The information you give to me will help me find better ways to help you.
It is voluntary to answer these questions and the answers you give will not be shared with your relatives, or friends. All answers will be confidential. In this research I would also be looking at your prescriptions or profile to see whether the medicines have helped you and whether you are adhering to treatment.

If you require assistance in filling this questionnaire please notify your doctor so that I could get somebody to assist you. It would take about 10 minutes of your time in filling out the questionnaires. Do not write your name on the questionnaire, however you need to sign your name on the informed consent form giving me permission to conduct the survey and interview you and to look at your scripts/profile. If you do not wish to participate there will be no negative consequences at any stage regarding your treatment. As your participation is voluntary you may also withdraw at any stage from the study.

I thank you very much for your help.

This study has received ethics approval from the University of Natal, Nelson R.Mandela School of Medicine, Research Ethics Committee, reference no. The contact details are as follows: Medical Research Administration, telephone: 031-2604495; fax: 031-2604410; email: ethicsmed@nu.ac.za.

PHASE 3: Consent form & Questionnaire:

I , (name)----------, hereby consent to participate in the study. The study has been explained to me in a language that I understand and I do not have any objections to having my information given to the researcher. I understand all information will be confidential . I am also aware that if at any stage I withdraw from the study there will be no penalties for my action and that I could withdraw from the study if I choose not to continue.

Signed

Dated:

Dear Patient,

PLEASE INDICATE WITH A TICK IN THE APPROPRIATE COLUMN.

There are no right or wrong answers.

DO NOT WRITE YOUR NAME

Section 1:

In this section we wish to survey your demographic characteristics:

1. What is your gender?.

Male	
Female	
Transgender	

2. How old are you in years?

<10	10-19	20-29	30-39	40-49	50-59	60-69	70 and Greater than 70yrs.

3. How do you describe yourself?

SA of African origin	SA of Indian origin	SA of Coloured origin	SA of European Origin	Other—please specify

4. What was the last grade you completed?

1 through 8 grades	9 thro 12 grades	Uncompleted diploma/degree	Completed Degree/diploma	No formal schooling.

5. Are you :

Single	Married	Single with child/children	Married but not living with partner	Living with partner	Separated	Divorced	Widowed

6. Are you employed?

Yes	
No	

7. If yes, do you work

Formally	
Informally (hawker, street trader, prn)	

8. Where do you live?

Informal housing	Formal housing	Flat	Hostel	Other-specify

8a) In which area do you live eg Pinetown, Chatsworth, Umlazi.

_____

_____

9. With whom do you live?

No one	Spouse	Partner	Friend	Parent/Family	Other-Specify

10. How long ago were you diagnosed with having HIV.

1 month ago	2 months ago	3-4 months ago	6 months to 11months ago	1 year ago	2 years ago	3-7 years ago	Greater than 7 years	Not Sure

10a. What made you seek treatment from doctor, that resulted in you being confirmed of having HIV and AIDS , OR how did you know about your HIV status.

_____

_____

11. Have you informed anyone else about your HIV status.

Yes	
No	

11a. If Yes who did you inform?

Spouse	Partner	Friend	Parent/Family	Other-specify

12. Do the following people support you in any way?

	Yes	No
Family		
Friends		
Neighbours		
Others-specify		

12a. If yes what type of support do they give you:

Financial	Emotional	Transport	Caregiver	Other

13. Do you have a community health care worker in your area?

Yes	
No	

14. If yes what distance does he or she live from you? OR how many minutes away does she live from you?

100-300metres	301-500metres	501-1000metres	>1km	>2km	5-10mins	15-30mins	1 hr	>1hr

14b. Are you in contact with your community health worker.

Yes	
No	

15. . Do you have a Medical Aid Health Insurance?.

Yes	
No	

16. If Yes, what is the name of your Medical Aid-Health Insurance?

---

17. Do you consume alcohol

Yes	no

18. If yes what quantity do you drink of the following?

	Quantity per day
Beer	
Whiskey	
Gin/Vodka	
Wine	
Brandy	
Juba	
Other	

19. Have you ever used:

	Never	Rarely	Sometimes	Most of the time	Always
Marijuana					
Cocaine					
Heroine					
_Sugars					
_Glue sniffing					
Other- please specify					

Section 2:
In this section we wish to survey your medicine taking:

20. Are you taking any medicines?:

Yes	
No	

21. If YES what medicines are you taking:

---

22. How many medicines do you take per day for your HIV infection?

1 pill	2-3 pills	4-6 pills	7-9 pills	More than 9 pills

23. Have you missed taking your medicine any day.

Yes	No

24. If YES how often would you say that you miss taking your medicine

Once a day	Once a week	Twice a week	Other-specify

24b How often has this happened in the:

Last month	Past 2 months	Last 6 months	Last year

25. People may not take their medicines for different reasons. If you did miss taking your medicines please indicate if it was for any of the reasons below. Also indicate how often this was the reason for your not taking the medicine. YOU

	Never	Rarely	Sometimes	Most of the time	Always
Were away from home					
Forgot to take your pills					
Had too many pills to take					
Had too many side effects					
Did not want anyone to know your HIV status					
Fell asleep between doses					
Were feeling sad					
Had problems taking pills at specific times of the day					
Had other illnesses as well					
Had difficulty going to get medicine					
Do not have someone to remind you to take the pills					
Do not have a telephone to order your pills					
Do not know why you are taking the medicine					
Do not know your lab results.					
Were not part of decision making about your illness with doctor.					
Find there are too many directions to take medicine.					
Ran out of medicines					
Did not have money to buy medicines					
Found that your medicines were stolen					
Shared your medicines, and did not have enough for yourself					
Are busy with other things					
Find difficulty in swallowing your medication					
Did not eat food					

25b. Can you give other reason/s why you had not taken your medicine.

a.----------

b----------

c.----------

26. Do you experience any of the following side effects:

Ketoacidosis	
Dizziness	
Insomnia	
Numbness,tingling or pain in feet or hands (neuropathy)	
Nausea , vomiting	
Diarrhoea	
Anaemia, neutropenia	
Tiredness,weakness	
Abdominal pain (pancreatitis)	
GIT intolerance	
Hepatitis	
Kidney stones	
Diabetes	
Lipodystrophy	
Other –List below	

27. How many pills did you take yesterday?

1 pill	2-3 pills	4-6 pills	7-9 pills	More than 9 pills

28. How many pills did you take the day before yesterday?

1 pill	2-3 pills	4-6 pills	7-9 pills	More than 9 pills

29. When was the last time you missed taking your medicine?

Within the past 2 days	Within the past 1 week	2-4 weeks ago	Never missed taking pills	Do not know

30. There are some reasons why people take their medicines. Indicate by ticking the reasons why you take your medicines.

Being reminded to take medicines	
Few pills to take per day	
Giving me incentives like tokens, clothing etc	
Understand side effects of drug	
Get information from health care provider	
Included in decision making process	
Educated about illness	
Easy access to health care provider	
Have health insurance	
Understand how to take my medicine	
Tablets will save my life	
Tablets make me feel better	

31. Do you feel the medicines are working for you?

Yes	No

32. If YES can you tell me how you know they are working.

_____

_____

33. If NO can you tell me why you feel that way?

---

34. Do you have someone to remind you to take your medicine?

Yes-always	Yes-often	Yes-sometimes	Yes-rarely	No-Never

35. How often did you have your blood taken in the past 12 months for HIV and AIDS?

1 time	2 times	3 times	4 times	More than 4 times	Not taken	Not sure

36. How many times did doctor change your HIV medicine in the past 12 months?

1 time	2 times	3 times	4 times	More than 4 times	Not sure	Did not change

37. How often do you visit your doctor?

Every month	Every 2 months	Every 3 months	Whenever I feel sick—specify no of times in the past 12 months.	Every 6 months	Only when he calls me	Not sure

37a Do you find it difficult to visit your doctor?

Yes	No

37b If YES why?

Transport problems	Lack of time	Too Costly	Too far from where you live.	Travelling time too long	Do not like going to a doctor	Cannot get time off work.

38. Do you have more than 1 doctor that you visit?

Yes	No

39. Have you visited your regular doctor in the last 6 months?

Yes	No

40. If yes how many times?

1 time	2 times	3 times	4 times	More than 4 times	Not sure

41. Does your regular Doctor talk to you on the following topics?

	Yes	No	If YES what does he say to you—explain briefly
Condom use			
ABC of management			
Sexual practices			
Immunization			
Nutrition			
Side effects of drugs			
Opportunistic infections			
Alcohol use			
Adherence			
HIV status			
Lifestyle promotion			
Cost of treatment			
Support systems			

42. Do you have any other medical condition such as :

	Yes	No
Diabetes		
High Blood Pressure		
TB		
Psychiatric problems		
High Cholestrol Levels		
Cardiac Disease		
Other-Please specify		

43. Do you take any other medicine (eg. vitamins ,complementary, herbs) not given by doctor?

	Bought from Pharmacy	Bought from health shop.	Bought from supermarket	Bought from herbalist
Yes				
No				

44. Besides a doctor do you visit any of the following persons on your own accord for your HIV infection.

	Yes	No
Traditional Healer		
Ayurvedic Dr		
Herbalist		
Reflexologist		
Dietician		
Psychologist		
Pharmacist		
Religious Leader/Priest		
Homeopath		
Psychiatrist		
Hospice		

45. If you have limited HIV and AIDS funds what do you do when your benefits are exhausted?
Do you

Stop taking medicine	Borrow money to buy drugs	Stop medicine till into benefits again.	Go to public sector for acute management	Buy medicines on credit from doctor/pharmacist.	Other- please specify what you do

46. Do you apply any topical cream on your body?.

	Name of cream	No. of times apply cream per day	Area where cream is applied to
Yes			
No			

Thank you for taking the time to answer the questions. I greatly appreciate your efforts and contributions.
Do you have any questions or comments.

Thank you once again

Mrs P.(Vassie) Naidoo.
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Email: naidoopj@ukzn.ac.za
Cell: 0839645429

Patient history Profile:

Dear Doctor,

I hereby consent to have my medical record which will include my prescriptions to be given to the researcher in order to access information towards the study titled: Evaluation of the clinical and drug management of HIV/AIDS patients in the private health care sector of the Ethekweni metro of KwaZulu-Natal. Sharing models and lessons for application in the public health care sector.

Signed:

Dated:

Patient No.: (same as questionnaire number)
[ ]

Regime Number	Dates of visit for past 12 months	CD4 level at time of visit	Viral load at time of visit	Any other complicatin treated at time of visit	Any other opportunistic Infection treated	Weight or any other clinical indicators	Medical Aid Y N

Table of drug names:

Number	Name of drug	Number	Name of drug
1	DDI	**11**	**Zalcitabine**
2	**3TC**	**12**	**Stavudine**
3	**D4T**	**13**	**Prophylaxis**
4	**Abacavir**	**14**	**Indinavir**
5	**Tenofovir**	**15**	**Ritonavir**
6	**Zidovudine**	**16**	**Lopinavir**
7	**Efavirenz**	**17**	**Atazanavir**
8	**Nevirapine**	**18**	**Prophylaxis**
9	**Saquinavir**	**19**	**Other-name**
10	**Nelfinavir**	**20**	**Other-name**