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# Patient outcomes in an antiretroviral programme in the setting of a solo private general practice

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# PATIENT OUTCOMES IN AN ANTIRETROVIRAL PROGRAMME IN THE SETTING OF A SOLO PRIVATE GENERAL PRACTICE

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**A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfillment of the requirements for the degree of Master of Public Health**

**November, 2013**

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**DECLARATION**

I, George Molebatsi Ntshabele declare that this research report is my own work. It is being submitted for the degree of Master of Public Health at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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November 2013

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**DEDICATION**

I dedicate this work to:

My wife TSHEPISO, for the understanding and support showed throughout my studies. Words will never be enough to express my gratitude and thanks for your support and encouragement throughout my studies.

My sons, Karabo and Mofenyi, for the sacrifices you had to make for daddy to complete this project.

Lastly, a special thanks to my late parents Othaniel Mogotsi Magwantana Ntshabele and Monica Motshabi Kgakana Ntshabele for raising me into the person I am. Eternal gratitude for your efforts. May their souls forever rest in peace.

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## ABSTRACT

***Background:*** The HIV/AIDS epidemic is continuing to impact negatively on the health of populations globally. The region most affected by this epidemic is sub-Saharan Africa, with two-thirds of people living with HIV/AIDS located in this region. In order to combat this epidemic, countries are putting up efforts to scale-up the provision of antiretrovirals to affected individuals. South Africa faces challenges similar to other sub-Saharan countries in the scaling-up of antiretrovirals, such as cost of drugs, inadequate laboratory infrastructure and the low and declining number of health professionals. Therefore, the contribution of private general practitioners as part of the overall strategy to combat the HIV/AIDS epidemic needs to be considered. However, the performance of antiretroviral programmes in the private sector are unknown and there is therefore a need to explore patient outcomes in antiretroviral programmes being run by general practitioners in the private sector. The findings of this study will add to understanding what the outcomes of ARV programmes by GPs in private practice could be in a public-private partnership.

***Aims:*** The main aim of the study was to evaluate patient outcomes in an antiretroviral programme in the setting of a solo private general practitioner.

***Methods:*** This was a cross-sectional study using retrospective data from March 2005 to February 2008. A total of 170 patient records from a private general practitioner's rooms were examined. The data were analysed using the using the median, interquartile and proportions. The Chi square was used to test for association between baseline characteristics and patient outcomes in the univariate analysis.

***Results:*** The increase in median CD4 count was 242 cells/µl and 265 cells/µl at 6 months and 12 months respectively. The proportion of patients who achieved viral suppression at 6 months and 12 months was 75% and 73% respectively. Rate of loss to follow-up was 29% and 38% at 6 months and 12 months respectively, which was much higher than in other settings. Although there were no statistically significant associations established by

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the study, the patterns emerging from the study showed that the baseline characteristics that were a risk for poor virological outcomes during the period of the study were female gender, younger age group, higher WHO clinical staging, lower CD4 count and higher viral load. Baseline characteristics that were a risk for loss to follow-up during the period of the study were male gender, younger age group, higher WHO clinical staging, lower CD4 count and higher viral load.

***Conclusion:*** Patient outcomes in an antiretroviral programme in the setting of a solo private general practitioner are comparable with patient outcomes in antiretroviral programmes in public sector settings in terms of immunological and virological outcomes. However, the lost to follow-up rate was much higher than in public sector settings.

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**ACKNOWLEDGEMENTS**

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## LIST OF ABBREVIATIONS

AIDS – Acquired Immune Deficiency Syndrome

ARVs – Antiretrovirals

DOH – Department of Health

DOL – Department of Labour

DOTS – Directly observed treatment, short course

CHGA – Commission on HIV/AIDS and Governance in Africa

HAART – Highly active antiretroviral therapy

HIV – Human Immunodeficiency Virus

GP – General Practitioner

LTFU – Loss to follow-up

PEPFAR – President's Emergency Plan for AIDS Relief

STI – Sexually Transmitted Infection

TB - Tuberculosis

UNAIDS – United Nations Programme on HIV/AIDS

USA – United States of America

WHO – World Health Organisation

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# CHAPTER ONE

# INTRODUCTION

## 1.1 **BACKGROUND**

The HIV/AIDS epidemic is continuing to have a negative impact on the health of populations globally. According to the WHO (2011) report on the epidemic, a total of 34 million people worldwide were living with HIV/AIDS in 2010. Sub-Saharan Africa remains the region most affected with 68% (22.9 million) of people living with HIV/AIDS being located in the region.

The report also highlights the following:-

- The number of new infections stood at 2.7 million in 2010 of which 1.9 million were in sub-Saharan Africa.
- Two-thirds of all adult and child deaths due to AIDS worldwide occurred in sub-Saharan Africa (1.2 million out of 1.8 million deaths).

The high prevalence of the epidemic in sub-Saharan Africa has a serious impact on the health outcomes of the people of the region. This epidemic also creates a challenge for countries in the sub-Saharan Africa as they strive to achieve the Millennium Development Goals, especially the following three goals and targets:-

- To reduce child mortality. The target is to reduce the under-5 mortality rates by two-thirds between 1990 and 2015.
- Improve maternal health. The target is to reduce the maternal mortality ratio by three-quarters, between 1990 and 2015.

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- Combat HIV/AIDS, malaria and other diseases. The target is to have halted and began to reverse the spread of HIV/AIDS by 2015 (Human Development Report 2003).

It is quite clear that the burden of HIV/AIDS on sub-Saharan Africa poses a challenge on health systems and is likely to set back attempts by countries in sub-Saharan Africa to meet the Millennium Development Goals.

The treatment of people who are in the stage of AIDS of the disease is one of the components of the overall strategy to combat the HIV/AIDS epidemic (DOH, 2007). Treatment of AIDS is by means of a cocktail of drugs called antiretroviral (ARVs). Although these drugs are not a cure for AIDS, they do improve the general health of affected individuals and they prolong lives (Simon et al, 2006).

A report by the Commission on HIV/AIDS and Governance in Africa (CHGA), articulated the challenges of scaling up HIV/AIDS treatment in Africa as follows (CHGA Report, 2004):-

- The low and declining number of health professionals;
- Financial cost and sustainability of the drugs programme;
- Inadequate laboratory and patient care infrastructure;
- Poor patient follow-up leading to low adherence.

However, the report also articulates developments which should enable many victims of the HIV/AIDS epidemic in many African countries to access antiretroviral as follows:-

- The emergence of a simpler treatment regimen;

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- The dramatic drop in the cost of ARVs;
- Agreement on a medical treatment protocol for resource-poor settings;
- Increased international funding for antiretroviral treatment for low-income countries.

Despite these factors access to ARVs in sub-Saharan Africa is still a huge challenge. Of the estimated 10.4 million people in sub-Saharan Africa needing ARVs by December 2010, only 5 million were indeed receiving the ARVs (WHO, 2011). Therefore, scaling-up provision of ARVs in sub-Saharan Africa is crucial in the fight against this epidemic.

South Africa, just like its counterparts in sub-Saharan Africa, faces a huge crisis created by the HIV/AIDS epidemic. By 2010, a total of 5.6 million South Africans were HIV positive (DOH, 2011). Of the estimated 2.5 million people needing to be on ARVs, approximately 1.4 million people were receiving the treatment. This means that ARV coverage was at about 53% by 2010 (WHO, 2011). In order to turn this epidemic around, sub-Saharan Africa specifically needs to develop innovative initiatives to increase coverage and expand access to ARVs.

**1.2 PROBLEM STATEMENT**

At the moment, government HIV treatment sites in South Africa are already buckling under the pressure of demand for ARVs. The state has over the years failed to attract enough doctors into the public health sector and many posts remain vacant (DOL, 2008). One of the ways to be considered as part of a strategy to increase human resources to combat the HIV/AIDS epidemic would be to involve general practitioners (GPs) in

private practice. This involvement would be to use their practices as treatment sites which are subsidized by the state or some other agency to provide HIV care and treatment to people without medical insurance at no cost to the patient. There are models in South Africa where GPs provide HIV care and treatment to people without medical insurance at no cost to the patient. These models make GPs appealing as a vehicle for expanding coverage of care and treatment in the fight against the HIV/AIDS epidemic.

In the light of the burden of the HIV/AIDS epidemic in the public health system in South Africa, a general practitioner in solo private practice setting can play a role to ensure wider coverage of ARVs in the public health system. However, patient outcomes in the setting of a solo GP have not been explored before and are therefore unknown. The findings of this study are important as they will add to understanding what the outcomes of ARV programmes by GPs in private practice could be in a public-private partnership

## 1.3 AIMS AND OBJECTIVES OF THE STUDY

### AIMS

The aim of the study was to evaluate the patient outcomes in an antiretroviral programme in the setting of a solo private general practice.

### SPECIFIC OBJECTIVES

1. To evaluate patient outcomes of an antiretroviral programme at month 6 and month 12 in a solo general private practice from March 2005 to February 2008 by using the CD4 count and viral load;

2. To assess loss to follow-up at month 6 and month 12;

3. To identify factors associated with good virological response in these patients;

4. To identify the factors associated with loss to follow-up in these patients.

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## 1.4 SUMMARY OF THE REPORT

Chapter two explores literature to further elucidate on the issues and concepts that have been described as central to this study.

Chapter three describes the methodology used in this study. The chapter describes the research instrument, the participants and the process of data analysis.

Chapter four deals with the presentation of the findings from the study in terms of the aims and the objectives of the study

In chapter five the findings of the study are discussed in light of literature reviewed. The findings of the study are also compared with the findings from other settings.

Chapter six provides the conclusion and summarises the main findings of the study. It explores the limitations and suggests some of the implications for potential future areas of research in the area of patient outcomes in patients on ARV programmes in the setting of a solo private general practitioner.

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# CHAPTER TWO

# LITERATURE REVIEW

## 2.1 INTRODUCTION

The response of the South African government to the HIV epidemic in the 1990's was characterized by the then health minister's insistence that the country was unable to provide and monitor ARVs because of toxicity, financial constraints, inadequate health infrastructure and competing health demands. The minister's response came out in the background of an environment where the president of the country was questioning the link between HIV and AIDS (Garbus, 2003).

The fight against the epidemic was then placed under the leadership of the then deputy president, who despite the political context of AIDS denialism, produced a strategic plan that was lauded by the UNAIDS representative as ambitious and credible (UNAIDS, 2007). The HIV and AIDS and STI Strategic Plan for South Africa, 2007-2011 (Department of Health, 2007), has two primary aims, namely:-

- To reduce the number of new infection by half
- To reduce the impact of HIV and AIDS on individuals, communities and society by expanding access to appropriate treatment, care and support to 80% of all people diagnosed with HIV.

The interventions necessary to realize the above goals are structured under four priority areas, namely:-

- Prevention;

- Treatment, care and support;
- Human and legal rights;
- Monitoring, research and surveillance.

GPs are able to contribute in all these four priority areas. However, the new plan is not very specific as to how GPs are intended to fit in the plan. It is important to engage the services of GPs in the fight against the HIV/AIDS epidemic because in many developing countries, when faced with illness, people seek treatment by visiting a private sector provider first (Smith et al, 2001). According to Smith et al (2001), the following are some of the reasons why patients consult private sector providers:-

- Easy geographic accessibility;
- Shorter waiting periods, longer and more flexible working hours;
- Greater availability of staff and drugs;
- Greater confidentiality when dealing with diseases which carry social stigma;
- Perceptions that private sector providers are more considerate and sensitive to client concerns;
- Perceptions that private sector services are technically superior to public sectors services.

This view is corroborated by Chabikuli et al (2004) who argue that when it comes to sexually transmitted infections (STI) care, GPs are major providers of care. This is largely due to the fact that GPs are widely available across the country and their practices are often open after hours when public facilities are closed. In addition, there are perceptions that compared to the public sector; GPs are less judgmental and moralistic towards people with illnesses carrying a social stigma such as STIs. For STIs, poor

people prefer to pay for a GP consultation where anonymity, confidentiality and dignity are more likely to be part of the treatment experience, rather than receive free services from the public sector, even if they believe that the free services offered by the public service is of high technical quality. However, the same study has produced evidence suggesting that the technical quality of healthcare provided by GPs is often poor.

GPs can offer long-term involvement in primary care clinics in their communities (Tumbo et al, 2006). The involvement of GPs in providing primary health care for the state is desirable because it addresses the great shortage of experienced health professionals in South Africa. However the issues are not as straightforward as they often seem. Constraints associated with involving private service providers in primary health care are articulated by Palmer et al (2003) as including the following:-

- Private service providers are concentrated in the urban centers where public sector health services are relatively well- resourced
- There is less opportunity for the public sector to make use of private service providers in poorly resourced areas as the cost of set-up may far supersede return on investment.
- Private service providers provide mainly curative services with poor follow-up and continuity of care for chronic patients.
- The technical quality of the care provided by GPs is often poor.

The literature review generally shows that GPs have the potential to play an important role in providing primary health care for the government. Faced with the HIV/AIDS

epidemic, it would be beneficial to all stakeholders to include GPs as part of the strategy to combat this epidemic. However, GPs will need to be provided with adequate support to ensure that the issues around the quality of care provided by GPs are addressed.

In South Africa, it is not clear as to the role GPs are playing in the provision of ARVs and the patient outcomes from ARV programmes run by GPs and the private sector are not known. This study will assess these outcomes in a solo GP practice.

## 2.2 PATIENT OUTCOMES

The literature on patient outcomes in public sector ARV programmes in developing countries and industrialised nations was reviewed to gain insight into these patient outcomes. These patient outcomes were later compared with patient outcomes from this study.

### 2.2.1 Immunological outcomes

2.2.1 Immunological outcomes

CD4 cells are fundamental to the development of specific immune response to infection, particularly against intracellular pathogens (Langford et al, 2007). Since these are primarily targeted by HIV, their depletion severely limits the host immune system's capacity to respond to any infection. (Stebbing et al, 2007). CD4 count is one of the important predictor of the progression of the disease as well as a significant predictor of survival (Hogg et al, 2001). WHO ART treatment guidelines use CD4 count as one of the markers for initiating therapy (WHO, 2006). It is also an important monitoring tool for the response to treatment through periodic scheduled CD4 count determinations. Lower

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CD4 counts are associated with greater risk for disease progression, with the greatest increase in risk occurring when levels drop to below 200 cells/µl (Langford et al, 2007). A CD4 count is thus important to identify those individuals who are asymptomatic but have a low CD4 count as they are at a late stage of the disease and therefore need to be initiated on treatment (Baggaley et al, 2006). A rise in the CD4 count is expected following successful initiation of ARVs. This is often a biphasic response with an initial increase in the first 2 months of therapy, followed by a decline in the CD4 count, which is then followed by a slower increase in the CD4 count (WHO, 2000). According to Phillips et al (2008) the following are some of the factors affecting the increase or decrease in the CD4 count:-

- Interruption of drug supply
- Adherence patterns
- Rate of switch to second line treatment after treatment failure
- Number of active drugs in the cocktail
- Viral load
- Rate of development of resistance
- Incidence of tuberculosis or WHO stage IV disease whilst on ARV therapy

With the above factors in mind, we will now look at results as reported by various studies in terms of CD4 count response to ARVs, as illustrated in Table 2.1.

Table 2.1 shows that the monthly increase in CD4 count for those studies reporting in a 6 months period ranged from 13 cells/µl to cells/µl 43 whilst the monthly increase for those reporting in a 12 months period ranged from 13 cells/µl to 16 cells/µl.

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**Table 2.1 Response of CD4 count to ARVs by various studies reviewed in the literature**

| Period of reporting (months) | Author(s) | Increase in CD4 count (cells/µl) | Average monthly increase in CD4 count (cells/µl) | Country | Setting |
|---|---|---|---|---|---|
| 6 | Hoen et al (1999) | 260 (median) | 43 | France | Public |
| | Smith et al (2004) | 114 (mean) | 19 | England | Public |
| | Coetzee et al (2004) | 134 (mean) | 22 | RSA | Public |
| | Grabar et al (2005) | 167 (median) | 28 | France | Public |
| | Hossenpour et al (2006) | 122 (mean) | 20 | Malawi | Private |
| | Stringer et al (2006) | 155 (mean) | 26 | Zambia | Public |
| | Charalambous et al (2007) | 248 (median) | 41 | RSA | Pivate |
| | Vajpayee et al (2007) | 77 (median) | 13 | India | Public |
| 12 | Smith et al (2004) | 181 (mean) | 15 | England | Public |
| | Stringer et al (2006) | 175 (mean) | 16 | Zambia | Public |
| | Charalambous et al (2007) | 271 (median) | 23 | RSA | Private |
| | Vajpayee et al (2007) | 155 (median) | 13 | India | Public |
| 24 | Smith et al (2004) | 248 (mean) | 12 | England | Public |
| | Coetzee et al (2004) | 288 (mean) | 12 | RSA | Public |
| | Charalambous et al (2007) | 462 (median) | 19 | RSA | Private |
| 96 | Sow et al (2007) | 213 (mean) | 2 | Senegal<br>Ivory Coast<br>Uganda<br>Kenya | Public<br>Public<br>Public<br>Public |

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### 2.2.2 Virological Outcomes

The basis for monitoring the efficacy of ARV therapy is the quantification of HIV-1 RNA (viral load). The goal of therapy is to achieve undetectable plasma HIV-1 RNA (WHO, 2000), or to reduce the level of circulating virus as much as possible, for as long as possible (O'Brien et al, 1996). According to Arduino et al (2001), viral load is a predictor of disease progression. A high viral load is predictive of poor clinical outcomes. There is also generally an inverse relationship between the viral load and the CD4 count i.e. a high viral load is associated with a low CD4 count and a low viral load is associated with a high CD4 count. This is corroborated by Raboud et al (2001) who found in their study in Canada that those patients with undetectable viral loads showed a longer positive virological response than those patients with a viral load above the detectable limit. Viral load testing is also important in detecting treatment failure, especially in the situation of a high CD4 count as the CD4 count may only decline after a substantial period of time (Baggaley et al, 2006). In an earlier study Hoen et al (1999) reported that viral suppression can be achieved in virtually all patients fully compliant to triple therapy.

Table 2.2 shows the results of various studies in terms of achieving viral suppression from the time of initiating ARVs. In general, the table shows that better viral suppression was shown for those studies with a longer study period as opposed to those with a shorter study period Table 2.2 also shows that at 6 and 12 months, the level of suppression for developing countries investigated in the literature review was comparable to those of the developed countries.

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**Table 2.2 Response of viral load to ARVs by various studies in the literature review**

| Period of Reporting (months) | Author(s) | Proportion of patients with suppressed viral load | Value of viral suppression used (copies/ml) | Country | Setting |
|---|---|---|---|---|---|
| 1 | Bussman et al (2000) | 56 | <400 | Botswana | Public |
| 2 | Bussman et al (2000) | 78 | <400 | Botswana | Public |
| | Tam et a l (2007) | 72 | <500 | Canada | Public |
| 1 – 3 | Lucas et al (1999) | 42 | <500 | USA | Public |
| 3 | Coetzee et al (2004) | 88 | <400 | RSA | Public |
| 3 – 7 | Lucas et al (1999) | 44 | <500 | USA | Public |
| 6 | Coetzee et al (2004) | 89 | <400 | RSA | Public |
| | Smith et al (2004) | 84 | <400 | England | Public |
| | Charalambous et al (2007) | 75 | <400 | RSA | Private |
| | | 63 | <50 | RSA | Private |
| 7 – 14 | Lucas et al (1999) | 37 | <500 | USA | Public |
| 12 | Coetzee et al (2004) | 84 | <400 | RSA | Public |
| | Smith et al (2004) | 84 | <400 | England | Public |
| | Charalambous et al (2007) | 72 | <400 | RSA | Private |
| | | 63 | <50 | RSA | Private |
| 18 | Coetzee et al (2004) | 75 | <400 | RSA | Public |
| 24 | Coetzee at al (2004) | 70 | <400 | RSA | Public |
| | Smith et al (2004) | 80 | <400 | England | Public |
| | Charalambous et al (2007) | 72 | <400 | RSA | Private |
| | | 65 | <50 | RSA | Private |

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Moore et al (2005) studied the virological responses from 1996 to 2002 in the same cohort and the results of the study are shown in Table 2.3 below. The data shows that in every year, there was an increase in the proportion of patients in whom viral suppression had been achieved at month 12 as compared to month 6.

**Table 2.3 HIV-1 RNA suppression in ARV-naïve patients by year of initial HAART Use**

| Response | 1996 | 1997-1998 | 1999-2000 | 2001-2002 |
|---|---|---|---|---|
| HIV RNA <400 copies/µl by month 6 | 58.6% | 56.8% | 74.7% | 74.3% |
| HIV RNA <400 copies/µl by month 12 | 72.4% | 67.8% | 83.3% | 78.1% |

Moore et al (2005)

### 2.2.3 Characteristics associated with viral suppression

Since the introduction of HAART, the morbidity of patients infected with HIV in developed countries has been reduced and their survival greatly improved (Tuboi et al, 2005). The goal of therapy is to suppress the HIV RNA to a level that is undetectable because an undetectable viral level is associated with a better and durable treatment response and therefore better clinical outcomes (Rastegar et al, 2003). Table 2.4 shows the baseline characteristics associated with viral suppression according to the literature reviewed. The table shows that the baseline characteristics associated with viral suppression are older age group, higher CD4 count and lower viral load. Another baseline

character impacting on virologic outcome was identified by Fielding et al (2008) as being the WHO clinical staging. They reported that the patients with a more advanced WHO clinical stage (stage 3 and 4) were less likely to achieve viral suppression at 12 months as compared to those patients with WHO clinical stages 1 and 2.

**Table 2.4 Baseline characteristics associated with viral suppression according to literature reviewed**

| Period of reporting (months) | Author(s) | Baseline characteristics associated with viral suppression | | | | Country | Setting |
|---|---|---|---|---|---|---|---|
| | | Gender | Age group | Level of CD4 count | Viral load | | |
| 6 | Tuboi et al (2005 | F | Older | Higher | Lower | Brazil | Public |
| 7 - 14 | Rastegar et al (2003) | M | Older | Higher | Lower | USA | Public |
| 12 | Knobel et al (2001) | M | Older | Higher | Lower | Spain | Public |
| 36 | Bosch et al (2007) | Not predictive | Older | Lower | Not reported | USA Puerto Rico Italy | Public |

### 2.2.4 Adherence

According to Mukherjee et al (2006), adherence to antiretroviral therapy delays the progression of HIV to AIDS and the development of resistance. Adherence is described as engagement and accurate participation of an informed patient in a plan of care, and it includes the extent to which the patient follows instructions due to the patient's consent and understanding of the plan of care, as well as being a partner in the plan of care (Rabkin et al (2003). Taking ARVs on a routine basis can be cumbersome and not easy to live with, follow or remember. The ability of the patient to take the drugs consistently and

at exactly the same time depends on the individual's frame of mind, support of family and the community at large (Nsimba et al., 2010).

According to Chesney (2000), factors having a negative effect on adherence in general can be classified into patient factors, treatment factors and health care system factors as shown in Table 2.5.

**Table 2.5 Factors having a negative effect on adherence (Chesney, 2000)**

| Patient factors | Treatment factors | Health care system factors |
|---|---|---|
| • male gender<br>• younger age<br>• depression<br>• lower levels of education<br>• low self-efficacy<br>• extreme pain<br>• extreme anxiety<br>• no change in health status despite taking treatment<br>• non-white | • dose frequency of > twice daily<br>• number of pills to be taken<br>• type of medication<br>• inability to take medication when away from home<br>• food requirements<br>• drug side effect<br>• poor patient-health care provider relationship | • Past negative experience (eg. Negative staff attitude, drug shortages. Long waiting periods) |

According to Ware et al (2009) adherence is also threatened by the following factors:-

- Out-of-pocket expenses
- Time travelling to and attending clinical appointments
- Stigma and fear of disclosure
- Conflicting messages from health care practitioners and religious authorities

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- Stopping taking medication when symptoms disappear.

Social support has been identified as one of the coping mechanisms for patients to adhere to their ARVs. Evidence seems to suggest that people with chronic conditions who had adequate social support adapted better to the crises of illness, demonstrated less anxiety and depression, and had fewer somatic symptoms than people without adequate social support (Swindells et al, 1999). Gallant (2003) further argues that in the case of chronic conditions, illness-specific or regimen-specific social support may have a stronger influence on self-management behaviour than more general types of social support and thus result in improved adherence. In South Africa, the government, through the Department of Health (DOH) has recruited Community Health Care Workers (CHCWs) as one of the measures to improve adherence to ARVs. Some of the functions of CHCWs in the health care system in terms of management of HIV and AIDS/STIs is described as follows:-

- To provide comprehensive information on HIV & AIDS and counteract the effects of stigmatisation
- To provide information on the prevention and treatment of HIV & the use of condoms
- To promote adherence to ARVs and identify side-effects
- To support activities of daily living
- To support family members and people in the community caring for the patients on ARVs

All these measures are meant to provide meaningful social support to patients living with HIV & AIDS as well as those already on ARVs (DOH, 2007).

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### 2.2.5 Loss to follow-up and patient retention

Patient retention refers not only to retention of patients in a referral chain but also to the retention of patients in a single health care programme over time ( Booysens et al, 2006 citing Barber et al, 2001). Patients known to be alive and receiving highly active antiretroviral therapy at the end of a follow-up period are considered to be retained and patients are considered lost to follow-up if they are later than 3 months for a scheduled appointment or medicine pick-up (Rosen et al, 2007). Patient retention impacts on loss to follow-up and adherence. According to Booysen et al (2006), the factors affecting retention can be categorized into three broad categories, namely, predisposing factors, need factors as well as enabling and impeding factors, as shown in Table 2.6.

**Table 2.6 Factors affecting patient retention**

| Predisposing factors | Need factors | Enabling & impeding factors |
|---|---|---|
| Socio-demographic characteristics (age, gender, education)<br>Psychologicalcahracteristics (autonomy, cognitive impairment)<br>Health beliefs (attitudes, values, knowledge)<br>Social structure (occupation, ethnicity, culture) | Evaluated biologically constructed need (clinical biomarkers)<br>Perceived socially constructed needs (self-reported health status) | Personal characteristics (income, health insurance)<br>Household characteristics (number of children)<br>Organisational characteristics (availability of healthcare workers and facilities)<br>Community characteristics (stigma, social relationships) |

Table 2.6 shows results of LTFU by various studies reviewed in the literature.

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**Table 2.7 Results of LTFU reported by various studies reviewed in the literature**

| Period of reporting (months) | Author(s) | Proportion of patients LTFU (%) | Deaths included in analysis | Country | Setting |
|---|---|---|---|---|---|
| 4 | Yu et al (2007) | 5 | Yes | Malawi | Public |
| 10 | Rosen et al (2007) | 22 | Not Reported | Systematic Review of sub-Saharan Africa | Public |
| 12 | Karcher et al (2007) | 27 | Yes | Kenya | Public |
| | Bussman et al (2009) | 2 | Yes | Botswana | Public |
| | Maru et al (2007) | 59 | Yes | India | Private |
| 13 | Severe et al (2005) | 7 | Yes | Haiti | Public |
| 18 | Hofmeyer et al (2009) | 3 | No | RSA | Mixed |
| 24 | Bussman et al (2009) | 4 | Yes | Botswana | Public |
| 45 | Maru et al (2007) | 68 | Yes | India | Public |

### 2.2.6 Characteristics associated with loss to follow-up and patient retention

The baseline characteristics having an impact on loss to follow-up were identified by Maru et al (2007) in their 3 year study as being younger in age, having a lower CD4 count at baseline and having a lower monthly income. In their 2 year study, Yu et al (2007) reported that the baseline characteristics of patients lost to follow-up were younger in age, females and were of WHO clinical stage 3 and 4. A similar finding was reported by Nacher et al (2006) whose study concluded that the following were risk factors for being lost to follow-up:-

- the younger age group
- a lower baseline CD4 count,
- foreign nationality, and

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- patients followed up before availability of HAART.

In a study in a an urban public clinic, Dalal et al (2008) found that a lower baseline CD4 count and a higher baseline viral load were some of the factors associated with loss to follow-up in a 12 month period of their study. However, they also reported that age, gender and ethnicity were not predictive factors for loss to follow-up, in contrast with other studies (Nacher et al, 2006; Yu et al, 2007) in which age and gender were found to be risk factors to loss to follow-up. Other factors found to be responsible for loss to follow-up included drug toxicity, non-compliance and treatment failure whilst black ethnicity, current smoking, high pill burden and recent viral control were found to be factors predictive of loss to follow-up (Yuang et al, 2006).

## 2.3 SUMMARY OF THE CHAPTER

In summary, the literature suggests that patients with illnesses that carry a social stigma are more willing to seek help form private healthcare providers. The literature review also showed that patients with HIV/AIDS benefit from ARV programmes through increased CD4 counts over time. Baseline characteristics associated with better viral suppression were shown to be older age group, higher CD4 count, lower viral load, WHO clinical staging and adherence. The literature also suggests that social support in any form is associated with improved adherence and therefore better patient outcomes for patients with chronic conditions.

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# CHAPTER THREE

# METHODOLOGY

## 3.1 STUDY DESIGN

The study was a cross-sectional study using retrospective data of patient outcomes in an antiretroviral programme in the setting of a solo private practice. The patients in the study were receiving ARVs as part of the routine management of their HIV/AIDS.

### 3.1.1 Study Population

The study population consisted of records of patients at site 205 of the Aurum Health Research ARV Programme, who had being initiated on ARVs from March 2005 to February 2008.

### 3.1.2 Sampling

The practice was chosen for the study because in the area, it was the site with the biggest number of patients enrolled in the programme. The study sample consisted of the records of all the patients on the ARV programme at Aurum Health Research site 205, who were ARV naïve when initiated on ARVs, between March 2005 and February 2008. Patients who were already on ARVs when they joined the programme were excluded from the study. Another group that was excluded was females who had gone into a short term course of ARVs as part of the Prevention of mother-to-child transmission (PMTC) programme as this group stopped taking ARVs after delivery.

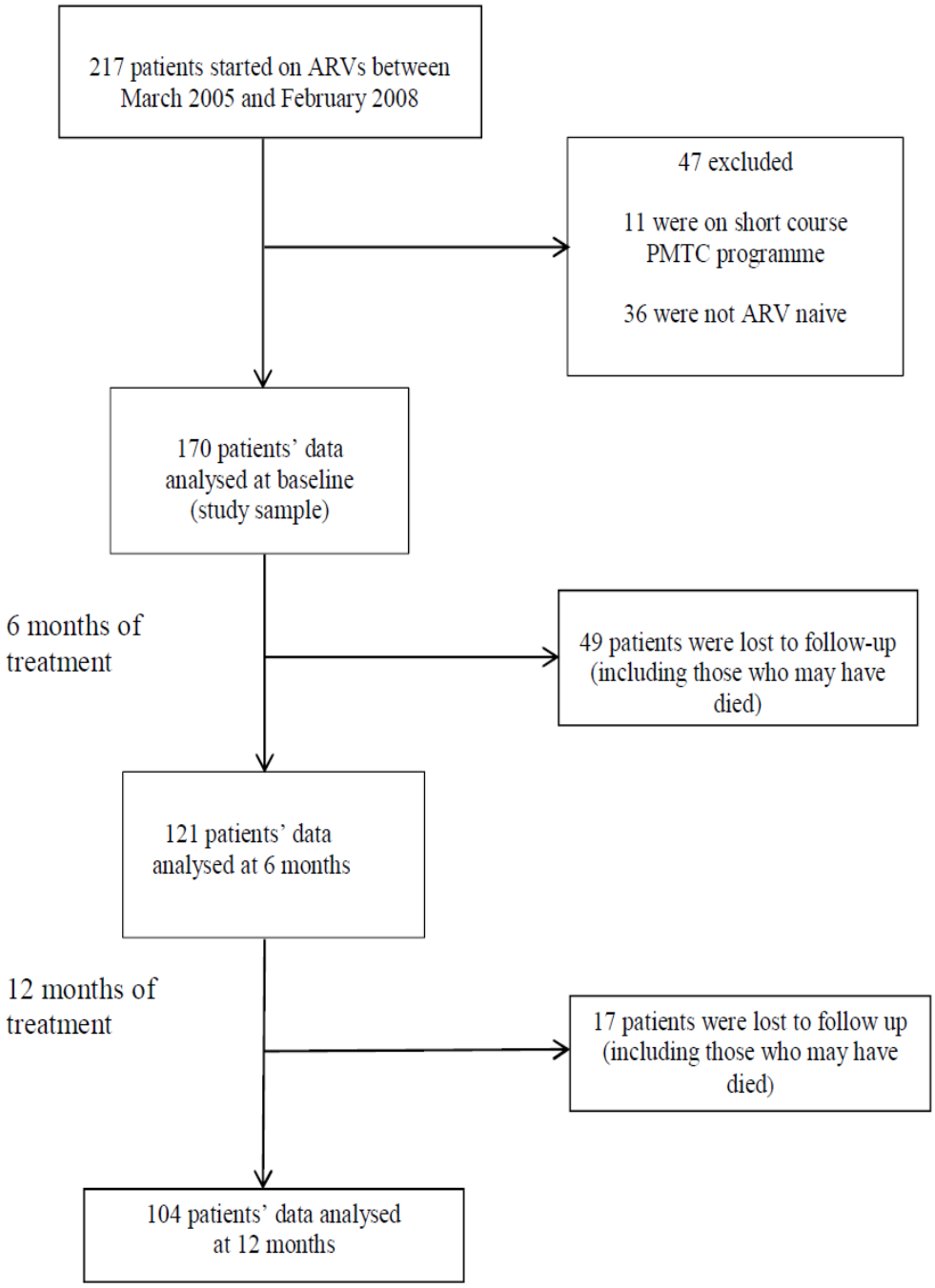



**Figure 3.1 Flow diagram of the study sample.**

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A total of 217 patients had been enrolled on the progamme within the prescribed period. Out of this number, 47 were excluded using the exclusion criteria described above. The final sample consisted of 170 patient records. The sample evolved as shown in Figure 3.1.

### 3.2 SETTING OF THE STUDY

The study was conducted at the rooms of a solo general practitioner in private practice. The researcher was the general practitioner responsible for the day to day running of the practice. The practice was situated in a small rural town in the Limpopo Province and the town borders the North West Province. The town is surrounded by three big mines. The practice is a treatment site for the President's Emergency Programme for Aids Relief (PEPFAR) under the auspices of Aurum Institute. There were two public sector treatment sites in the area, one in each province. The treatment site for the North West province was 80 kilometers away while the treatment site for the Limpopo province was 50 kilometers away. The practice was chosen because in the area, it was the site with the biggest number of patients enrolled in the programme. Enrollment in the ART programme at the solo practice was free and voluntary for any person who had tested positive for HIV and did not have medical insurance. The programme was run by the doctor with the help of a nursing sister employed by Aurum Institute. Patients with CD4 count of <200 and those with WHO clinical stage IV condition or conditions, irrespective of CD4 count, were initiated on ARVs in line with the guidelines of the South African government programme (DOH, 2004). Patients who developed serious side effects were referred to local hospitals for the management of the side-effects and some then chose to continue with their ARV treatment at the referral hospital. Aurum Health Research

through the PEPFAR programme paid for the doctor's consultations, nursing sister's consultations, practice staff administration's time as well as the cost of drugs and their delivery to the site. Patients had to pay for their transport to and from the practice. No community based workers were engaged for this site as no funding was made available for this service. Patients who missed their follow-up dates were contacted by telephone by the nursing sister or the medical doctor to remind them to visit the practice for their follow-up visits. The impact that the additional work of providing ARVs had on the practice was manifested as follows:-

- Increase in patient load for the practice,
- Increased waiting time for patients not on the programme as the medical practitioner had to attend to the patients on the programme in addition to those not in the programme.
- Beneficence for those patients who needed to be on ARVs because for the first two years of the programme, there was no public programme providing ARVs for the area, with the nearest public ARV site being 90km away.

### 3.3 SCOPE OF THE STUDY

The study investigated patient outcomes in an antiretroviral programme in the setting of a solo private practice using the following criteria:-

- CD4 count and viral load at month 6 and 12 after initiating of ARVs
- Loss to follow-up at month 6 and month 12
- To analyse factors associated with good virological outcomes in the patients included in the study

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- To analyse factors associated with loss to follow-up in these patients

## 3.4 DATA COLLECTION

### 3.4.1 Description of data sources

The antiretroviral programme was designed by Aurum Institute and was implemented in selected private practices throughout South Africa. The sites used standard guidelines that were developed for the programme by Aurum Institute. The guidelines provide guidance on all aspects of HIV care, including;-

- provisioning of counseling
- guidelines on antiretroviral therapy
- guidelines on clinical and laboratory monitoring and
- prophylaxis of opportunistic infections
- Training on programme guidelines was provided by Aurum staff before the start of the programme and ongoing refresher training was provided periodically afterwards. Demographic data and initial clinical data were collected at registration by the researcher and the nursing sister working for Aurum Institutes. Follow-up visits were conducted every two weeks for the first three months, and then once a month from month 4 onwards. Clinical data were collected at every subsequent visit.

The data were collected on standardized forms and then transported to the central offices of Aurum Health Research where the data were double-entered onto an Access database (Microsoft Corporation, Seattle, USA). Staff could access the data through a username and a password but could not amend the data.

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Before initiation of therapy, eligible patients had at least 2 clinic visits and also participated in a three-step counseling process to prepare them for taking ARVs. Drugs were supplied through a central pharmacy. The drugs were supplied by means of a courier service and each parcel was labeled for a specific patient. The programme used standardized drug regimens in line with national treatment guidelines, with the first line regimen being stavudine, lamivudine and efavirenz and the second line being abacavir, didanosine and lopinavir-rotinavir. Drug substitutions were made if necessary, for example, nevirapine was substituted for efavirenz in women of child-bearing age and zidovudine was substituted for patients with peripheral neuropathy. Other changes to the drug regimens were made with consultation with the clinical HIV consultants appointed by Aurum Health. All ARV initiations, changes and stops were recorded by the medical practitioner on a form which detailed the regimen and the reason for the changes and the stops.

Blood specimens for measuring CD4 count and viral load (plasma RNA-1 levels) were collected in line with the programme guidelines i.e. at baseline, at 6 weeks, at 6 months and every 6 months afterwards. The blood specimens were then sent to one central laboratory for analysis. CD4 counts were determined using either FACSCOUNT (BD Biosciences, San Jose, California) or FACSCalibur (BD Biosciences, San Jose, California). Viral loads (plasma RNA-1 levels) were measured using the Versant HIV-1 RNA 3.0 assay (bDNA) (Bayer Corporation. Tarrytown, New York, USA). The results

were sent to the central database at Aurum Institute headquarters where they were integrated with the demographic and clinical data.

Patients who missed their scheduled visits were followed up by means of telephone calls to remind them to come to the practice for their medication and follow-up visits. Patients who did not present themselves to the clinic for a period of more than 2 months were regarded as lost to follow-up.

### 3.4.2 Data extraction for the study

Appendix 1 shows all the data that were collected for the programme. For the purpose of this study, only the following data were accessed and analysed:-

- Demographic data (Age, gender)
- Number of patients still on the programme at 6 months and 12 months after initiation of ARVs
- Number of patients who were lost to follow-up at 6 months and 12 months after initiation of ARVs. The number of patients lost to follow-up included those who may have died. There was no method of verifying the number of deaths.
- WHO clinical staging at initiation of therapy
- CD4 count at initiation of ARVs, at 6 weeks, 6 months and at 12 months after initiation of ARVs
- Viral load at initiation of ARVs, at 6 weeks, 6 months and at 12 months after initiation of ARVs.

The data were accessed by the researcher from the central database and cleaned. Where gaps occurred, the researcher had to go to patient files to fill the gaps and complete the

data set. For patients who had missed their scheduled visits at month 6 and/or 12, the CD4 count and viral load measurements closest to those months were classified as being responses to treatment at month 6 and/or 12. Closest was defined as not more than 2 months from the scheduled visit. Although other studies had identified other factors (such as haemoglobin level, regimen changes and co-infection with TB) associated with the outcomes of this study, data for these factors were not available for this study.

### 3.5 PILOTING

No piloting was done for the study as secondary data was used for this study.

### 3.6 DATA ANALYSIS

Data was captured using Microsoft Access. It was then coded and exported to STATA v.9 (Stata Corporation, College Station, Texas, USA) software. The median was used to describe the central tendency of CD4 count at 6 weeks, 6 months and 12 months. The median was also used to categorise age into two age groups for comparison (≤ 35years and □35 years). Interquartile range to determine the spread of variables was used for analysis of baseline characteristics age and CD4 count. It was also used for was used for analysis of change in CD4 count at 6 weeks, 6 months and 12 months. Proportions were used to determine the percentage with good immunological outcomes at month 6 and month 12, Proportions were also used to determine the percentage with good virological outcomes at month 6 and month 12 and the percentage lost to follow-up at month 6 and month 12. Good virological outcome was defined as having achieved viral suppression which was defined as a viral load of <50 copies/ml. Patients who missed their scheduled

visits were followed up by means of telephone calls to remind them to come to the practice for their medication and follow-up visits. Patients who did not present themselves to the clinic for a period of more than 2 months were regarded as lost to follow-up.

Univariate analysis was done to determine the association between baseline variables and having viral suppression and loss to follow-up at months 6 and 12. Chi Square at 95% confidence interval was used to test for association between baseline variables and patient outcomes in univariate analysis. The variables that were analysed to evaluate factors associated with virological response and with loss to follow-up were gender, age, WHO staging, baseline CD4 count and baseline viral load.

## 3.7 ETHICAL CONSIDERATION

### 3.7.1 Ethics committee approval

The research project was approved by the University of the Witwatersrand's Committee for Research on Human Subjects (Medical) and the postgraduate committee. Approval was obtained from Aurum Institute for the project.

### 3.7.2 Informed consent

At registration, a translator explained to the how the project worked and the patient chose whether to be part of the programme or not. As part of the registration procedure, the patient was then asked to sign a document giving authority for his/her information and data collected during his/her participation in the programme to be used for research purposes.

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### 3.7.3 Confidentiality

The data was presented in such a way that the identities of the research subjects were not revealed in any way.

### 3.7.4 Dignity

The data collection was done in a way that respects the dignity of the research subjects and with as little pain and suffering as possible.

### 3.7.5 Beneficence

The data collected was being used primarily to monitor the response of the participants to treatment and to optimize their disease management. No harm was inflicted to the participants and they benefited from the data collected in terms of the management of their condition.

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# CHAPTER FOUR

# RESULTS

## 4.1 BASELINE CHARACTERISTICS OF THE STUDY POPULATION

**Table 4.1 Baseline characteristics of study populations that were enrolled in the programme at months 0, 6 and 12**

| | Baseline | 6/12 | 12/12 |
|---|---|---|---|
| **Characteristic** | **n = 170** | **n = 121** | **n = 104** |
| Gender, n (%) | | | |
| F | 101 (59) | 47 (39) | 37 (36) |
| M | 69 (41) | 74 (61) | 65 (64) |
| Age in years, median (IQR) | 35 (30-41) | 35 (30-41) | 34 (30-39) |
| Age categories, n (%) | | | |
| ≤ 35 years | 82 (48) | 58 (48) | 54 (52) |
| > 35 years | 88 (52) | 63 (52) | 50 (48) |
| WHO clinical staging, n (%) at initiation of treatment | | | |
| 1 | 41 (24) | 35 (29) | 32 (31) |
| 2 | 35 (21) | 22 (18) | 17 (16) |
| 3 | 61 (36) | 44 (36) | 38 (37) |
| 4 | 33 (19) | 20 (17) | 17 (16) |
| CD4 count in cells/µl, median (IQR) | 99 (49-166) | 242 (167-340) | 265 (197-418) |
| CD4 categories in cells/µl, n (%) | | | |
| <50 | 47 (28) | 32 (26) | 27 (26) |
| 51 – 150 | 69 (40) | 48 (40) | 43 (41) |
| >150 | 54 (32) | 41 (34) | 34 (33) |
| Viral load categories in copies/ml, n (%) | | | |
| <10000 | 19 (11) | 16 (13) | 13 (13) |
| 10000 – 100000 | 75 (44) | 55 (46) | 48 (46) |
| >100000 | 76 (45) | 50 (41) | 43 (41) |

The baseline characteristics of the study population at baseline, 6 months and 12 months are shown in Table 4.1. Table 4.1 shows that in terms of baseline characteristics, there

was very little difference between the group at initiation of treatment, the groups that remained at 6 months and 12 months after initiation of treatment.

## 4.2 IMMUNOLOGICAL OUTCOMES

Table 4.2 shows the change in median CD4 count at 6 weeks, 6 months and 12 months.

**Table 4.2 Change in median CD4 count at 6 weeks, 6 months and 12 months**

| | Total number of patients | Median CD4 count (cells/µl) | IQR | Average monthly increase in CD4 count (cells/µl) |
|---|---|---|---|---|
| Baseline | 170 | 99 | 49 – 166 | |
| 6 weeks | 130 | 210 | 117 – 313 | 140 |
| 6 months | 121 | 242 | 167 – 340 | 40 |
| 12 months | 104 | 265 | 197 - 418 | 22 |

The trend observed in Figure 4.2 is that the average monthly CD4 count increased rapidly after initiation of treatment but the increase decreased with progression of time.

## 4.3 VIROLOGICAL OUTCOMES

Table 4.3 shows that the proportion of patient with viral suppression was 39%, 75% and 71% at 6 weeks, 6 months and 12 months respectively.

**Table 4.3 Proportion of subjects with viral suppression at baseline, 6 weeks, 6 months and 12 months (<50 copies/ml)**

| | Total number of patients | Number of patients with viral suppression | % of patients with viral suppression |
|---|---|---|---|
| Baseline | 170 | 3 | 0.02 |
| 6 weeks | 130 | 51 | 39 |
| 6 months | 121 | 91 | 75 |
| 12 months | 104 | 74 | 71 |

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## 4.4 LOSS TO FOLLOW-UP AND PATIENT RETENTION

Table 4.4 shows that 29% and 38% of the patients had been lost to follow-up at 6 months and 12 months respectively.

**Table 4.4 Retention and loss to follow-up (including those who may have died) at months 6 and 12**

| | Retained n (%) | LTFU n (%) | TOTAL n (%) |
|---|---|---|---|
| 6 months | 121 (71) | 49 (29) | 170 (100) |
| 12 months | 104 (61) | 66 (39) | 170 (100) |

## 4.5 FACTORS ASSOCIATED WITH VIRAL SUPPRESSION AND LOSS TO FOLLOW-UP AT MONTHS 6 AND 12

Univariate analysis was done to determine the association between baseline variables and having viral suppression and patient retention at months 6 and 12.

### 4.5.1 Association between baseline variables and viral suppression at months 6 and 12

Table 4.5 shows the association between baseline variables and having viral suppression at 6 and 12 months. Generally, the table shows that there was no significant association between the baseline variables being investigated and having viral suppression either at months 6 and or at month 12.

**Table 4.5 Association between baseline variables and viral suppression at 6 and 12 months**

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| | Patients having viral suppression | | p-value | |
|---|---|---|---|---|
| | 6 months n (%) | 12 months n (%) | 6 months | 12 months |
| Gender | | | | |
| M | 37 (79) | 30 (81) | | |
| F | 54 (73) | 44 (68) | p = 0.475 | p = 0.145 |
| Age groups | | | | |
| ≤ 35 yrs | 42 (72) | 34 (65) | | |
| > 35 yrs | 49 (78 | 40 (80) | p = 0.495 | p = 0.098 |
| WHO Staging | | | | |
| 1 | 27 (77) | 24 (75) | | |
| 2 | 17 (77) | 11 (69) | | |
| 3 | 37 (84) | 28 (76) | | |
| 4 (condition most advanced) | 10 (50) | 11 (65) | p = 0.032 | p = 0.821 |
| Baseline CD4 (cells/µl) | | | | |
| <50 | 20 (63) | 17 (63) | | |
| 50 – 100 | 20 (77) | 16 (67) | | |
| 101 – 150 | 20 (91) | 17 (89) | | |
| >150 | 31 (75) | 26 (76) | p = 0.126 | p = 0.195 |
| Baseline VL (copies/ml) | | | | |
| <10000 | 14 (88) | 11 (85) | | |
| 10000 - 100000 | 43 (78) | 33 (72) | | |
| >100000 | 34 (68) | 30 (70) | p = 0.229 | p = 0.568 |

The pattern shows that a greater proportion of males (79%) had achieved viral suppression at 6 months as compared to females (73%). The same pattern is observed at

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12 months with 81% of males having achieved viral suppression as compared to 68% of females.

Looking at the association between age and having viral suppression, the pattern shows that the group of >35 years had achieved a greater rate of viral suppression (78% and 80% at 6 months and 12 months respectively) as compared to age group 35 years and less.

The pattern for the association between WHO clinical staging and having achieved viral suppression at 6 and 12 months shows that patients with a highest baseline WHO clinical staging (stage 4) had a poor viral suppression than those with a lower WHO clinical staging. However, the patients in the WHO clinical stage 3 had better viral suppression rates than those in WHO clinical stages 1 and 2 at months 6 and 12 respectively. There was no significant statistical association between WHO staging and viral suppression at 6 months ($p = 0.032$) and at 12 months ($p = 0.821$).

Looking at the association between baseline CD4 count and viral suppression, the pattern shows that those patients with a higher baseline CD4 count had better viral suppression at months 6 and 12 than those with a lower baseline CD4 count. The group with baseline CD4 count of 101 – 150 cells/µl had better viral suppression rates as compared to the other groups. There was no significant statistical association between baseline CD4 count and viral suppression at 6 months ($p = 0.126$) and at 12 months ($p = 0.195$).

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The pattern for association between baseline viral load and viral suppression at 6 and 12 months shows that those patients with a lower baseline viral load had better viral suppression rates at 6 and 12 months than those patients with a higher baseline viral load. There was no significant statistical association between baseline viral load and viral suppression at 6 months ($p = 0.229$) and at 12 months ($p = 0.568$).

### 4.5.2 Association between baseline variables and loss to follow-up at months 6 and 12 months

Table 4.6 shows the association between baseline variables and LTFU at 6 and 12 months.

For gender, the pattern shows that males were lost to follow-up than females at both months 6 and month 12. There was no significant statistical association between gender and loss to follow-up at 6 months ($p = 0.466$) and 12 months ($p = 0.095$).

For age group, there was no particular pattern shown with age group ≤ 35years being more lost to follow-up at 6 months while age group > 35 years were more lost to follow-up at month 12 as compared to age group ≤ 35 years. There was no significant statistical association between age group and loss to follow-up at 6 months ($p = 0.902$) and at 12 months ($p = 0.220$).

For WHO staging there was no particular trend shown. The group that was more likely to be lost to follow-up at month 6 and month 12 was WHO stage 4. There was no significant statistical association between WHO staging and being lost to follow-up at 6 months ($p = 0.071$) and at 12 months ($p = 0.095$).

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**Table 4.6 Association between baseline variables and LTFU at months 6 and 12**

| | Patients LTFU | | p-value | |
|---|---|---|---|---|
| | 6 months n (%) | 12 months n (%) | 6 months | 12 months |
| Gender | | | | |
| M | 22 (32) | 32 (46) | | |
| F | 27 (27) | 34 (34) | p = 0.466 | p = 0.095 |
| Age groups | | | | |
| ≤ 35 yrs | 24 (29) | 27 (33) | | |
| > 35 yrs | 25 (28) | 37 (42) | p = 0.902 | p = 0.220 |
| WHO Staging | | | | |
| 1 | 6 (15) | 9 (22) | | |
| 2 | 13 (37) | 17 (49) | | |
| 3 | 17 (28) | 22 (36) | | |
| 4 (condition most advanced) | 13 (29) | 16 (48) | p = 0.071 | p = 0.050 |
| Baseline CD4 (cells/µl) | | | | |
| <50 | 15 (32) | 20 (43) | | |
| 50 – 100 | 13 (33) | 14 (36) | | |
| 101 – 150 | 17 (27) | 11 (37) | | |
| >150 | 13 (24) | 19 (35) | p = 0.737 | p = 0.877 |
| Baseline VL (copies/ml) | | | | |
| <10000 | 3 (16) | 5 (26) | | |
| 10000 - 100000 | 75 (27) | 26 (35) | | |
| >100000 | 76 (34) | 33 (43) | p = 0.071 | p = 0.301 |

For baseline CD4 count, the group that was more likely to be lost to follow-up at month 6 and month 12 was the group with baseline CD4 count <50 cells/µl. There was no significant statistical association between baseline CD4 count and loss to follow-up at 6 months (p = 0.737) and at 12 months (p = 0.877).

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For baseline viral load, the group trend was that the higher the viral load, the more likelihood of being lost to follow-up at 6 months and 12 months. There was no significant statistical association between baseline viral load and loss to follow-up at 6 months ($p = 0.071$) and at 12 months ($p = 0.301$).

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# CHAPTER FIVE

# DISCUSSION

## 5.1 INTRODUCTION

The study looked at patient outcomes in an antiretroviral programme in the setting of a solo private general practice. This was in the background of a need to scale-up access to care and treatment for patients with HIV/AIDS. The study found out that GPs in private practice have the potential to achieve patient outcomes comparable with patient outcomes in public sector settings.

## 5.2 IMMUNOLOGICAL CHANGES

The studies examined in the literature review (Table 2.1) showed that the monthly increase in CD4 count (mean/median) for those studies reporting in a 6 month period was ranged from 13 cells/µl to 43 cells/µl whilst the monthly increase for those reporting in a 12 month period ranged from 13 cells/µl to 16 cells/µl. In this study, a monthly median increase in CD4 count as compared to baseline CD4 count was found to be 24 cells/µl and 14 cells/µl at 6 months and 12 months respectively. The results of this study are comparable with results of other studies done in different settings.

## 5.3 VIROLOGICAL CHANGES

The results of this study showed viral suppression of 75% and 73% at 6 months and 12 months respectively. In their study, Charalambous et al (2004) used the same viral load

cut-off as this study and reported levels of viral suppression of 63% at both 6 months and 12 months. In their Khayelitsha study, Coetzee et al (2004) reported levels of viral suppression of 89% and 84% at month 6 and month 12 respectively. The results of this study were similar to the USA study by Moore et al (2005) which showed that for those patients in their study who started HAART in the years 1999 – 2000, the proportion of patients who achieved viral suppression was 74.7% at 6 months and 83.3% at 12 months, whilst the level of viral suppression for those who started HAART in the years 2001 – 2002 was 74.3% at 6 months and 78.1% at 12 months. Central to viral suppression is the issue of adherence. This study did not address the issue of adherence and hence there isn't enough evidence to determine the reason for the difference in the level of viral suppression for the period under investigation. Although there is this difference, the results are encouraging and indicate that in the setting of a solo GP in a private setting, levels of viral suppression comparable to other settings can potentially be achieved. Achieving acceptable levels of viral suppression would however depend on addressing issues around adherence and loss to follow-up.

### 5.3.1 ASSOSIATION BETWEEN BASELINE VARIABLES AND VIRAL SUPPRESSION

Univariate analysis of the study showed that at 6 months 79% of males had achieved viral suppression as compared to 73% of females. At 12 months 81% of males had achieved viral suppression as compared to 68% of females. Although Tuboi et al (2005) had found in their study that males were least likely to achieve viral suppression, other studies have shown that the trend was that males were more likely to achieve viral suppression throughout the various periods under study (Rastegar et al, 2003). The results of the

current study show that the trend is that more males seem to achieve viral suppression than females. However, statistical tests show that the association between gender and viral suppression at 6 months and 12 months was not statistically significant.

Age is one of the baseline characteristics that has been shown to have an association with viral suppression at both 6 months and 12 months. An older age group has been reported to be more likely to achieve viral suppression as compared to a younger age group (Rastegar et al, 2003; Knobel et al, 2005; Bosch et al, 2007). This finding was corroborated by Tuboi et al (2005) who in their study observed that the younger age group was least likely to achieve viral suppression at 6 months as compared to the older age groups. The results of this study show that at 6 months and 12 months, the age group >35 years had achieved the rate of viral suppression 78 and 80% respectively. These figures are higher than those for age group ≤35 years. These findings are in line with findings of studies in different settings from that of a solo GP in private practice.

WHO clinical staging has been found to be associated to achieving viral suppression at 12 months by Fielding et al (2008), who observed in their study that patients with a more advanced WHO clinical stage (stage 3 and 4) were less likely to achieve viral suppression at 12 months as compared to those patients with WHO clinical stages 1 and 2. In this study, the rate of viral suppression for WHO clinical stages 1, 2 and 3 for both months and 12 are within proximity to each other as compared to the rates for WHO clinical stage 4. At month 6, the rate of viral suppression for WHO clinical stages 1, 2 and 3 was far better as compared to the rate of viral suppression of 50% for WHO clinical stage 4. At month 12, the rate of viral suppression for WHO clinical stages 1, 2 and 3 was also

better as compared to the rate of viral suppression of 65% for WHO clinical stage 4. Although univariate analysis shows that there is no statistically significant relationship between baseline WHO clinical staging and achieving viral suppression, the pattern shown by the results of the study is comparable with the results reported in the literature, even though the literature is restricted to only one study findings.

One of the variables described to have an association with viral suppression at various periods after initiation of HAART is the baseline CD4 count. In this study, the trend for both month 6 and month 12 was that those patients with a lower baseline CD4 count were least likely to achieve viral suppression. The studies reviewed in the literature review all seem to show that a higher baseline CD4 is associated with an increased likelihood of achieving viral suppression at various periods of observation in the various studies (Rastegar et al, 2003; Knobel et al, 2005; Bosch et al, 2007). Although univariate analysis of this study shows that there is no statistically significant relationship between baseline CD4 count and achieving viral suppression, the pattern shown by the results of the study is comparable with the results reported in the literature.

Baseline viral load was also shown to have an impact on viral suppression. According to Tubai et al (2005), patients with a higher baseline viral load were least likely to achieve viral suppression at 6 months after initiation of HAART. This finding was similar to the findings by other studies whose results showed that patients with a lower baseline viral load were most likely to achieve viral suppression during the various periods of observation (Rastegar et al, 2003; Knobel et al, 2005; Bosch et al, 2007). Univariate analysis of the current study shows that there is no statistically significant relationship

between baseline CD4 count and achieving viral suppression, but the pattern shown by the results of the study is comparable with the results reported in the literature.

### 5.4 LOSS TO FOLLOW-UP

In this study, the rate of loss to follow-up was 29% at 6 months and 38% at 12 months. Different studies have shown varying rates ranging from very low to very high rates of loss to follow-up. At the lower end of the spectrum Bussman et al (2009) found a loss to follow-up rate of 2.4% at month 12 and Hofmeyr et al (2009) reported a rate of loss to follow-up of 3% at 18 months. This is in contrast with Maru et al (2007) who reported a loss to follow-up rate of 59% at 12 months and Karcher et al (2007) who reported a loss to follow-up rate of 12% at 12 months. The loss to follow-up rates in this study was higher than studies in the literature review conducted in the public sector setting, but better than the study conducted by Maru et al (2007) in the private sector setting. It is also worth noting that all the studies reviewed in the literature had included deaths in their reports, except for the study by Hofmeyer et al (2009). In a systematic review, Rosen at al (2007) found out that the rate of loss to follow-up in both the best case and worst case scenarios was the same at 20% at 6 months whereas at 12 months, the rate of loss to follow-up in the worst case scenario was 43% and 24% for the best case scenario. The rates of loss to follow-up in this study are generally higher than those in the literature reviewed and there is a need to find out the reasons for these high rates of loss to follow-up.

In the studies reviewed in the literature, studies with a low rate of loss to follow-up had used community healthcare givers and/or social support groups for follow-up and

adherence support, except for the study by Bussman et al (2009) which did not have the use of community healthcare workers or social support groups. The community in which the practice is situated is a mining town and there is a lot of migrancy as workers migrate from one job to another, either voluntarily looking for better opportunities or forced to migrate at the instruction of the employer. The patients who migrate without informing the practice are recorded as lost to follow-up and this also contributed to the high rate of loss to follow-up.

### 5.4.1 ASSOCIATION BETWEEN BASELINE VARIABLES AND LOSS TO FOLLOW-UP

Univariate analysis of the study showed that at 6 months 32% of males had been lost to follow-up as compared to 27% of females. The same trend was seen at 12 months where 46% of males and 32% of females were lost to follow-up. Although in their study Dalal et al (2008) had found that gender was not a risk factor for loss to follow-up, the findings of another study found gender to be a risk factor for loss to follow-up (Yu et al, 2007). The pattern in the current study showed that males were more at risk to be lost to follow-up compared to females.

On examining age as a risk factor to loss to follow-up, the study found that at month 6, the rate of loss to follow-up was comparable between age groups $\leq 35$ years and $> 35$ years. However at month 12, the rate of loss of the older age group is more than that for the younger age group. A younger age has been identified as a risk factor for loss to follow-up Maru et al (2007) and the findings of this study does not compare with studies reviewed in the literature.

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WHO clinical staging is a risk factor for loss to follow-up, with patients who are in stage 3 and stage 4 being more likely to be lost to follow-up than those in stage 1 and 2 (Yu et al, 2007). In this study the highest rate of loss at to follow-up at 6 months was seen in those patients with clinical stage 4 with rates of 40% while stage 2 had the highest rate (49%) at month 12. The findings of this study do not compare with studies reviewed in the literature.

Baseline CD4 count has been identified as a risk factor for loss to follow-up. Studies reviewed in the literature found that patients with a lower baseline CD4 count were more at risk of loss to follow-up compared with those patients with a higher baseline CD4 count ( Maru et al, 2007; Dalal et al, 2008). In this study the trend was that patients with lower baseline CD4 count were more at risk for loss to follow-up. At both 6 months and 12 months, the general trend in this study was that patients with lower baseline CD4 count were more likely to be lost to follow-up than those patients with a higher baseline CD4 count. The results of this study are comparable with those in the literature reviewed.

Baseline viral load is one of the characteristics described to have an association with rates of loss to follow-up. According to Dalal et al (2008), there was an association between a higher baseline viral load and loss to follow-up at 12 months. In this study the trend was also that a higher baseline viral load was a risk factor to loss to follow-up at both month 6 and months 12. The results of this study are comparable with those in the literature reviewed. Another factor that contributed to the loss of follow-up was that patients who

developed side-effects were referred to local hospitals for the management of the side-effects and then chose to continue with their ARV treatment at the referral hospital.

One of the measures instituted to reduce loss to follow-up was to call those patients who had missed their appointments and remind them to come and fetch their medication. This helped as those who were found did come to fetch their medication and opened up channels of communication where they were more confident to call the practice for requesting an alternative appointment date if they were going to miss their appointments. However, a significant number was still lost to follow up as they did not have fixed line telephones and thus relied on prepaid cellphone numbers. These cellphone numbers proved to be unreliable as people changed them frequently without updating their information on our records.

### 5.5 INVOLVING GPs IN ARV PROGRAMMES

As pointed out in the literature review, there seems to be advantages in the engagement of GPs as sites for ARV treatment because of easy geographic accessibility, shorter waiting periods, longer and more flexible working hours, greater availability of staff and drugs, greater confidentiality when dealing with diseases which carry social stigma, perceptions that private sector providers are more considerate and sensitive to client concerns and perceptions that private sector services are technically superior to public sectors services (Smith et al, 2001; Chabikuli et al, 2004). The study shows that GPs in private practice have the potential to produce reasonable patient outcomes for an ARV programme. However, the study also highlights the limitations of inadequate viral suppression which hinges heavily on issues around adherence. In addition, the high loss to follow-up rate

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suggests that active measures need to be put in place to minimize the loss to follow-up. Both limitations can be reasonably addressed by the engagement of community health care workers. Community health care workers in the South African health care system have been trained to conduct home visits to promote voluntary HIV testing and act as DOTS (directly observed treatment, short course) supporters for patients on TB (tuberculosis) treatment (Schneider et al, 2008). Although this seems to be a viable option, there are concerns of confidentiality as the community health worker is a lay person without any affiliation to any professional body. As a result, the majority of ambulant patients have not shown an interest in their services. Even families with resources and the capacity to care for their terminally ill have not been keen on the services of the community health workers. Despite the above, community health workers provide an essential service to the destitute, the terminally ill with no family support, child headed families and anybody who values their intervention. A beneficial approach would be to provide the service of CHWs in the practice and identify patients who would prefer to have home visits so that they can benefit from the service. The rights of patients to decline or accept this intervention would have to be respected at all times. In addition, the migrant employees should be extensively counseled to understand that in the case where they relocate, they can be properly referred to a treatment site at their new location and should thus come to report their intended move so as to get a referral letter. If the intended relocation is reported timeously to the practice, arrangements could be made to provide the patient with a 3 months' supply of treatment to prevent a break in the treatment as arrangements for treatment are being finalized at the new treatment site. In this way, the rate of loss to follow-up will improve and continuity of care ensured.

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## 5.6 LIMITATIONS OF THE STUDY

The following limitations were experienced during the conduction of this study:-

### 5.6.1 Data collected

Data used for the study was routinely collected data and was not collected specifically for the purpose of this study and thus resulted in limited variables.

### 5.6.2 Data analysed for the study

Other studies have shown that the following baseline variables may be associated with the patient outcomes being interrogated in this study but these were not part of the current study because the data for these variables were not available in the database.

- adherence monitoring
- body weight
- body mass index
- haemoglobin level
- initial regimen
- regimen changes during the study period
- infection with TB
- presence of opportunistic infections
- deaths during the study period

The above variables have been shown by other studies to have significant association with patient outcomes for patients on ARV programmes. For example, adherence is key to viral suppression and increase in the CD4 count and thus improved patient outcomes. It is also important in determining whether the patient is having treatment failure or is not

improving because of non-adherence. Factors such as initial body weight, haemoglobin level, co-infection with TB and other opportunistic infections, initial regimen and regimen changes during the treatment period have all been shown by other studies to have a negative effect on patient outcomes in ARV programmes. Having the above data might have given an understanding on whether these variables had had an influence on the patient outcomes in this study. Data on deaths would have helped to differentiate between loss to follow-up due to deaths and loss to follow-up due to other reasons.

### 5.7 Generalizability of study findings

Findings of the study apply to site 205 of the Aurum Institute for Health Research ARV Programme but may be similar to other solo GP programmes in the Aurum Health Research ARV programme. The findings of the study are important as they will add to understanding of what the outcomes of private general practitioners could be in a public-private partnership.

In conclusion, generally, except for the higher rate of loss to follow-up, the findings of this study are comparable with finding of other studies done in different setting to the one of a solo general practitioner in private practice.

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# CHAPTER SIX

# CONCLUSIONS AND RECOMMENDATIONS

## 6.1 CONCLUSIONS

According to the study, the increase in median CD4 count at month 6 and month 12 was comparable with median increases in CD4 count at similar periods in other studies. This finding is important as it adds knowledge as to the potential performance that can be achieved by an ARV programme in the setting of a solo private general practitioner.

Although the rate of viral suppression at both month 6 and month 12 was lower than the rates achieved in other studies, the finding is important and indicate that the reasons behind this lower rate of suppression must be explored.

The study concludes that the male gender, the older age group, a higher baseline WHO clinical staging, a lower baseline CD4 count and a higher baseline viral load are risk factors for poor immunological outcomes, poor virological outcomes and loss to follow-up.

With the exception to the higher rate of loss to follow-up, the findings of this study are generally comparable with findings of studies done in settings different from that of a solo GP in private practice.

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The findings of the study suggest that there is merit in engaging private practitioners as part of a comprehensive strategy to combat HIV/AIDS in a public-private partnership. The model that is envisaged would be the provision of HIV/AIDS care and treatment to patients with no medical insurance at no cost to the patient. The programme would have to be funded by the state or another agency and the GPs should be willing to give discounted rates for their services, as this has been shown to be possible with the previous GP models such as the one that was run by Aurum Health.

The finding of the study will be forwarded to Aurum Institute and the Department of Health, Limpopo Province.

## 6.2 RECOMMENDATIONS

The recommendations below were based on the analysis and findings of the study. Suggestions on future research topics have also been made.

### 6.2.1 Further research

Since there are other similar GP sites in the programme, it would be desirable to undertake the same study combining the data from more GP sites to establish as to whether there will be statistically significant associations between the baseline variables and the patient outcomes.

### 6.2.2 Strategies to reduce LTFU

The loss to follow-up was higher than in other studies. There is a need to find out why there was such a difference so that the problems can be attended to and thus reduce the

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rate of loss to follow-up. Another problem identified as a contributing factor to a higher rate of loss to follow-up was inadequate patient tracing methods. It is recommended that practices running a programme of this nature should use the services of community healthcare workers because their intervention in tracing patients both telephonically and physically can greatly reduce the rate of loss to follow-up in the programme. Other less resource-intensive ways such as using cellphone message reminders can also help in ensuring the reduction of the rate of loss to follow-up. Migrant workers should be extensively counselled so that they understand that in the case where they have to relocate, they should report to the site so that they can be referred to another treatment site in their new location. This will help in addressing the high rate of loss to follow-up.

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# APPENDIX A – ETHICS COMMITTEE APPROVAL

**UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG**

Division of the Deputy Registrar (Research)

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**
R14/49 Ntshabele

| | |
|---|---|
| **CLEARANCE CERTIFICATE** | **PROTOCOL NUMBER M081148** |
| **PROJECT** | Patient Outcomes in an Antiretroviral Programme in the Setting of a Solo Private General Practice |
| **INVESTIGATORS** | Dr GM Ntshabele |
| **DEPARTMENT** | School of Public Health |
| **DATE CONSIDERED** | 08.11.28 |
| **DECISION OF THE COMMITTEE*** | Approved unconditionally |

**Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.**

**DATE** 08.11.26 **CHAIRPERSON** .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : B Ngoma

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**DECLARATION OF INVESTIGATOR(S)**

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

.....

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## APPENDIX B – LETTER OF PERMISSION FROM AURUM INSTITUTE

AURUM INSTITUTE

Association Incorporated under S21
Registration No. 1998/009355/08
041-083-NPO

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Website: www.auruminstitute.org

Ethics Committee
University of the Witwatersrand

31 October 2008

To whom this may concern

**RE: Letter of permission to use data collected at Dr Ntshabele's site**

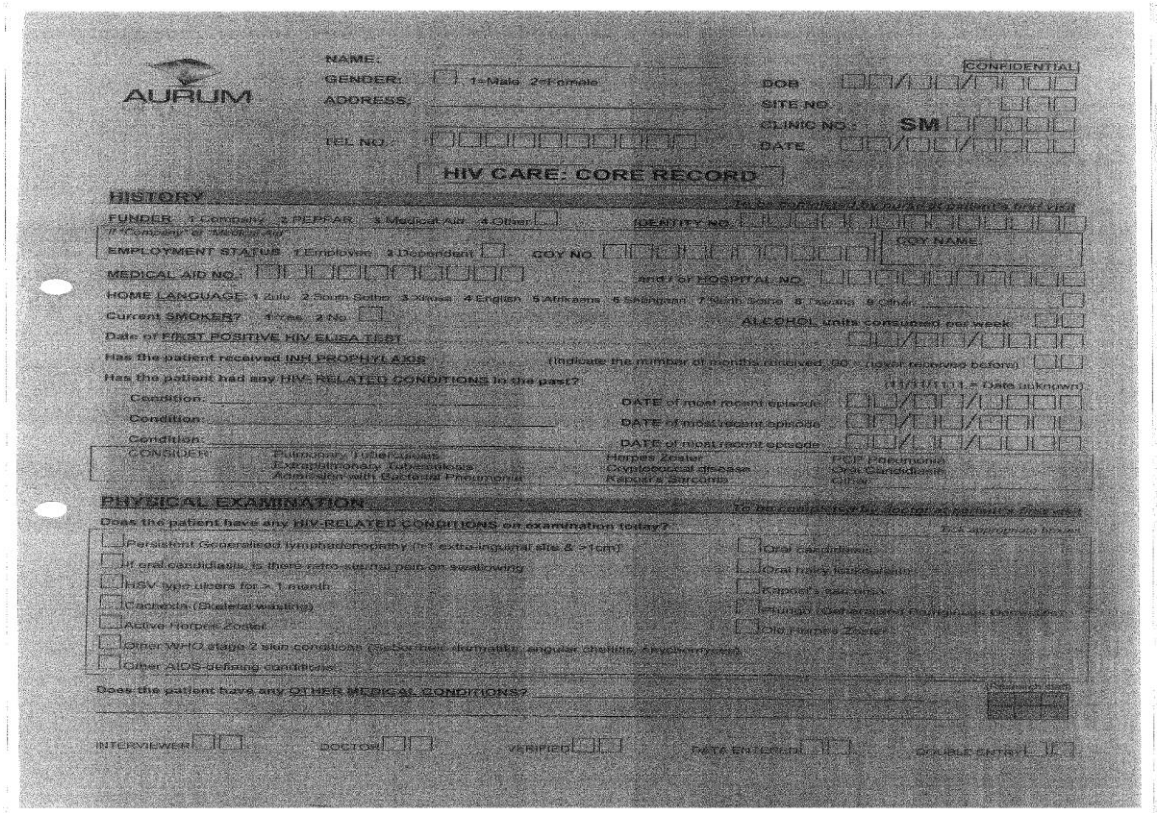
The aim of the study is to evaluate the outcomes for patients on an ARV programme in a solo private general practice with the view of presenting the model as part of a comprehensive strategy to fight the HIV/AIDS epidemic. The study will use the secondary data collected by Aurum Institute for Health Research at Site 205 from March 2005 until February 2008.

It is my pleasure to give permission on behalf of Aurum for the study to be done.

**Salome Charalambous**
**Interim PEPFAR Programme Manager**

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## APPENDIX C – DATA COLLECTION TOOLS



AURUM

NAME:
GENDER: 1=Male 2=Female
ADDRESS:
TEL NO:

CONFIDENTIAL
DOB
SITE NO:
CLINIC NO.: SM
DATE

HIV CARE: CORE RECORD

HISTORY

FUNDER: 1 Company 2 PEPFAR 3 Medical Aid 4 Other
IDENTITY NO:
EMPLOYMENT STATUS: 1 Employee 3 Dependent
GOV NO:
GOV NAME:
MEDICAL AID NO.:
and / or HOSPITAL NO.:
HOME LANGUAGE: 1 Zulu 2 South Sotho 3 Xhosa 4 English 5 Afrikaans 6 Shangaan 7 North Sotho 8 Tswana 9 Other
Current SMOKER? 1=Yes 2=No
ALCOHOL units consumed per week:
Date of FIRST POSITIVE HIV ELISA TEST:
Has the patient received INH PROPHYLAXIS (indicate the number of months received, 99 = never received before)
Has the patient had any HIV- RELATED CONDITIONS in the past? (11/11/1111 = Date unknown)
Condition:
DATE of most recent episode:
Condition:
DATE of most recent episode:
Condition:
DATE of most recent episode:
CONSIDER: Pulmonary Tuberculosis, Extrapulmonary Tuberculosis, Admission with Cotrimoxazole Pneumonia, Herpes Zoster, Cryptococcal disease, Kaposi's Sarcoma, PCP Pneumonia, Oral Candidiasis, Other

PHYSICAL EXAMINATION

Does the patient have any HIV-RELATED CONDITIONS on examination today?
Persistent Generalised lymphadenopathy (>1 extra-inguinal site & >1cm)
If oral candidiasis, is there retro-sternal pain on swallowing
HSV type ulcers for > 1 month
Cachexia (Skeletal wasting)
Active Herpes Zoster
Other WHO stage 2 skin conditions (Seborrheic dermatitis, angular cheilitis, Papulopruritic)
Other AIDS-defining conditions:
Oral candidiasis
Oral hairy leukoplakia
Kaposi's Sarcoma
Thrush (Oesophageal/Pulmonary Candidiasis)
Old Herpes Zoster
Does the patient have any OTHER MEDICAL CONDITIONS?

INTERVIEWER: DOCTOR: VERIFIED: DATA ENTERED: SCANNED ENTRY:

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AURUM INSTITUTE

NAME: _____ CLINIC NO.: SM/WC ☐☐☐☐☐

CELL NO.: ☐☐☐☐☐☐☐☐☐☐ DATE: ☐☐/☐☐/☐☐☐☐

## HIV CARE: VISIT FORM

### HISTORY

*To be completed by nurse*

Has there been any of the following SINCE THE LAST VISIT? Date (11/11/1111 = Date unknown)

Hospitalisation ..... 1 Yes 2 No ☐ ..... ☐☐/☐☐/☐☐☐☐

TB diagnosed ..... 1 Yes 2 No ☐ ..... ☐☐/☐☐/☐☐☐☐

If TB diagnosed, Type of TB ..... 1 Pulmonary 2 Extra-pulmonary 3 Both 9 Unknown ☐

If TB diagnosed Smear diagnosis ..... 1 Smear positive 2 Smear Negative 9 Unknown ☐

KARNOFSKY SCORE ..... ☐☐☐

CURRENT SYMPTOMS: ( 1 = YES 2 = NO )

SYMPTOMS TB SUSPECT†

☐ Cough ☐☐ Duration of cough (weeks) ☐ Night sweats ☐☐ Duration of night sweats (weeks)

☐ Unintentional weight loss in last 6 months ☐ Fever ☐☐ Duration of fever (weeks)

†Any of these symptoms for > 2 weeks, or weight loss – please refer for further TB investigation (collect sputum AFB and TB culture)

☐ Sputum production ☐ Skin rashes *[61] ☐ Abdominal pain *

☐ Chronic diarrhoea (>4 weeks) ☐ Acute diarrhoea (<4 weeks) *[54] ☐ Muscle pain *[77]

☐ Headache *[64] ☐ Change in body shape * ☐ Sexually Transmitted Infections

☐ Numbness or tingling in feet *[73] ☐ Vomiting *[53] ☐ Nausea*[52]

☐ Other symptoms in the last 2 weeks Specify: _____

PATIENT ADHERENCE: *( 97 = OR 7 IF NOT ON ART )*

In the PAST 3 DAYS, HOW MANY PILLS do you think you missed? ..... 00 No pills missed ☐☐

In the PAST 7 DAYS, WHEN DID YOU MAINLY MISS pills? 00 No pills missed 01 Morning 02 Evening 03 Morning & Evening ☐☐

Choose the MAIN REASON WHY the patient missed medication: ☐☐

1 Uncertain about how to take it
2 Was depressed
3 Too much medication to take
4 Forgot
5 Slept through the dose
6 Was away from place of residence
7 Too busy
8 Change in daily routine
9 Felt worse when taking medication
10 Didn't want others to notice
11 Didn't think medication was needed
12 Didn't want to mix pills with alcohol / drugs
13 Forgot because drank alcohol / took drugs
14 Shared medication with others
15 Medication was stolen
16 Couldn't get it from clinic / pharmacy
17 Other – Specify: _____

Are you on DIRECTLY OBSERVED TREATMENT (DOT)? 1 Yes 2 No ☐



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CELL NO.: ☐☐☐☐☐☐☐☐☐☐ DATE: ☐☐/☐☐/☐☐☐☐

### VITAL SIGNS

*To be completed by nurse*

Height (cm) ..... ☐☐☐ Weight (kg) ..... ☐☐☐ Temperature (°C)..... ☐☐,☐

BP _____ mmHg Pulse _____ beats / min RR _____ breaths / min

Urinalysis ..... 1 Pos 2 Neg PROTEIN ☐ BLOOD ☐ LEUCOCYTES ☐

FEMALE PATIENTS: Date of LMP ☐☐/☐☐/☐☐☐☐

PREGNANT? 1 Yes 2 No ☐ IF PREGNANT, DUE DATE ☐☐/☐☐/☐☐☐☐

### PHYSICAL EXAMINATION

*To be completed by doctor*

FINDINGS: _____

CHEST X-RAY

ASSESSMENT OF CHEST X-RAY 1 Normal 2 Abnormal: TB 3 Abnormal: Other 7 NA ☐

CLINICAL ASSESSMENT (INCLUDE CURRENT WHO STAGE, REGIMEN & START DATE OF HAART OR PROPHYLAXIS)

Is there a NEW WHO STAGE 3 condition? 1 Yes 2 No ☐ DATE of onset ☐☐/☐☐/☐☐☐☐

Is there a NEW WHO STAGE 4 condition? 1 Yes 2 No ☐ DATE of onset ☐☐/☐☐/☐☐☐☐

IS PATIENT A TB SUSPECT † (any of: cough/fever/night sweats for > 2 weeks OR weight loss) 1 Yes 2 No ☐

IS PATIENT BEING ADMITTED 1 Yes 2 No ☐

IS PATIENT BEING REFERRED FOR TB TREATMENT 1 Yes 2 No ☐

REFERRAL SITE: .....

### INVESTIGATIONS

*Doctor to indicate which tests need to be done at this visit:*

☐ FBC + DIFF ☐ HIV PCR (UP TO AGE 18MTHS) ☐ Sputum TB D&C 2*

☐ CD4 ☐ U&E / Creatinine / Glucose ☐ RPR / VRDL / TPHA*

☐ LFT ☐ Viral Load ☐ Lipid Profile

☐ ALT & AST ☐ Confirmatory HIV ELISA test ☐ Pap Smear

☐ Amylase ☐ Sputum TB D&C 1* ☐ Lactic acid

Other _____ *Note: these tests are not covered by PEPFAR funding and are for the patient's own account

FOLLOW UP DATE ☐☐/☐☐/☐☐☐☐ FIT FOR WORK? 1 Normal 2 Light / Restricted duties 3 Sick leave ☐

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NAME: _____ CLINIC NO.: SM/WC ☐☐☐☐☐

CELL NO.: ☐☐☐☐☐☐☐☐☐☐ DATE: ☐☐/☐☐/☐☐☐☐

## TREATMENT STOP FORM

*To be completed by doctor*

**Has any MEDICATION BEEN STOPPED since the last visit?** *(Please record any stop >7 days)* 1 Yes 2 No ☐

**NB: IF PATIENT BECOME PREGNANT – NEED TO INDICATE PMTCT WITH A STOP FORM AND A START FORM**

***If "Yes" to the above, complete the following:***

| MEDICATION CODE | STOP DATE | STOPPED BY WHOM | REASON STOPPED |
|---|---|---|---|
| COM Combivir (AZT/3TC) 300/150mg<br>EFV Efavirenz 600mg nocte<br>ALU Aluvia (LPV/r) 200/50mg 2 tabs bd<br>KAL Kaletra (LPV/r) 133/33mg 3 caps bd<br>ABC Abacavir (Ziagen) 300mg bd<br>DDI Didanosine (ddI) 200mg bd<br>DD2 Didanosine (ddI) 125mg bd<br>D42 Stavudine (d4T) 30mg bd<br>AZT Zidovudine (AZT) 300mg bd<br>3TC Lamivudine (3TC) 150mg bd<br>NV1 Nevirapine 200mg dly (x2 wks)<br>NV2 Nevirapine 200mg bd<br>RTV Ritonavir 100mg bd - Booster<br>SQV Saquinavir 600mg tds<br>TR3 Triomune (NVP/3TC/D4T 30mg)<br>TRU Truvada (TDF 300/FTC 200) 1 tab/d<br>TDF Tenofovir 300mg dly<br>KYV Kivexa (comb ABC & 3TC)<br>ATV Atazanavir (Reyataz)<br>IND Indinavir 800mg tds<br>INH INH 300mg dly<br>CMX Cotrimoxazole 960mg dly<br>CM2 Cotrimoxazole 480mg dly<br>DIF Fluconazole 100mg dly<br>DF2 Fluconazole 200mg daily<br>DAP Dapsone 100mg dly<br>PYR Pyridoxine 25mg dly<br>**PMTCT PROPHYLAXIS (PEPFAR)**<br>LCA Long - course AZT<br>AZB Zidovudine syrup x 7 days<br>AZC Zidovudine syrup x 28 days<br>NVB Nevirapine Sd syrup for baby | (DD / MM / YYYY) | 1 = Attending Doctor<br>2 = Other Doctor<br>3 = Nurse<br>4 = Patient | 01 Adverse effect / Toxicity<br>02 Treatment failure<br>03 Drug interaction<br>04 Prescribing error<br>05 Treatment unavailable<br>06 Treatment not collected<br>07 Patient non-adherence<br>08 Pregnancy<br>09 Patient request<br>10 Patient died<br>11 CD4>250 (CMX only)<br>12 Treatment completed (INH only)<br>13 Other<br>14 Left employment<br>15 Transfer<br>16 Completed PMTCT<br>17 Obstetric complication (e.g. TOP, Abortion, etc.)<br>**(16 & 17 need to complete PMTCT Record form)** |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

*NB: Fluconazole for Oesophageal thrush should only be prescribed for 21 days maximum

**If OTHER REASON, give details:** _____

***If TREATMENT IS TO BE RE-CONTINUED a start form must be completed again***

Doctor's signature:

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NAME: _____ CLINIC NO.: SM/WC ☐☐☐☐☐

CELL NO.: ☐☐☐☐☐☐☐☐☐☐ DATE: ☐☐/☐☐/☐☐☐☐

**REPEAT SCRIPT x 5**

## TREATMENT START FORM

*To be completed by doctor*

**Is any TREATMENT BEING STARTED today?** 1 Yes 2 No ☐

***If "Yes" to the above, complete the following using the reference table below:***

**TYPE OF TREATMENT** 1 HAART 2 PMTCT HAART 3 PMTCT Prophylaxis 4 Other Prophylaxis 5 PEP **(x 1/12 ONLY)** ☐

| | TREATMENT 1 | TREATMENT 2 | TREATMENT 3 | TREATMENT 4 | TREATMENT 5 |
|---|---|---|---|---|---|
| CODE | ☐☐☐ | ☐☐☐ | ☐☐☐ | ☐☐☐ | ☐☐☐ |
| PAED DOSE | _____ | _____ | _____ | _____ | _____ |

| CODE | DRUG (*TRADE NAME*) | ADULT DOSE & PRESCRIPTION | | PAEDIATRC DOSE* (NB Check guidelines) |
|---|---|---|---|---|
| COM | *Combivir* (AZT/3TC) | 300mg / 150mg bd | **1 TAB** BD | 200mg – 600mg daily |
| EFV | Efavirenz (*Stocrin*)* | 600mg nocte | **1 TAB** NOCTE | 300mg/m² bd |
| ALU | *Aluvia* (Lopinavir / Ritonavir) | 200mg / 50mg | **2 TABS** BD | 300mg/m² bd |
| KAL | Kaletra (Lopinavir / Ritonavir) | 133mg/33mg | **3 CAPS** BD | 8mg/kg bd |
| ABC | Abacavir (*Ziagen*) | 300mg bd | **1 CAP** BD | 90 – 120mg/m² bd |
| DDI | Didanosine (ddI / *Videx EC 400MG* ) | 200mg bd | **2 TABS** BD | 100 – 120 mg/m² |
| DD2 | Didanosine (ddI / *Videx EC 250MG*) | 125mg bd | **2 TABS** BD | 1mg/kg bd |
| D42 | Stavudine (d4T/ *Zerit*) | 30mg bd | **1 CAP** BD | 180mg/m² bd |
| AZT | Zidovudine (AZT / *Retrovir*) | 300mg bd | **1 TAB** BD | 4mg/kg bd |
| 3TC | Lamivudine (3TC) | 150mg bd | **1 TAB** BD | 120mg/m² once daily |
| NV1 | Nevirapine (*Viramune*) | 200mg daily | **1 TAB** OD x2wks – INITIATION | 120 – 200mg/m² bd |
| NV2 | Nevirapine (*Viramune*) | 200mg bd | **1 TAB** BD – CONTINUATION | 250 – 400mg/m² |
| RTV | Ritonavir (*Norvir*) – PI Booster | 100mg bd | **1 CAP** BD | 50mg/kg tds |
| SQV | Saquinavir (*Invirase*) | 600mg tds | **3 CAPS** TDS | |
| IND | Indinavir (*Crixivan*) | 800mg tds | **2 (400mg) CAPS TDS** | |
| TRU | Truvada (Tenofovir/Emtricitabine) | 300mg/200mg | **1 TAB** DAILY | |
| TR3 | Triomune (Nevirapine/3TC/D4T) | 200/150/30 mg | **1 TAB** DAILY x 2 wks then BD | |
| TDF | Tenofovir | 300mg | **1 TAB** DAILY | |
| ATV | Atazanavir(Reyataz) | 300mg | **1 TAB** DAILY | |
| KIV | Kivexa (ABC/3TC) | 600/300mg | **1 TAB** DAILY | |
| INH | INH | 300mg daily | **3 TABS** DAILY | |
| CMX | Cotrimoxazole | 960mg daily | **1DS OR 2 SS TABS** DAILY | |
| CM2 | Cotrimoxazole | 480mg daily | **1 TAB** DAILY | |
| DF1 | Fluconazole (*Diflucan*) | 100mg daily | **1 TAB** DAILY X maximum 21 DAYS | |
| DF2 | Fluconazole (*Diflucan*) | 200mg daily | **2 TAB** DAILY | |
| DAP | Dapsone | 100mg daily | **1 TAB** DAILY | |
| PYR | Pyridoxine | 25mg daily | **1 TAB** DAILY | |
| **PMTCT PROPHYLAXIS (PEPFAR)** | | | | |
| LCA | AZT 300mg bd from 28 weeks, through labour (q3h) and postpartum bd X 7 days PLUS Sd Nevirapine at onset of labour | | | |
| AZB | Zidovudine | Paediatric syrup 4mg/kg 12 hourly (bd) x 7 days | | |
| AZC | Zidovudine | Paediatric syrup 4mg/kg 12 hourly (bd) x 28 days | | |
| NVB | Nevirapine | Oral solution Single dose 2mg/kg within 72hours | | |

**Efavirenz consent form signed?** 1 Yes 2 No 7 N/A ☐

**When is the patient expecting to go on LEAVE?** ☐☐/☐☐/☐☐☐☐ Date **HOW LONG will the leave period be?** ☐ Number of weeks

Doctor's Name: _____

Qualifications: _____

MP / Practice no.: _____

Doctor's signature:

Aurum signature:



Oct 2008

CONFIDENTIAL

AURUM

NAME: _____ CLINIC NO.: SM/WC ☐☐☐☐☐

CELL NO.: ☐☐☐☐☐☐☐☐☐☐ DATE: ☐☐/☐☐/☐☐☐☐

## ART ADVERSE EVENTS FORM

*To be completed by doctor*

**Has the patient had any ADVERSE EVENTS since the last visit?** *(Consider both CLINICAL & BIOCHEMICAL)* 1 Yes 2 No ☐

***If "Yes" to the above, complete the following using the reference tables below:***

| | ADVERSE EVENT 1 | ADVERSE EVENT 2 | ADVERSE EVENT 3 | ADVERSE EVENT 4 | ADVERSE EVENT 5 |
|---|---|---|---|---|---|
| (A) EVENT CODE | ☐☐ | ☐☐ | ☐☐ | ☐☐ | ☐☐ |
| (B) SEVERITY | ☐ | ☐ | ☐ | ☐ | ☐ |
| (C) NEW | ☐ | ☐ | ☐ | ☐ | ☐ |

*(Mark if this is a new adverse event, but not if it is a continuation of a previous adverse event)*

Details: _____

### ADVERSE EVENT CODES

**HAEMATOLOGY**
11 Haemoglobinaemia
12 Neutropenia
13 Leukopenia (decreased WBC)
14 Thrombocytopaenia

**CHEMISTRY**
21 Hyponatraemia
22 Hypernatraemia
23 Hypokalaemia
24 Hyperkalaemia
25 Elevated Blood Urea (BUN)
26 Elevated Creatinine
27 Hypoglycaemia
28 Hyperglycaemia
31 Elevated Triglycerides
32 Elevated Cholestrol
33 Elevated LDL
34 Acidosis
36 Low bicarbonate
40 Low Albumin
41 Elevated AST (SGOT)
42 Elevated ALT (SGPT)
43 Elevated ALP
44 Hyperbilirubinaemia
45 Elevated Amylase
46 Elevated Lipase
47 Elevated CPK
48 Elevated Lactate

**CLINICAL**

Gastrointestinal
51 Dysphagia
52 Nausea
53 Vomiting
54 Diarrhoea
55 Constipation
56 Abdominal pain
57 Clinical hepatitis
58 Clinical Pancreatitis

Cutaneous
61 Rash / Dermatitis
62 Local allergic reaction

Miscellaneous
63 Fever, oral > 12hrs
64 Headache
65 Systemic allergic reaction
66 Fatigue / Malaise
67 Eye / visual changes
76 Arthralgia / Arthritis

Neuromuscular
71 Neuro-cerebellar (Ataxia)
72 Neuro-psychological / Mood
73 Paraesthesia (burning, tingling)
74 Neuro-muscular weakness
75 Neuro-sensory
77 Myalgia
78 Dementia
79 Delirium
80 Insomnia
81 Seizures
82 Vertigo

Urinary
91 Haematuria
92 Proteinuria

Endocrine / Metabolic
68 Lipodystrophy
94 Diabetes mellitus
95 Gynaecomastia
98 Lipoatrophy

Pregnancy Outcomes (grd4)
83 Congenital Malformations
84 Preterm labour
85 Spontaneous Abortion
86 Other obstetric complication

### ADVERSE EVENTS SEVERITY GRADING

| | | |
|---|---|---|
| 1 | MILD | Transient, no medical intervention required |
| 2 | MODERATE | Mild-moderate limitation in activity, minimal / no intervention required |
| 3 | SEVERE | Marked limitation in activity, intervention required |
| 4 | LIFE-THREATENING | Intervention required, hospitalization probable |

INTERVIEWER ☐☐ DOCTOR ☐☐ VERIFIED ☐☐ DATA ENTERED ☐☐ DOUBLE ENTRY ☐☐

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