Prevention of Mother-to-Child Transmission of HIV practices by private general practitioners affiliated to the Aurum Institute

By

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Declaration

I, Mashapha Thililelwi Shirley, declare that this research report is my own work. It is being submitted in partial fulfilment of the requirements for the degree of Master of Public Health - Maternal and Child Health at the University of Witwatersrand in Johannesburg, South Africa. It has not been submitted for any degree examination before at this or any other University.

Signature:

Mashapha TS 15/02/2016

Dedication

I dedicate this research report to my parents, siblings and friends for their love, support and encouragement during my studies.

Abstract

Introduction: The mother-to-child transmission (MTCT) of HIV refers to the transmission of HIV from an HIV-infected woman to her child during pregnancy, labour, delivery or breastfeeding. This is the most common form of HIV transmission to infants and children. Without treatment, the likelihood of transmitting HIV from mother-to-child ranges between 15-45%. The national prevention of mother-to-child transmission (PMTCT) programme was first introduced in South Africa in 2001. Effective PMTCT programmes require women and their infants to receive a cascade of interventions including HIV testing during pregnancy, use of antiretroviral treatment (ART) by pregnant women living with HIV, safe childbirth practices and appropriate infant feeding, infant HIV testing and other post-natal healthcare services. The aim of this study was to describe Prevention of Mother-to-Child Transmission of HIV services among private general practitioners participating in a partnership programme with the Aurum Institute, assessing compliance to PMTCT Guidelines 2008 and 2010 as well as the MTCT rate at around six weeks.

Methods: This was a retrospective review of records of women who enrolled into the PMTCT programme with the private general practioners affiliated to the Aurum Institute between January 2008 and April 2010. A total of 301 files of women enrolled on the PMTCT programme were reviewed. Data were collected from the women's files and the Aurum database using a data abstraction form.

Results: Even though HIV and TB guidelines were provided to all GPs, only less than 40% had copies of the guidelines in their general practice during the audit conducted in 2010. The GPs adhered to the 2008 and 2010 PMTCT Guidelines and even exceeded the NDoH target when it came to CD4 count testing and provision of lifelong ART to those who were eligible.

In 2008, 91% of HIV positive pregnant women were tested for CD4 count, 99% were given lifelong ART and 74% of HIV exposed babies were tested at approximately six weeks by PCR. GPs did not adhere to guidelines in the provision of PMTCT prophylaxis where 21, 3% of women received prophylaxis and 77% of women received lifelong ART even though they were only eligible for prophylaxis. . GPs adhered to 2010 PMTCT guidelines regarding CD4 testing and provision of lifelong ART. Baseline CD4 count was completed in 93% of women and 94% received lifelong ART. In 2010, PCR testing was conducted in 66% of HIV exposed babies, which was lower than the NDoH target of 80%. The overall MTCT rate in this study was 1.8%; a lower MTCT rate among women who became pregnant on ART than those initiating ART during pregnancy (0% versus 3.2%).

Conclusions and Recommendations: The GPs affiliated to The Aurum Institute showed good adherence to the PMTCT guidelines at most steps of the PMTCT cascade, for example: CD4 count testing and provision of ART. The study concludes that with proper training, support and mentoring, GPs can render comprehensive PMTCT services. The study also concludes that later initiation of ART had increased risk of MTCT and that women who received ART compared to prophylaxis had a lower MTCT rate. Further research is recommended to evaluate HIV and TB services rendered by GPs not affiliated or in private public partnership with any institution.

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‘

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Abbreviations and Acronyms

3TC	Lamivudine
AFA	Aid for AIDS
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Zidovudine
BRHC	Broad Reach Health Care
CD4	CD4+ T-cells or T4 ‘helper’ lymphocytes
CTX	Co-trimoxazole
DNA	Deoxyribonucleic acid
DoH	Department of Health
EFV	Efavirenz
ELISA	Enzyme-linked immunosorbent assay
FTC	Emtricitabine
GPs	General practitioners
HAART	Highly active antiretroviral therapy
HCT	HIV counselling and testing
HIV	Human immunodeficiency virus

HPCSA	Health Professions Council of South Africa
IQR	Interquartile Range
MCH	Maternal and Child Health
MDG	Millennium Development Goals
MRC	Medical Research Council
MS	Microsoft
MTCT	Mother- to- child transmission of HIV
NDoH	National department of Health
NHI	National Health Insurance
NSP	National Strategic Plan
NVP	Nevirapine
PCR	Polymerase chain reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Care
PMTCT	Prevention of mother- to- child transmission of HIV
SD	Standard deviation
TB	Tuberculosis
TDF	Tenofovir
VCT	Voluntary counselling and testing
WHO	World Health Organisation

CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

1.1 Background

Human Immune Deficiency Virus (HIV) is an important global health problem. World Health Organization (WHO) estimated that thirty five million people were living with HIV globally in 2013 (1). An estimated 0.8% of adults aged 15-49 years worldwide are living with HIV (1). Although the burden of the epidemic continues to vary considerably between countries and regions, Sub-Saharan Africa remains most severely affected, with nearly 1 in every 20 adults living with HIV and accounting for 71% of the people living with HIV worldwide (1). The 2013 mid-year population estimates in South Africa showed that the overall HIV prevalence was approximately 10% (approximately 5.3 million people). For adults aged 15–49 years, an estimated 15, 9% of the population were HIV positive (2).

HIV is a main cause of child morbidity and mortality in South Africa, with HIV-related deaths accounting for more than one third of the total number of deaths in children under the age of five years (3). Vertical transmission (either in utero, during birth or postpartum during breastfeeding) is the main mode of HIV acquisition in these children (3). If a pregnant HIV positive woman does not receive antiretroviral drugs during pregnancy or labour, the risk of transmitting HIV to unborn baby is 15-30% and 15-20% during breastfeeding (3).

The prevention of mother-to-child transmission (PMTCT) programme was first introduced in South Africa in 2001. During that year, the HIV prevalence among the antenatal clinic attendees was 24.8% (4).

Since the introduction and implementation of the PMTCT programme throughout the country, the HIV prevalence among antenatal attendees has remained unchanged for the past four years (5). The data reported above excluded data collected from private General Practitioners (GP). The 2010 National PMTCT policy recognises that in order to prevent HIV from among women and children, the four elements of PMTCT are integral. These include:

1. Primary prevention of HIV, especially among women of childbearing age
2. Preventing unintended pregnancies among women living with HIV
3. Preventing HIV transmission from a woman living with HIV to her infant; and
4. Providing appropriate treatment, care, and support to women living with HIV and their children and families (6).

The South African PMTCT Guidelines (6 states that all pregnant women should be offered an HIV test at their first antenatal visit (6). Pregnant women who test HIV positive should be staged according to WHO staging and blood taken for CD4 count. If stage 3 and 4 or CD4 count less than 350, should be provided with lifelong ART both for their own health and for prevention of MTCT to the baby. If stage 1 and 2 or CD4 count above 350, should be given PMTCT prophylaxis from as early as possible until after one week post-cessation of breastfeeding (6). In April 2013, South Africa introduced new regimens for HIV positive pregnant women. The PMTCT Guidelines requires that all HIV positive women should receive triple therapy of ARVs in a fixed dose (7). This was after the World Health Organization (WHO) released new guidelines which stated that all HIV positive pregnant

women should receive triple therapy (8). The private sector (both for-profit and not-for profit) plays an important role in providing health care in South Africa. In 2006, 58% of general practitioners (GPs) and 63% of specialists (e.g. gynaecologists, paediatricians etc.) were working in the private sector (9).

Statistics from the Health Profession Council of South Africa (HPCSA) indicated that almost 1 300 GPs were registered to practice in 2006 (9). The large percentage of medical practitioners working in the private sector warrants that delivery of any public health interventions are inclusive of this group. According to the 2003 South African Demographic and Health Survey, 6% of women delivered their babies at private sector facilities, a number which may have increased over the years as access to medical insurance improves (10). These women may have received antenatal care including PMTCT from private practitioners.

Since 2003, The Aurum Institute, a non-profit organisation has received funding from the United States' President's Emergency Fund for AIDS Relief (PEPFAR) to support the scale up of the HIV prevention, care and treatment programme in South Africa. In 2004, Aurum entered into a partnership with private GPs to provide HIV care and treatment services to HIV- infected patients. In the partnership, Aurum provided the GPs with initial and on-going training and mentoring on HIV management including PMTCT, ARV drug supplies, funding for laboratory services and patients' consultation fees. The general practitioners on the other hand provided patient care and recorded all patient visits and consultations on Aurum designed patient management forms. The patient management forms were completed in duplicate; with the original copy remaining at the general practitioner and a copy being sent to Aurum Institute for data capturing and filing.

The services offered by the GPs included HIV counselling and testing for children, adults and pregnant women, provision of antiretroviral therapy (ART) and ARV prophylaxis for eligible women, prophylaxis for HIV exposed infants, HIV testing for HIV exposed infants at 6 weeks and 18 months, counselling on feeding options and HIV treatment for children who test HIV positive.

This research report describes a study that was conducted to assess compliance with National PMTCT Guidelines by general practitioners following the PMTCT cascade or processes. The study describes the overall mother-to-child transmission rate and practices at the general practitioners' sites regarding provision of PMTCT.

1.2 Statement of the problem

The researcher hypothesised that the provision of PMTCT services and compliance to national guidelines differed between GP practices and that there were practice level factors which were associated with outcomes and compliance to guidelines. This was apparent due to the fact that some doctors would send prescriptions which did not follow the national guidelines, whereas other doctors would stick to the national guidelines, even though all doctors received the same training and received updates of guidelines on a regular basis.

Identifying practice level factors that are associated with better patient care, and giving feedback on identified problem-areas (regarding compliance with guidelines) to the GPs, might assist in them scaling up their level of HIV/PMTCT care. When properly trained and supported, private GPs could play an important role in providing PMTCT services, thereby contributing towards reducing under five mortality and elimination of mother-to-child transmission.

1.3 Justification for the research

There is not enough information and evidence on the provision of PMTCT services by private GPs, their compliance with national guidelines, the outcomes of these services and the factors associated with healthcare services provided by private GPs in South Africa.

Unlike public sector service providers who are evaluated regularly, private GPs often work in isolation and with minimal supervision. Their activities are rarely monitored and their patient outcomes not evaluated. There are pregnant women who receive antenatal care, receive HIV counselling and testing, ART for PMTCT and infant polymerase chain reaction (PCR) testing from private practitioners. There is little evidence on how well GPs in private practice comply with PMTCT guidelines when they provide services to HIV positive mothers. Although the GPs involved in the partnership received training and support on HIV care and treatment from Aurum, this would not guarantee compliance with the National PMTCT Guidelines. This study maybe more significant in recent years with the introduction of GP contracting within the National Health Insurance (NHI) where GPs will be rendering their services in the primary health care.

1.4 Literature review

1.4.1 PMTCT missed opportunities

There are gaps and missed opportunities in the provision of PMTCT services in both public and private sectors and these are related to patients, service providers and institutions. . According to a national HIV/TB review conducted in 2014, uptake of PMTCT services was high with more than 98% of women getting HIV tested during pregnancy and 91.7% of HIV-positive mothers receiving ARV treatment or prophylaxis (10). However, CD4 testing (78.3%) and early infant diagnosis (EID) uptake (35.1%) were lower and represented on-going missed opportunities in the PMTCT programme (10).

In the public sector, evaluation of the provision of PMTCT services across the world have shown improvements in access, coverage and outcomes, such as low rates of mother to child HIV transmission(11).

A study evaluating infant early HIV diagnosis in primary health care settings in South Africa, showed that more than 90% of facilities reported offering any onsite PMTCT service, but only 69% of these facilities offered PMTCT services daily (12). This highlights that there are gaps in public health facilities where PMTCT services are not offered daily, therefore missing opportunities of identifying HIV infected mothers and children.

The HIV epidemic in South Africa calls for efficient use of human resources for health to ensure increased coverage of treatment services. HIV treatment coverage in South Africa has faced numerous challenges with poor patient retention, suboptimal adherence and treatment failure due to poor access to services (13).

Broad Reach Healthcare (BRHC) developed a private-sector treatment model to provide an augmentative solution for accessing HIV care for patients in the public sector (13). They provided training to GPs and surgery staff on a range of topics related to HIV/AIDS management, including clinical management, the moral, ethical and legal issues of HIV disease management, and the administrative and logistical issues related to improving care in Mpumalanga and Kwazulu Natal (13). The evaluation of the programme showed that the private-sector treatment model combined with adherence support resulted in low defaulter and higher patient retention rates as compared to reports from public-sector models (13). These findings suggest that providing HIV treatment for patients in the private-sector is a suitable model to rapidly augment public-sector capacity (13).

The Aid for AIDS (AfA) programme provides HIV/AIDS and TB services, including establishing a patient's HIV status, providing clinical assessment, provision of care and treatment (including PMTCT), ongoing monitoring, and medicine supply from their preferred or network doctor (14). In 2006, a study reviewing the delivery of HIV and AIDS, sexually transmitted infections and tuberculosis care within the private sector, reported a relatively low mother-to-child transmission rate of 1.2% in women who received HAART from private sector doctors. (14).

Similar to Broadreach and AFA, the Aurum Institute model of offering HIV/AIDS management showed that a properly managed private general practitioner based model can achieve comparable results to public service programmes. This partnership with private general practitioners' model of HIV/AIDS management can be used to expand access to ART in areas where the public sector is unable to meet demand (15).

1.4.2 Role of private health sector in PMTCT programme

The role of the private health sector in delivering HIV/AIDS services is not well studied and established in many countries. A study was conducted to assess the role of private health facilities and pharmacies in HIV/AIDS service delivery in Ethiopian order to quantify the role of the private health sector in HIV/AIDS and TB services. It concluded that the private sector had increased access to reproductive health services in the country and identified it as a solid foundation upon which further public-private collaboration could be achieved and that it is an untapped resource that could contribute to increasing both access and quality of HIV/AIDS services (16).

In South Africa the provision of PMTCT services is happening in both the public and private sector. The provision of PMTCT services by GPs has not been previously described or widely studied (proved refs of studies that you have identified). A study KwaZulu-Natal study conducted in 1999 to measure the prevalence of HIV among pregnant women at a South African private medical centre showed that only 30% of women were tested for HIV infection, and among these, 14% were identified as HIV-infected. (17). These missed opportunities are not happening in the private sector alone.

A study conducted in Chris Hani Baragwanath Hospital found that of 1 510 children admitted, 29.5% were HIV infected (18). The study further found that problems with PMTCT implementation in infants under 6 months, included lack of maternal antenatal HIV testing, poor uptake of maternal/infant Nevirapine prophylaxis, limited use of co-trimoxazole (CTX) prophylaxis and delayed PCR testing (18).

A study conducted in KwaZulu-Natal reported that private sector doctors providing care to HIV infected patients, thought that they required more training/knowledge in certain clinical areas such as overall care, ARV therapy, therapeutic monitoring, side effects management, HIV prevention, psychological counselling, nutritional and special support, particularly for younger doctors as they were more involved in the management of HIV/AIDS (17).

HIV services must be fully decentralised and integrated into the fabric of the health system with every health worker within a facility equipped with the knowledge and skills to provide HIV services. This training can begin from pre-services undergraduate education and will enhance effectiveness, improve quality, and minimise or eradicate stigma and discrimination in all supported sites (19). Aurum Institute followed this approach and supported affiliated GPs through training and in-service workshops, mentoring (through calls, email) and also reviewed scripts sent in by GPs.

1.4.3 HIV/AIDS (PMTCT) management training

The need for training of health care workers in the HIV care and treatment has not only been highlighted by the private practitioners but also in public institutions. A study from Botswana reported that health care workers felt discomfort in managing HIV patients because of lack of knowledge and training. This affected the country's PMTCT program negatively because in

2003 only about 30% of pregnant women were tested for HIV, an area were HIV prevalence was around 40% (20). While addressing the health care worker training needs it is also important to look at the site or provider level factors affecting the delivery of PMTCT services.

Studies have been conducted at public institutions to look at the site level factors affecting PMTCT delivery but little is known about these factors in the private sector.

Some of the issues to look at are whether the doctors' knowledge about HIV/AIDS, their willingness to treat patients with HIV/AIDS, available infrastructure and resources, among others. A study assessing public-private partnership in HIV treatment, showed that private sector GPs are able to effectively maintain patient treatment outcomes and potentially contribute to HIV treatment scale-up with the relevant support mechanisms in place. The model demonstrated how an assisted private sector based programme can be effectively and efficiently used to target specific health concerns, key populations or serve as a stop-gap measure to meet urgent health needs (21).

A study conducted in Kenya in 2005 found that participant-level factors (such as age, education etc.) were not significant determinants of PMTCT HIV test acceptance (22). The study recommended that PMTCT programmes should evaluate the role of site-level (provider and testing service) factors on PMTCT acceptance (22). The findings of the study suggested that the identification and improvement of site-level factors could improve PMTCT uptake. On the basis of published literature, training and availability of site staff (counsellors, nurses and physicians), participation of physicians and nurses in offering PMTCT HIV testing, instituting a better participant flow to minimize inconvenience, availability of test kits and

laboratory technicians at the site and the time required to return HIV test results are some of the possible factors that could play a role in determining test and PMTCT acceptance (22).

Factors like these compromises patient care e.g. without HIV test kits no HIV test will be done to patients, without CD4 count results it was difficult to decide on ART regimen for the pregnant woman, until the new PMTCT Guidelines which states that all HIV positive pregnant women should be given triple therapy.

Botswana experienced a low uptake of PMTCT services in public facilities in 1999-2003 (20). A survey conducted in Botswana to determine the causes for low uptake of PMTCT services, reported that patient level factors like fear, stigma or resistance from partners were not frequent reasons for refusing an HIV test and PMTCT services (20). However, providers of HIV services reported discomfort in managing HIV positive patients due to their lack of knowledge and skills and were not confident enough to offer patients HIV testing (20). The PMTCT cascade starts with prevention of HIV, HIV test, without HIV test results it means no PMTCT intervention will be offered to those who need it. Thus, both site-level and patient-level factors need to be addressed in order to increase the effectiveness of HIV/PMTCT services.

South Africa has introduced National Health Insurance (NHI) and is currently in the pilot phase of implementation in eleven districts. The NHI is intended to bring about health care reform that will improve service provision. It will promote equity and efficiency so as to ensure that all South Africans have access to affordable, quality healthcare services regardless of socio-economic status (23). As part of health care system reform, primary health care services will be delivered through accredited and contracted private providers

practicing within a district (23). Research studies advocates that all GPs to be contracted in the NHI should be assessed or screened to identify their competency in the HIV diagnosing and managing patient living with HIV/AIDS as well as undergo HIV/AIDS prevention, diagnosis and management training and orientation on relevant South African HIV guidelines.

1.4.4 Conclusions

In conclusion, the studies above showed that GPs are providing HIV and PMTCT services on different scales. They also emphasise the important role which can be played by GPs in providing HIV care including the provision of PMTCT services. It is also clear that there is a need to provide training and mentoring on HIV management to private GPs.

We have seen from the studies above that GPs are willing to be integrated into the health system and offer comprehensive HIV services.

1.5 Aims and objectives

1.5.1. Study aim

The aim of the study was to describe Prevention of Mother-to-Child Transmission (PMTCT) of HIV services among private general practitioners participating in the Aurum Programme during the period January 2008 and April 2010. The study also intended to explore the provision of PMTCT services by the general practitioners in respect to compliance to NDoH PMTCT guidelines, overall MTCT rate and site level factors e.g. training, staff categories etc.

1.5.2. Specific study objectives

The specific study objectives were:

1. To describe the practice levels factors (such as availability of HIV guidelines, availability of health care providers, type of trainings received) of GPs participating in the Aurum programme.
2. To determine the compliance of GPs participating in the Aurum programme to National PMTCT Guidelines (relevant within the specified study period), with respect to the PMTCT cascade: CD4 count testing, prescription of treatment/prophylaxis, provision of ARV prophylaxis or ART regimens, and early infant HIV testing at 6 weeks.
3. To determine an overall mother to child transmission rate at around 6 weeks (4 – 12 weeks) for patients cared for at GPs participating in the Aurum programme.

CHAPTER 2

METHODOLOGY

2.1.Introduction

This chapter describes the methodology used to conduct the research study on prevention of mother to child transmission of HIV services by private general practitioners affiliated to Aurum Institute HIV programme. The research study design, study population and sample, data collection method, data analysis and ethical considerations will be discussed.

2.2.Setting

The Aurum Institute developed a model for HIV care (including ART provision) using private practitioners with donor funding from the President's Emergency Plan for AIDS Relief (PEPFAR), which commenced in January 2005. The private practitioner model of ART delivery was a centrally-managed programme which included HIV specialist support, HIV training, data management, laboratory and pharmaceutical services. Treatment regimens

and initiation criteria for provision of ART were in accord with South African national guidelines.

Table 2.2.1 Description of 2008 and 2010 PMTCT Guidelines used during the study period

2008 PMTCT Guidelines	2010 PMTCT Guidelines
HIV positive pregnant women with CD4 count of >200 were eligible to be initiated on AZT at 28 weeks gestation.	HIV positive pregnant women with CD4 count >350 or WHO clinical stage 1 or 2 were eligible to receive AZT as early as 14 weeks.
HIV positive pregnant women with CD4 count of ≤200 or WHO stage IV, they were eligible for lifelong ART.	HIV positive pregnant women with CD4 count ≤ 350 or WHO clinical stage 3 or 4 were eligible to be initiated on lifelong ART

In order to qualify to provide HIV management in partnership with Aurum, a doctor had to attend ART training course provided by Aurum, and it was also dependent on the availability of funds. The Aurum partnership with the GPs was audited for HIV patient retention in 2010. During the audit, data on the characteristics of general practices were collected on standardized audit forms. This data were used to describe the site level factors influencing compliance to the national PMTCT guidelines 2008 and 2010. The study included private general practices affiliated to Aurum Institute from nine Provinces in South Africa (table 2.2.2).

Table 2.2.2 Distribution of General Practices

Province Name	Number of private GPs
Eastern Cape	**1**
Free State	**5**
Gauteng	34
KwaZulu-Natal Provinces	1
Limpopo	7
Mpumalanga	4
North West	7
Northern Cape	1
Western Cape	1
Total	**61**

PMTCT services were introduced by the Aurum GPs in late 2008. However as there was no person who was coordinating the PMTCT activities at Aurum during this period, and thus there was poor coordination of PMTCT services provided by GPs participating in the Aurum programme. The PMTCT leader was only appointed in 2009, and new PMTCT enrolments stopped in May 2010 due to funding constraints. Those who were already enrolled in the programme continued receiving the PMTCT services through participating GP practices.

2.3.Study Design

A descriptive, cross-sectional study was used to review the compliance to national PMCT guidelines by private general practitioners affiliated to Aurum Institute.

2.4. Study population

The study population comprised HIV-infected pregnant women who received PMTCT services between January 2009 and September 2010 at GP practices affiliated with the Aurum Institute in all nine provinces. Records from all general practices affiliated with the Aurum Institute in all provinces regarding the PMTCT services to all HIV-infected women were reviewed and records of women were included in the analysis according to the study inclusion criteria.

The inclusion criteria for the study included the following:

All HIV-infected pregnant women who were enrolled on PMTCT programme between January 2009 and September 2010 at general practices affiliated to Aurum Institute and babies born by HIV positive pregnant women receiving the PMTCT services at these practices during the same period were included in the study.

Exclusion criteria

- Women who received PMTCT services from private general practitioners affiliated to Aurum Institute before January 2009, due to poor coordination of the programme during this time.
- Women already enrolled in the programme and who fell pregnant and received PMTCT services from October 2010, were excluded because new enrolment had stopped due to lack of funding.

2.5.Sample size

Three hundred and one women who received PMTCT through Aurum-affiliated GP practices during the period under observation were included in the study.

2.6.Data sources and data collection

Data were collected from the Aurum Institute database, patient files, and the audit which was conducted in 2010 by the Aurum Institute.

- **Aurum database**: Aurum developed a patient management system and data collection tools for all the affiliate GPs. An assessment form and core record form were completed at the patient's first visit. A laboratory form to record results and visit forms were completed during follow up visits. After completion of the forms, the practice retained the original copies (in patient files) and sent a duplicate to Aurum offices for data capturing.
- **Patient Files**: The information on patient files were used to verify information collected from database. Comparing the two sources (database and patient files), patient files were found to be more reliable, had more recent information and were more complete as compared to the database.
- **The audit:** This was meant to check the retention of patients at the GP practice. It was a once off exercise conducted in 2010. All the GPs were visited and all the patients' files were checked using an audit tool developed by Aurum.

2.7.Measuring tool or instrument

Two data extraction sheets were developed and used to extract data. Patient level data were collected from patients' individual files and Aurum HIV care and treatment database. Practice level data was collected from the audit records. The data collection instruments are attached as annexures.

2.8.Variables

Data was collected at the GP practice level as well as the individual patient level.

i) **Practice level data:** data for practice level variables were collected from the completed audit forms. The following data elements were extracted: availability of PMTCT/ART guidelines, availability of health care staff (nurse, doctor), and whether staff received and HIV-related training from Aurum.

ii) **Patient level data:** patient level data collected include demographics, clinical and immunological status, treatment regimens, and infant feeding method at around six weeks, and PMTCT outcome.

2.9.Data analysis

Individual-patient data collected from file review were cleaned and entered into MS Excel and MS Access and each patient was assigned a unique identifier. All analyses were conducted using Stata 11.0. The general practices were described in terms of practice level variables such as type of staff training received, availability of ART guidelines, availability of doctor and/or nurse/s.

The women who received PMTCT services through the partnership in terms of age, employment status, gravidity and parity, the chi-square test and Wilcoxon rank-sum test were used to compare women who were on ART at enrolment to those who were not. A p-value of < 0.05 was considered statistically significant. The numbers of women receiving services at each practice and at each step of the PMTCT cascade were determined and used to calculate the:

- Proportion of registered HIV positive women who receive CD4 count testing
- Proportion of HIV-infected pregnant women receiving ARV prophylaxis
- Proportion of HIV-infected pregnant women receiving HAART
- Proportion of HIV-exposed babies tested by PCR at around 6 weeks.

MTCT rate - the overall transmission rate were determined as the total number of HIV exposed infants with a positive HIV DNA PCR at six weeks / total number of HIV exposed infants tested at six weeks.

2.10. Ethical considerations

Permission to access PMTCT data was obtained and granted by the Research Director at The Aurum Institute in 2011, before data was collected. Ethics approval by University of Witwatersrand Human Research Ethics Committee (Medical) was obtained and granted in 2012 (certificate number M121033). To protect patients' identity, no patients' names were used during the study process. The files were retrieved using the unique study number allocated to each patient enrolled in the study.

As this was a retrospective study there was no risk to the study participants, so no consent form was used. Data was stored on a computer and an access code was created to ensure confidentiality.

2.11. Summary

This chapter discussed the methodology used to conduct this study on private practitioners' compliance to South African PMTCT 2008 and 2010 Guidelines and site level factors influencing compliance or non-compliance. A quantitative approach was used and a descriptive, cross-sectional research design was adopted. This chapter also discussed the data collection methods which was review of records (patients' individual files and site level factors from the Aurum audit conducted in 2010). These instruments collected data looking at the PMTCT cascades (CD4 count testing, Provision of either PMTCT prophylaxis or ART. Site level factors included training, availability of doctor and/or nurses, availability of guidelines etc. Before data was collected, permission to access and use data was obtained from Aurum Institute and ethical clearance certificate was received from University of Witwatersrand. Patients' confidentiality was maintained throughout.

CHAPTER 3

RESULTS

3.1. Introduction

This chapter describes the results of the study. The results presented in this chapter include a description of the study population, and the participating general practices; the general practitioners' compliance to National PMTCT Guidelines for 2008 and 2010, as well as the MTCT rate. The geographical location of the General Practitioners site were not linked to individual level data during data collection, as a result a description of site level factors associated with compliance and the MTCT rate are not presented. Data collection took place from 13 to 29 November 2012. Data was collected using the data abstraction form. MS Access 2007 and MS Excel 2007 were used for data capturing and management. Stata 13 was used for the data analysis.

3.2 Description of General Practitioners' Sites

3.2.1 Geographical Information

The Aurum Institute had enrolled sixty six general practitioners across the country to provide HIV/AIDS services. The audit was conducted by Aurum Institute to understand the status of health care provision at the GP sites in 2010. It was conducted in all sixty six GP sites in the nine provinces. Below is the GP sites distribution across South Africa:

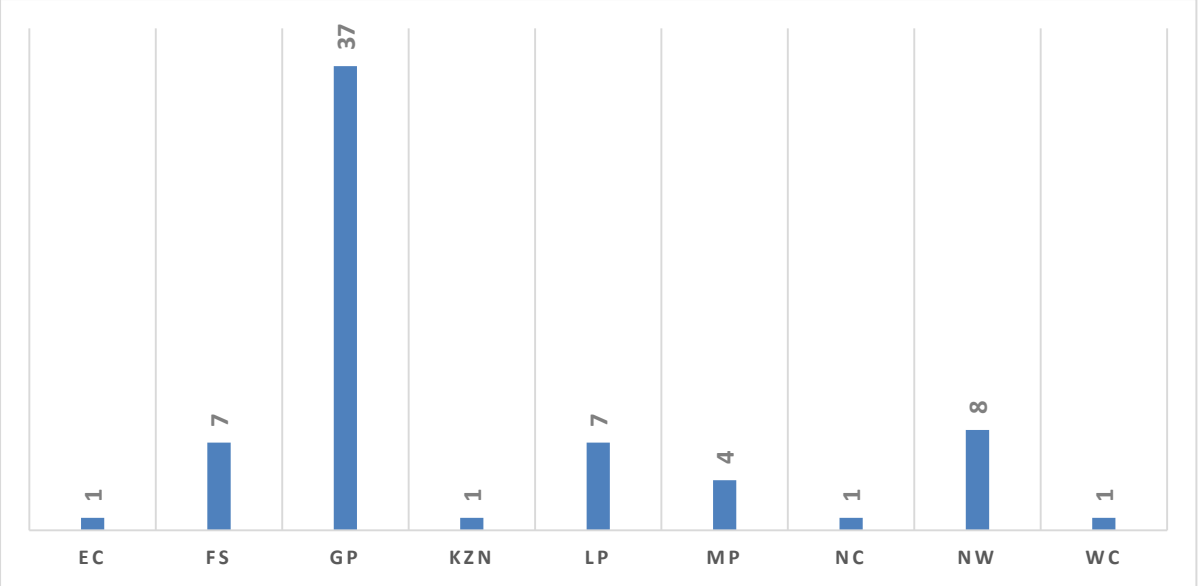

Figure 3.2.1.1 GP sites geographical distribution

Figure 3.2.1.1 shows that Gauteng province had more GP sites than any other Province, followed by North West.

3.2.2 Description of the general practices according to audit findings

3.2.2.1 Availability of clinical guidelines

HIV (adult, paediatric and PMTCT) guidelines were provided to all GP sites by the Aurum Institute at the start of the programme and new guidelines were introduced. Audit findings showed that these guidelines were not found or their presence verified at the time of audit (table 3.2.2.1). The majority of GP sites (69.7%) had Wellness/Pre-ART guidelines and only 27.3% had PMTCT, Paediatric and ART guidelines.

Table 3.2.2.1 Availability of Clinical Guidelines

Guidelines	Number	Percentage (%)
HIV counselling and testing	22	33.3
PMTCT	18	27.3
Paediatric	18	27.3
ART	18	27.3
Post exposure	8	12
Tuberculosis	7	10.6
Pre ART/Wellness	46	69.7

3.2.2.2 Patient Statistics

In total, 19 838 files were issued to GPs. This includes PMTCT, adult and paediatric files. At the time of audit, only 12 135 patient files were found to be active, the rest were transferred out, lost to follow up, deceased or deregistered from the programme.

Table 3.2.2.2 Patients statistics

Item	Number
Total number of empty files ever issued	19838
Total number of active files (at time of data collection)	12135
Total number of deregistered files	6465
Total number of patient deaths	1418
Total number of patients transferred out	585
Total number of patients lost to follow up	4142

3.2.2.3 Treatment statistics

Only 224 patients were found to be on PMTCT from all sixty six GP sites (table 3.2.2.3), as compared to 301 PMTCT patients found on the Aurum database or with patient files kept at Aurum offices. The audit found that 9065 patients were started on ART.

Table 3.2.2.3 Treatment statistics

Item	Number
Patients on ART	9065
Patients on Cotrimaxazole	6497
Patients on INH prophylaxis	951
Patients on PMTCT	224
Number of Paediatric Patients	293

3.2.2.4 Equipment and Assets

Almost all GP sites had a desktop/laptop, fax machine, printer, internet access and an email account. These were used to send pharmacy scripts to Aurum Institute clinicians for review and authorisation and also to send patients visit forms in time.

Table 3.2.2.4 Availability of technological equipment

Item	Number	Percentage (%)
Desktop/Laptop	55	83.3
Fax machine	56	84.8
Printer	56	84.8
Internet access	56	84.8
Email account	53	80.3

3.2.3 Training

The audit findings showed that the following training were attended by doctors, nurses and lay counsellors working at the GP sites:

1. Doctors attended a three-day HIV/AIDS management training course and a two-day clinical training course (provided by the Aurum Institute) which included ART regimens, adherence, adverse events and their management, changing treatment regimens, ART for children and tuberculosis (TB) treatment.
2. Nurses attended a two-day training course which included ART regimens, adherence, adverse events and their management, changing treatment regimens, ART for children and TB treatment. In addition nurses attended PMTCT, and there were also training specific for initiating and managing children on ART and Tuberculosis.
3. Other trainings attended by either nurses or counsellors include:
    - Basic HIV counselling and testing
    - Adherence counselling for adults and paediatric
    - Running support groups, reducing stigma and enhancing disclosure
    - Basic Tuberculosis
    - PMTCT for lay counsellors

3.2.4 Staffing

The audit findings showed that all GP sites had a medical doctor and nurse (professional or enrolled nurse). Most of the GP sites also had lay counsellors (76%) and 82% had administrative clerks.

3.3. Demographic characteristics of women

The study included 301 women who received PMTCT services at designated GP sites between January 2008 and April 2010. A total of 117 (39%) women fell pregnant and enrolled on PMTCT while already on ART, whereas 183 (61%) women were not on ART. Table 3.2 shows that majority of women enrolled in the PMTCT programme were black (97%) and 3% had missing data. The median age of the women in this sample was 33 years (IQR 29-37 years), with most of the participants aged 30 years and older. Employment data was available on 106 of the 301 women enrolled, and 89% of the women in this study were unemployed.

Table 3.3 Demographics characteristics of women enrolled in the study

Demographic characteristics	Total number (%)	Already on ART	Not on ART
Age of participants			
19-24 years	18(6.0)	6(5.1)	12(6.5)
25-29 years	71(24.0)	15(12.8)	56(30.4)
30-34 years	99(33.3)	38(32.4)	61(33.2)
>35 years	109(36.7)	57(49)	52(28.3)
Median(IQR)	31(28-35)	34(31-38)	32(29-37)
Ethnicity			
Black	292(97)	115(98.3)	177(96.2)
White	1(0.3)	0	1(0.5)
Other	4(1.3)	1(0.9)	3(1.6)
Missing	8(3)	1(0.9)	3(1.6)
Employment status			
Employed	34(11.3)	15(12.8)	19(10.3)
Unemployed	72(24.0)	36(31)	36(20)
Missing	195(64.7)	66(56.4)	129(70.1)

3.4. Maternal characteristics

Of the 301 women who presented at the GPs sites for PMTCT, 103 (62.5%) presented after 20 weeks gestation (table 3.3). Only 16.9% of women presented before 12 weeks gestation. The median gestational age at first visit was 24 weeks (IQR: 16-28 weeks). Women who had CD4 count done were 91% (273/301). Of these 95% (260/273) had CD4 count values recorded in their files. The median CD4 count was 288.5 cells/mm3 (IQR: 184.5-448.5 cells/mm3). Viral load was done on 52.2% (144/301) of women, and of these, 81.3% (117/144) had record of results of viral load in their files. Of women with results of viral load recorded in their files, 45.3% (53/117) had a viral load of less than 400 copies (virally suppressed). The median viral load was 7692 copies (IQR 1914-24207).

The majority of women (58.5%), were categorised under WHO stage 1, followed by stage 2 at 15% and stage 3 were 9.3%. No woman was categorised under WHO stage 4. Approximately 17% of women were either not clinically staged or data was not captured at the site, and 17.2% (52/301) had no record of WHO staging. Most women (82.1%) were receiving lifelong ART, only 15.3% were on ART prophylaxis and 2.6% had missing data (table 3.4).

When comparing those who were already on ART and those who were not, more women already on ART booked before 12 weeks gestation (17%). Most women who were not on ART enrolled for PMTCT services after 20 weeks gestation (74%). CD4 count at enrolment was likely to be done on women who received prophylaxis as compared to those already on ART, the same with viral load.

Table 3.4 Maternal Characteristics

Clinical information	Total number (%)	Already on ART	New PMTCT Enrolment
Gestational Age at first visit (N=166)			
0-12 weeks	29 (16.9)	20(17.1)	9(5)
13-20 weeks	34(20.6)	12(10.3)	22(12.0)
>20 weeks	103(62.5)	25(21.4)	78(42.6)
Missing data	135(45)	60(51.3)	74(40.4)
Median (IQR)	24 (16-28)		
CD4 count done			
CD4 Count	260(86)	83(71)	176(96.2)
Median (IQR)	288.5 (184.5-448.5)	329(217-477)	276(172-431)
Viral Load			
Viral load suppression	117(39)	52(44.4)	65(35.3%)
Median viral load (IQR)	7692(1914-24207)		6120(1616-24030)
WHO stage			
1 & 2	176(58.5)	55(48)	121(66)
3	45(15.0)	23(20)	22(12)
4	28(9.3)	18(16)	10(5.4)
Unknown	52(17.2)	19(16.2)	30(16.4)
Treatment			
Prophylaxis	46(15.3)	0	46(25.3)
ART	247(82.1)	117(100)	30(71)
Other & unknown	8(2.6)	0	7(3.8)

3.5. Obstetrics Characteristics

Most women had a normal vaginal delivery (82%), and 18% of women had a caesarean section. Women who were not on ART at enrolment had more caesarean section (15%) as compared to 11% of those already on ART.

Table 3.5 Obstetrics Characteristics

Clinical information	Total number (%)	Already on ART	New PMTCT Enrolment
Mode of delivery			
Normal Vaginal	184(82)	83(72)	101(55)
Caesarean Section	40(18)	13(11.2)	27(15)
Missing Data	77(26)	20(17.2)	56(30.4)

3.6. Infant Characteristics

There were two hundred and twenty-two (73.7%) live births in this study (table 3.5). The mean infant weight at birth was 3kg (SD: 0.62g). Most infants had a birth weight of between 2.6-3kg (41.8%), with only 5% of infants with a birth weight below 2kg (5.3%). Infants from women already on ART were more, likely to be tested for PCR (81%) as compared to 67% of new enrolments. All infants who tested PCR positive were born by women who were not on ART at enrolment (3.2%). The majority of women exclusively formula fed their infants (63.1%), with only 7.3% (22/301) of women exclusively breastfeeding their infants. There were a small number of women who practised mixed feeding (1.3%).

The overall MTCT rate for HIV exposed babies whose mothers were enrolled between January 2008 and May 2010 was 1.8%. There were also a number of infants who were not tested or who did not have record of results (27.3%).

Table 3.6 Infant Characteristics

Clinical information	Total number (%)	Already on ART	New PMTCT Enrolment
Birth Outcome			
Live birth	222(73.7)	98(83.7)	124(67.4)
Still birth	3(1.0)	0	3(1.6)
Abortion	3(1.0)	1(0.9)	2(1.1)
Neonatal death	2(0.7)	0	1(1.1)
Unknown	71(23.6)	18(15.4)	53(29)
Feeding Method at around six weeks			
Exclusive breastfeeding	22(7.3)	9(7.7)	13(7.3)
Exclusive Formula feeding	190(63.1)	81(70)	109(62)
Mixed feeding	4(1.3)	4(3.4)	0
Unknown	85(28.3)	22(19)	55(31.1)
PCR Testing			
PCR test done	217(72)	20(17.1)	60(33)
PCR tests not done	80(27)	95(81)	122(67)
Missing data	4(1)	2(1.7)	1(0.5)
PCR Results			
Negative	213(98.2)	96(99)	119(96)
Positive	4(1.8)	0	4(3.2)
Missing data	82(27.3)	1(1)	1(0.8)
Birth weight			
< 2.5kg	35(16.5)	17(15)	18(10)
2.5 – 2.9kg	82(38.7)	38(32.4)	44(24)
3 – 3.5kg	72(34)	21(18)	36(20)
>3.5kg	23(10.8)	16(14)	22(12)
Missing data	89(30)	25(21.3)	64(35)
Median (IQR)	2.9(2.6-3.3)	2.8(2.6-3.2)	2.9(2.7-3.3)

3.7. Compliance to 2008 and 2010 national PMTCT Guidelines

In 2008 – 2009, all pregnant women were to be tested for CD4 count as it would determine whether a woman is eligible for lifelong ART or for prophylaxis. Therefore all HIV positive pregnant women should have had a CD4 count test. Two hundred and twenty one (91%) of women had a CD4 count done as baseline, which is more than the target of 80% which was set by NDoH in table 3.7.1. The median CD4 count was 280 cells/mm3 (IQR: 179-438 cells/mm3).

All women in this study sample were on either prophylaxis or lifelong ART, regardless of whether they had a CD4 count done. Many women (77%) were given lifelong ART including those who qualified to be on prophylaxis. Of those who were eligible for prophylaxis but had received ART, 44% fell pregnant while already on lifelong treatment (table 3.7.1). All women who were eligible for ART received ART, except one patient who did not have a record of receiving any treatment. The overall performance of GP PCR testing was 74% for HIV-exposed babies, which was higher than the 40% target from NDoH at the time of data collection.

Table 3.7.1 Compliance to PMTCT 2008 Guidelines (per PMTCT Cascade) by General Practitioners affiliated to The Aurum Institute: (N=243)

Data Element	2008 NDoH PMTCT Guidelines	NDoH target 2008/9	GP actual performance
CD Count testing	CD4 count to be done in all HIV positive pregnant women same day or at an earliest convenience.	80%	CD4 count done: 221(91%) CD4 count not done: 22(9%)
Eligible for Prophylaxis	HIV positive pregnant women with CD4 count of >200 were eligible to be initiated on AZT from 28 weeks gestation.	80%	CD4 count >200 Eligible for Prophylaxis: 141 Received Prophylaxis: 30 (21, 3%) Received Lifelong ART: 108 (77%) No record: 02(1, 4%)
Eligible for Lifelong ART	HIV positive pregnant women with CD4 count of ≤200 or WHO stage IV	No target	CD4 count <200 Eligible for Lifelong ART: 66 Received lifelong ART: 65(99%) No record: 01 (1%)
PCR Testing	Early infant HIV testing using HIV PCR at 6 weeks of age irrespective of feeding option	40%	PCR done: 179 (74%) PCR not done or no record: 64 (26%)

Table 3.7.2 shows that CD4 count testing was done at 93% (54/58) of women and 7% (4/58) was either not done or no record of CD4 count done.

The median CD4 count was 317 cells/mm3 (IQR: 217-461 cells/mm3). The 2010 PMTCT Guidelines required that all HIV positive women should be tested for CD4 count to assess eligibility for either lifelong ART or prophylaxis. Of those tested, 47% (22/54) were eligible for prophylaxis, but only 50% received prophylaxis (table 3.7.2). PCR testing in 2010 was lower 66% (38/58) as compared to 2008 PCR testing 74% (179/243).

Table 3.7.2 Compliance to PMTCT 2010 Guidelines (per PMTCT Cascade) by General Practitioners affiliated to The Aurum Institute (N=58)

Data Element	2010 NDoH PMTCT Guidelines	NDoH 2009/10 target	GP actual performance
CD Count testing	CD4 count to be done in all HIV positive pregnant women same day or at an earliest convenience.	None	CD4 count done: 54 (93%) CD4 count not done: 04 (7%)
Eligible for Prophylaxis	CD4 > 350 and WHO stage 1 or 2	80%	CD4 count >350 Eligible for Prophylaxis: 22 (38%) Received Prophylaxis: 11 (50%) Received Lifelong ART: 09 (41%) No record: 02(9%)
Eligible for Lifelong ART	CD4 < 350 or WHO clinical stage 3 or 4)	30%	CD4 count <350 Eligible for Lifelong ART: 31 (53.4%) Received lifelong ART: 29(94%)

			No record: 02 (6%)
PCR Testing	HIV-exposed infants should be tested for HIV at 6 weeks of age, or before 6 weeks of age if they are sick	80%	PCR done: 38 (66%) PCR not done or no record: 20 (34%)

3.8. Mother to Child Transmission rate at around six weeks

The MTCT rate for women enrolled using 2008 National PMTCT guidelines was lower (1%) as compared to women enrolled during the period when 2010 PMTCT National PMTCT guidelines were in use (table 3.8). When comparing with NDoH target, GPs met the <5% target. In 2010, there was no MTCT target because of data collection issues. The table 3.4 below shows the overall MTCT rate of 1.8%, which is less than below 2% target of reducing MTCT rate by 2015. Women who were already ART had no mother-to-child transmission, while women enrolled not on ART had 3.2% MTCT rate.

Table 3.8 Mother-to-child transmission rate

Description	**NDoH target**	**GP Actual performance**
MTCT rate 2008/9 PMTCT Guidelines	<5%	1%
MTCT rate 2010 PMTCT Guidelines	No target	5%
Overall GP MTCT rate	1.8%	

CHAPTER 4

DISCUSSION AND RECOMMENDATIONS

4.1. Introduction

This chapter discusses the findings of this study which aimed to describe the provision of PMTCT services among general practitioners affiliated with the Aurum Institute and their implications for PMTCT provision by GPs and in the public sector. The chapter also further discusses the strengths and limitations of the study and makes recommendations for further research in this area. The study found that GPs adhered to national PMTCT guidelines on CD4 count testing, provision of ART and PCR testing. Most women who were eligible for prophylaxis received ART. The overall MTCT rate was 1.8%. The study found that the MTCT rate was lower among women who became pregnant on ART than those initiating ART during pregnancy (0% versus 3.2%).

4.2. Discussion

4.2.1. Compliance to National PMTCT Guidelines according to PMTCT cascades

Missed opportunities along the PMTCT cascade can increase the chances of infecting the unborn infant. In this study, women who were enrolled on the programme, were either tested for HIV elsewhere or at the GP site. There was no record available of where they were tested in the database that used for analysis in this study.

4.2.1.1. CD4 count testing

The 2008 National PMTCT Guidelines outlined specific interventions that were to be carried out for an HIV positive pregnant woman. These included issuing ART according to PMTCT clinical guidelines to prevent vertical transmission of HIV to the unborn baby. (27). Similarly, in the 2010 PMTCT guidelines, this was mentioned as one of the main aims of the National PMTCT programme (6). According to the PMTCT clinical guidelines, all HIV positive pregnant women should be clinically staged according to WHO staging and have their CD4 cell count taken on the same day as their HIV test, and preferably at the first ANC visit (or the earliest opportunity) (27,6).

In comparison with the NDoH 2008/9 target, 80% of HIV positive pregnant women were to be tested for CD4 count, GPs enrolled in this study tested 91% of women and had exceeded the national target. Most women were tested for CD4 count at enrolment (91%) to assess eligibility for lifelong ART or prophylaxis. However, there were cases of women who were tested but their results were not recorded or where women did not have a CD4 count taken at all (<10%). This finding on CD4 count testing was similar to what was observed in Kwazulu-Natal (17), which found that 2.9% HIV-positive women did not have a CD4 count done and an additional 31.3% did not receive their CD4 results (17). Similar to the findings in this study, the majority of the HIV-positive women in the Kwazulu-Natal study were initiated on either PMTCT Prophylaxis or lifelong ART at their first antenatal visit independent of their CD4 result. (24). A local study conducted in the Eastern Cape, also reported similar findings. (25).

4.2.1.2. PMTCT Prophylaxis or Lifelong ART

The provision of either lifelong ART or Prophylaxis was dependent on the results of the CD4 count and clinical staging of women at first consultation. If these were not done, it meant the pregnant woman would not receive appropriate treatment. In the current National PMTCT guidelines, CD4 count is no longer an eligibility criteria for either lifelong ART or prophylaxis as compared to 2008 and 2010 National PMTCT guidelines (26).

Some women in this study did not receive treatment as per the 2008 and 2010 National PMTCT Guidelines. Aurum GPs preferred to prescribe lifelong ART even when some women were eligible for prophylaxis and no justification for issuing lifelong ART was found in the patients' files, except for 44% of women from 2008 who fell pregnant while they were already on ART. Although this was non-compliance with guidelines, it was in the best interest of the patient as later guidelines showed that lifelong ART regardless of CD4 count was better for the mother (8).

The findings in this study concur with previous local studies (17). A Kwazulu-Natal study revealed that among the women who had a CD4 result, 48% were eligible for HAART according to the 2008 PMTCT guidelines, but 96.8% of the HIV positive women initiated dual ART prophylaxis for PMTCT independent of their CD4 result; and 9.2% of all HIV positive pregnant women initiated HAART (17). Among the women eligible for HAART (CD4<200 cells/mm^3), 29.1% initiated HAART during their pregnancy and 18 (2.9%) of HIV

positive pregnant women did not receive any antiretroviral drugs for PMTCT or treatment (17).

GPs participating in this study did not adhere to PMTCT treatment guidelines when prescribing prophylaxis as more women received lifelong ART even though they were ineligible. However, GPs adhered to national guidelines when prescribing lifelong ART to those who were eligible. The pharmacy prescriptions that were written by GPs were reviewed by clinicians at Aurum Institute, who in most cases changed the scripts to align them with guidelines.

4.2.1.3. PCR testing at around 6 weeks

There were approximately 34% of infants in this study who did not have a record of PCR testing at around six weeks of age in their mothers' files. This does not necessarily mean that these infants did not undergo PCR testing, but they may have been tested at public clinics at their six weeks immunization visit. Some mothers brought the results of tests conducted at public health care facilities to their GP visits to avoid further testing but others were unable to produce results.

Both the 2008 and 2010 National PMTCT guidelines mentioned one of its specific interventions as offering HIV testing using HIV PCR to HIV-exposed babies at six weeks immunization visit irrespective of whether the baby is breastfed or formula fed. (27,6). PCR testing conducted by Aurum-affiliated GPs in this study (at 72%) was higher than PCR testing coverage rates reported in similar studies in South Africa (17, 26).

When comparing the results of this study with the NDoH performance of 2008-2010, the GPs in this study complied with the PMTCT Guidelines and performed above the national target of 40% and 80%. When using the 2008 PMTCT guidelines, GPs conducted PCR tests for 74% of infants, which was still above national target of 40%.

When comparing to 2010 National PMTCT guidelines, GPs tested 66% of infants, which was below the national target of 80%, but above the NDoH actual performance of 54.6% (6).

4.2.2. Mother-to-child transmission rate

1.5.1.1 **An overall mother to child transmission rate at around 6 weeks (4 – 12 weeks).**

The overall mother-to-child transmission from the Aurum-affiliated GP programme was 1.8% in 2008 – 2010. For women who were enrolled using the 2008 PMTCT guidelines, the MTCT rate was 1% which was below the 5% NDoH target (27). This finding is consistent with previous studies which showed a relatively low mother-to-child transmission rate of 1.2% in women who received HAART by doctors in the private sector (14). These results highlight the opportunities reflected by National Strategic Plan (NSP 2012-2016) for private sector doctors to respond to South Africa's leading epidemics like HIV/AIDS (14).

For those enrolled using the 2010 PMTCT guidelines, the MTCT rate was 5%, which may be explained by the small number of women who were enrolled using 2010 PMTCT guidelines (43 women). In this study, the four women who delivered HIV positive infants, all received ART while already pregnant. Previous studies showed that women who received ART while already pregnant have a greater chance of transmitting HIV to their infants (24). There was no target from NDoH in 2010 but MTCT rate higher than the UNAIDS global elimination of mother-to-child transmission rate of <2% by 2015. There are no comparable studies found

which evaluated MTCT rate at the GP sites in South Africa. Evaluations that have been conducted were on the contributions of GPs in the provision of HIV services and thereby contributing towards reduction of HIV and TB.

The evaluation of the effectiveness of the national PMTCT programme conducted by MRC in 2010, reported a MTCT rate of 3.5%, which was lower than the 2010 MTCT rate in this study (12). The overall MTCT rate of 1.8% showed that PMTCT programme offered by GPs was more effective as compared to the public sector programme, though GP had smaller patient caseload as compared to public sector. Despite unavailability of PMTCT/ART guidelines at GP sites at the time of audit in 2010, this did not affect the performance of GPs negatively, as the MTCT rate is still lower than the NDoH 2013/14 MTCT rate of 2% against the 2008/10 GP MTCT rate of 1.8%.

1.5.1.2 **Mother-to-child transmission rate: Women enrolled on PMTCT while on ART versus women enrolled on PMTCT while not on ART**

Infants born to women who were enrolled on PMTCT while already on ART all tested negative at around six (6) weeks, meaning the MTCT rate for this group of women was 0%. All infants who tested PCR positive at around six (6) weeks were from women who were enrolled on PMTCT while not on ART. The MTCT rate of women who received ART while already pregnant was 3.2% as compared to 0% MTCT rate from women who were already on ART. The findings were similar to those from the study conducted in Johannesburg clinics between 2004 and 2008, which found that MTCT rates were lower in women who became pregnant on HAART than those initiating HAART during pregnancy (0.7% versus 5.7%), thus concluding that late initiation of HAART is associated with increased risk of MTCT (28).

4.2.3 Site Level Factors

The site level factors which were considered in this study included the availability of national PMTCT guidelines, the availability of health professions and the HIV/AIDS/TB training received by GPs and their staff. The Aurum Institute (15), took the following factors into consideration when recruiting and enrolling GPs to participate into the programme and the site level factors observed in this study will be discussed using their criteria for enrolment onto the programme (15).

4.2.3.1 Site Eligibility

Site eligibility was important for this study in order to assess if GPs complied with what was expected from them. One of the criteria for enrolment of GP sites into the Aurum programme was that the GP and the nurse must attend the Aurum ART initiation training before they could be allowed to run the Aurum Institute HIV programme. Thereafter, Aurum Institute delegates assess the sites and provide the GP with patient files, guideline documents and data collection tools (15). Thus, all GPs sites were expected to have PMTCT/ART clinical guidelines for reference when consulting patients.

4.2.3.2 Training

Training for the GPs and their staff was to assess their knowledge and skills to provide HIV services. The Aurum Institute offered various HIV/AIDS management training courses to all its affiliated GPs. These training courses includes:

- Three day HIV/AIDS management training course before initiation of the site
- Two day HIV/AIDS clinical training course which covered topics like ART treatment, ART adherence, adverse events, management of adverse events, tuberculosis management, ART for adults, adolescent and children. This course was intended for both doctors and Professional nurses.
- PMTCT training course (15)

Apart from the clinical courses offered to doctors and nurses, Aurum Institute offered the social courses which GPs were required to at least send a nurse or counsellor where there is any. These courses includes ART adherence counselling, running support groups, reducing stigma and enhancing disclosure, and ART adherence counselling for children (15).

In addition to entry training, in service training were also provided to all doctors, nurses and other staff to keep them updated with new development regarding Guidelines and management of HIV positive patients. All general practitioners sites were given HIV/TB Guidelines for reference, and new Guidelines were also distributed as they were introduced (15). All GP sites in this study, and their staff, had received HIV/PMTCT/TB training from Aurum Institute. This was in contrast to findings reported in prior studies, where GPs reported not feeling confident enough to diagnose, treat and manage HIV positive people because of lack of training (17).

4.2.3.3 Ensuring quality

The Aurum Institute made sure that the programme run smoothly and that quality work was done, for example: all prescriptions from the GPs were first assessed by Aurum Institute clinicians to ensure they adhered to national HIV/AIDS/PMTCT clinical guidelines before they could be sent to pharmacy for dispensing of medication. The clinicians form Aurum Institute were also available to GPs to answer any clinical questions through email, telephones and site visits (15).

Aurum Institute had site coordinators allocated to all GP sites to conduct monitoring visits every three months. During these monitoring visits, site coordinators would check patient files for completion, adherence to national HIV/AIDS/PMTCT clinical guidelines, and submission of clinical forms to Aurum Institute for capturing and answer any questions as much as they could (15). Patient files were selected randomly by site coordinators for assessment of above activities. Reports were produced and recommendations made (15).

When comparing the study findings and measures which were put in place by the Aurum Institute in ensuring that GPs an effective HIV programme, it is probable that these measures contributed positively to the outcomes of this study.

4.3. Strengths of the Study

This study includes data of HIV positive pregnant women receiving PMTCT services at GP sites across all nine South African provinces affiliated to Aurum Institute. It is one of the few studies examining the public-private partnership between government and private GPs offering PMTCT services.

4.4. Study Limitations

The following study limitations have been identified:

- The study was only confined to private GPs affiliated to The Aurum Institute and users of their services. This does not mean that GPs not affiliated with Aurum Institute were not providing HIV and PMTCT services. This was for convenience of the researcher as an employee of Aurum Institute at the time that the study was conducted. Aurum Institute had access to data as a funder of this programme.

- Because GPs from this study received considerable support in the provision of the services which includes training and mentoring of staff both onsite and offsite, provision of stationery and patients files, finance, provision of clinical guidelines, data capturing and quality assurance), the findings of the study does not represent all GPs providing PMTCT services and the women receiving PMTCT services through GPs in South Africa. Thus there are limitations to the generalizability of the study findings.

- The PMTCT cascade starts with HIV testing and diagnosis and this component was not included in the study. Therefore, the association between the time of testing and outcome of PMTCT programme cannot be accounted for in the study.

- As this was a retrospective record review, some relevant and very important information was missing due to incomplete data completion in the patient files. In some instances, the researcher used patient progress notes to obtain relevant missing data.

- Data on labour and delivery were not included in the study as this service was not provided by the GPs and their staff. Though Nevirapine to swallow during labour was issued by GPs, there was no data which indicated that women swallowed Nevirapine and other labour and delivery drugs; and thus these practices cannot be accounted for in the study.

- The GPs audit was conducted at a single point in time in 2011 and the main reason for the audit (from Aurum Institute) was to quantify loss to follow up and to establish reasons behind these loss to follow ups. It was not meant to establish the site level factors contributing to either adherence or non-adherence to PMTCT guidelines.

- The study sample was too small to find a significant association between PCR positivity rate and patient individual factors or site level factors. There was no dedicated employee from Aurum Institute who was coordinating PMTCT offered by GPs before 2008 and enrolment of women on PMTCT and HIV programme in general was stopped on the 30th April 2010 due to funding constraints. The outcome of the study might have been different if there were an increased number of participants.

- The individual and site level data were not linked on data collection, which made it impossible to determine any association between individual and site level factors in the study.

Despite these limitations, the data available provides useful information about the provision of PMTCT services by private GPs in the context of a public-private partnership in South Africa.

4.5. Recommendations

4.5.1 Recommendations for policy and practice

According to data collected by the World Health Organization (WHO) in 2006, approximately twenty one percent of patients receiving antiretroviral therapy (ART) in six

African nations (Botswana, Kenya, Namibia, Nigeria, South Africa, and Uganda) were receiving treatment in the private sector (28). Despite these potential benefits, including private sector involvement in the national strategy for meeting HIV needs has often been overlooked in some regions due to quality concerns about provider training, prescribing standards, regular testing and monitoring of HIV patients, adequate counselling on prevention, and appropriate management of opportunistic infections, among other things (28).

The findings for this study highlight the importance of public-private partnerships with GPs and also encourages such initiatives to reduce the workload at the PHC level. The following are recommended:

- GPs should on a regular basis receive training and updates on HIV and TB care and management.
- There should be mentoring and supervision of GPs by DoH to ensure that better quality of services are rendered.
- HIV and TB clinical guidelines should be distributed to all GP sites and they should be mandated to follow NDoH guidelines,
- GPs should provide monthly and quarterly reports to the nearest clinic/hospital for the services they are rendering for reporting purposes.
- GPs should utilize the same data collection forms from DoH for HIV and TB services.

4.5.2 Recommendations for further research

There are limited studies conducted to evaluate services rendered by GPs globally and in in South Africa. Therefore, the study recommends that further research to evaluate HIV and TB services rendered by GPs not affiliated or in private public partnership with any institution be

conducted. Further research is recommended to include the views of women or recipients of services to determine their experience of receiving HIV care through private GPs.

4.6. Conclusions

The GPs adhered to most of PMTCT cascades and exceeded the NDoH target for CD4 count testing in 2008 and 2010, ART provision in both 2008 and 2010 and PCR testing in 2010 National PMTCT guidelines. GPs did not adhere to provision of PMTCT prophylaxis, as most women who were eligible for prophylaxis received lifelong ART. Though all GPs were provided TB and HIV guidelines, during the audit most of the GPs did not have guidelines at their sites at the time of audit. The study concludes that with proper training, support and mentoring, private GPs can render comprehensive PMTCT and HIV services. The study also highlighted the need for ongoing training and mentoring of GPs contracted to the NHI pilot districts and seconded to the primary health care facilities (PHC). Proper use of National PMTCT Guidelines coupled by public private partnership plus the above mentioned recommendations can assist in further the reduction in the MTCT rate in South Africa and other countries facing similar challenges.

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PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I Mashapha Thililelwi Shirley (Student number: 213023) am a student registered for the degree of Masters in Public Health (Maternal and Child Health) in the academic year 2010.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature:

Date: 15.02.2016

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To whom this may concern

DATE	20.09.2011
NAME OF STUDENT	Thililelwi Shirley Mashapha 213023
ADDRESS OF STUDENT	Unit 143 Southern Villas, Daphne street, Naturena, 2095
TELEPHONE NUMBER	Cell: 084 941 2522 Work: 011 484 8844
FAX NUMBER	086 577 5208
RESEARCH TOPIC	Prevention of mother to child transmission of HIV practices by private general practitioners affiliated to the Aurum Institute.
PROGRAMME AREA	PMTCT programme at the Private general practitioners

This letter serves to indicate that approval is hereby granted to the above-mentioned student to proceed with research in respect with the study indicated above. The Aurum Institute grants the student to use data collected from the women attending the prevention of mother to child transmission of HIV/AIDS care and treatment at the general practitioners affiliated to Aurum Institute. Confidentiality for all patients eligible for study will be maintained by ensuring allocation of study numbers, no names or identity number will be used during the study and only those involved in the study will have access to the data. The Aurum Institute wishes her well in this important undertaking and looks forward to examining the findings of this research.

Sincerely,

Dr. Salome Charalambous
Associate Director

Title: Prevention of mother to child transmission of HIV practices by private general practitioners affiliated to the Aurum Institute.	**Data abstraction form: individual level data**

	1.	**Client code**	**Site Number:**
	2.	**Date data abstracted from client's record**	**Day** **Month** **Year**
	3.	**Time data abstraction commenced (24 hour clock)**	**hrs.**
	4.	**Date enrolled in the HIV care at GP practice**	**Day** **Month** **Year**

Client eligibility

	1.	**Was the client registered for PMTCT services through an Aurum affiliated doctor** 00=No; 01=Yes	
	2.	**Date client registered for PMTCT**	**Day** **Month** **Year**
	3.	**Is the client eligible for inclusion into the study?** *(client is eligible if answer for Q1= Yes and client is registered between January 2009 and September 2010)* 00=No; 01=Yes	

The following section should only be completed if the client is eligible for inclusion into the study

Demographics

	1.	**Client's date of birth** 01/JAN/97 = N/A 01/JAN/98 = missing CRF data	**Day** **Month** **Year**
	2.	**Age**	
	3.	**Client's ethnicity** 01=Black/African 02=Coloured/Mixed Race 03=Indian/Asian 04=White/European 05=Other, record 98=Missing CRF data	If other specify:
	4.	**Employment status at enrolment** **01=employed** **02=unemployed** **03=missing data in the record**	

Clinical information

	1.	**Gestation age at first visit (weeks)**	☐☐
	2.	**Gestation age at initiation of PMTCT Prophylaxis or PMTCT HAART (weeks)**	☐☐
	3.	**Was the client already on HAART at PMTCT enrolment?** 00=No, 01= Yes	☐☐
	4.	**Type of treatment/drug regimen** 01= PMTCT prophylaxis (AZT from 14 weeks or later) 02=PMTCT HAART (TDF+3TC/FTC+NVP or EFV) 03=AZT+3TC+NVP 04= Other 05=No treatment 98= missing data in the records	☐☐ Explain……
	5.	**Date treatment prescribed**	☐☐ ☐☐ ☐☐ **Day Month Year**
	6.	**Date treatment issued**	☐☐ ☐☐ ☐☐ **Day Month Year**
	7.	**WHO clinical stage** 01 = Stage 1 or 2 02= Stage 3 03=Stage 4 98= missing data in the records 99= not done	☐☐
	8.	**Was baseline viral load done?** 00=No; 01=Yes **Baseline HIV viral load (copies/ml)** Date viral load done	☐☐ ☐☐ ☐☐ ☐☐ **Day Month Year**
	9.	**Was the baseline CD4 count done?** 00=No; 01=Yes **Baseline CD4 count (cells/mm^3)** Date CD4 count done	☐☐ ☐☐ ☐☐ ☐☐ **Day Month Year**
	10.	**Type of delivery** 01= NVD 02=C/Section 98= missing data in the records	☐☐
	11.	**Birth outcome** 01= Live birth 02=Still birth 03= Abortion/miscarriage 04=Neonatal death 05=Loss to follow up 97= N/A (did not give birth) 98= missing data in the records	☐☐
	12.	**Current feeding method reported at around 6 weeks** 01= Exclusive breastfeeding 02= Exclusive formula feeding 03= Mixed feeding 98= missing data in the records **Did the baby ever breastfed?** 00=No; 01=Yes	☐☐ ☐☐
	13.	**Birth weight**	☐☐

	14.	**Was the PCR done?** 00=No; 01=Yes 98= missing data in the records	☐☐
	15.	**PCR result** 01= HIV negative 02=HIV positive 98= missing data in the records	☐☐
	16.	**Date PCR done**	☐☐ ☐☐ ☐☐ **Day** **Month** **Year**

Completion of data abstraction

	1.	**Time data abstraction completed**	☐☐ ☐☐ **hrs**
	2.	**Initials of person abstracting data**	
	3.	**Signature of person abstracting data**	

Title: Prevention of mother to child transmission of HIV practices by private general practitioners affiliated to the Aurum Institute.	Data abstraction form: Practice level data

Date of audit:

Day		**Month**		**Year**		

Time data abstraction commenced (24hour clock):

1. Geographical information

Province:	District:	Sub-district:	Practice/Site number:

2. Guidelines

	At the time of audit did the site have?	**00 = No, 01 = Yes**
2.1	HIV counselling and testing guidelines	
2.2	PMTCT guidelines	
2.3	Paediatric guidelines	
2.4	ART guidelines	
2.5	Post exposure prophylaxis guidelines	
2.6	Tuberculosis guidelines	
2.7	Pre-Art/Wellness guidelines	

3. Statistics at the time of audit

3.1	Total number of empty files ever issued	
3.2	Total number of current active files	
3.3	Total number of deregistered files	
3.4	Total number of death	
3.5	Total number of transfer out	
3.6	Total number of lost to follow up	

4. Patients on treatment/prophylaxis in the practice at the time of audit

Total Number of:

4.1	patients on ART	
4.2	patients on Cotrimaxazole Prophylaxis	
4.3	patients on INH Prophylaxis	
4.4	patients on PMTCT Programme	
4.5	paediatric patients on ART	

5. Staffing and Training at the time of audit

5.1 List the category of staff involved in the Aurum HIV/AIDS and TB programme

- ……..
- ……..
- ……..
- ……
- ……..
- ……...

5.2 List the trainings your staff attended from Aurum Institute

- ……
- ……
- ……
- ……..
- ……
- ……

6. Equipment's and assets

At the time of audit, did the practice have: 00 = No, 01 = Yes

6.1	Desktop/Laptop computer	
6.2	Fax machine	
6.3	Printer	
6.4	Internet access	
6.5	Email address	

	Time data abstraction completed (24hour clock)	
	Initials of person abstracting data	
	Signature of person abstracting data	

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Thililewi S Mashapha

CLEARANCE CERTIFICATE **M121033**

PROJECT Prevention of Mother to Child Transmission of Human Immunodeficiency Virus (HIV) Practices by Private General Practitioners Affiliated to the Aurum Institute

INVESTIGATORS Ms Thililewi S Mashapha.

DEPARTMENT School of Public Health

DATE CONSIDERED 26/10/2012

DECISION OF THE COMMITTEE* Approved unconditionally

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

DATE 26/10/2012 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr Mimie Jordaan

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...