

**A Retrospective clinical chart review study on the core
PMTCT activities at a regional hospital in Durban,
Kwa Zulu-Natal**

**Submitted in partial fulfilment of the requirement for the
Course work Masters Degree in Nursing
(Nursing Research)**

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Declaration

I, **Wilbroda Hlolisile Ngidi**, declare that A Retrospective Clinical Chart Review study on the core PMTCT activities at a Regional Hospital in Durban, Kwa Zulu-Natal is my own work and has not been submitted for any other degree or examination. All the sources have been acknowledged and indicated in the reference list.

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Dedication

This research is dedicated to my precious daughter, Amahle Bandile Ngidi.

Acknowledgements

My sincere acknowledgements go to the following individuals for their tireless support in assisting me to complete this research.

To the Almighty for giving me the strength, the courage and the wisdom to complete this research in spite of the challenges experienced.

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ABSTRACT

Background:

Despite years of implementation, the program for PMTCT is not reaching the HIV positive pregnant women. Poor documentation as well as poor monitoring and evaluation for the program has contributed to the poor performance. This has led to South Africa being one of the 12 countries in the world with an increasing child mortality rate which is related to HIV/AIDS. Multi-steps and the complexity of the program and poor documentation have resulted in gaps in the provision of care.

Objective: The aim of the study was to assess the documentation of the core activities of Prevention of Mother-to-Child Transmission of HIV program provided to pregnant women from antenatal, maternity and post-natal care at a selected Regional hospital in Ethekeini District.

Methods: A non-experimental retrospective descriptive exploratory design informs the study. Provides a description of whether the activities of PMTCT are performed through the use of documented activities on patient's charts. A data extraction tool was used to extract information, with the demographic information as well as the key activities of PMTCT. One hundred and thirty charts of women who had delivered in the hospital of study were sampled.

Results: The study revealed gaps in the documentation of some activities, with dual therapy initiated at antenatal clinic documented to be n=98(75%), whilst NVP to the baby was 105/130 (80%). The results are in contrast with Horwood's (2010) study which reported 91% receiving the Nevirapine prophylaxis. Although there are children missed by the program, it is interesting to note that more babies are receiving prophylaxis compared to women receiving NVP. The cd4 count, n=78(60%) uptake, seems not to be doing well, with only n=45(35%), which is supported by Horwood's (2010) study that showed much improvement in the cd4 uptake (70%) compared to the study results of 60%, but less cd4 results documented were reported by Horwood (2010), showing 33% respectively. **Conclusion:** The National strategic Plan's (SADOH, 2007-2011/2013) for South Africa, as well as the global Millennium Development Goals can only be achieved if all the activities for the PMTCT are improved. Documentation of activities remains the key to improved care.

ABBREVIATIONS AND ACRONYMS

3TC	Lamivudine
ANC	Antenatal Care
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
ART	Antiretroviral Therapy
AZT	Zidovudine
d4T	Stavudine
DT	Dual therapy
DOH	Department of Health
EFV	Efavirenz
EPI	Expanded Program on Immunization
HAART	Highly Active Antiretroviral Therapy
HIV	Human Immunodeficiency virus
LPV/r	Lopinovir/ ritonavir
MTCT	Mother-to-Child Transmission of HIV
NDOH	National Department of Health
NHC	National Health Council
NSP	Strategic Plan
NVP	Nevirapine
PCR	Polymerase Chain Reaction
PMTCT	Prevention of Mother-to-Child Transmission of HIV
RTHC	Road to Health Chart
SD NVP	Single-Dose Nevirapine
SADOH	South African Department of Health
TDF	Tenofovir
UNAIDS	United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund
UNMDG	United Nations Millennium Development Goals
VCT	Voluntary Counseling and Testing
WHO	World Health Organization

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CHAPTER 1

1.1 Introduction and study background

Human Immuno-deficiency Virus (HIV), the virus that causes Acquired Immuno-Deficiency Syndrome (AIDS) has become a world epidemic, and is evolving at speed around the world. Recently, an estimated decline in AIDS related deaths globally, from 2,1 million in 2004, to 1,8 million in 2009 was reported (UNICEF, 2010), whereas 32,8 million people are living with HIV globally, compared with 33,4 million reported in 2004. The decline implies that fewer people are dying of AIDS related deaths. In a global report, (2010) USAIDS estimated a 19% reduction in new infections of HIV/AIDS, with an estimated 5% global HIV prevalence reported by UNAIDS (2010), which indicates a reduced number of people who are already infected.

1.1.1 The situation in South African Context

Although this seems to be positive news, South Africa remains one of the sub-Saharan African countries with a continued rise in maternal and child mortality, and one of the 20 countries that had the highest HIV burden reported worldwide (WHO, 2010) with approximately 28% prevalence of HIV, compared to other countries which range from 5% to 28%. Of the 500 000 new HIV infections in South Africa, 140 000 are from KwaZulu-Natal, which is reported to be the most severely affected by the epidemic (UNICEF, 2010). At the end of 2007, women accounted for 50% of all adults living with HIV worldwide, of which 59% are in the sub-Saharan region (UNAIDS, 2008). With women more greatly affected, and at higher risk compared to men, HIV is even more widespread in pregnant women, which results in an increased risk for children.

1.1.2 The prevalence of Human Immuno-deficiency Virus in pregnant women

The National seroprevalence Survey which reports on the infected pregnant women per annum, has indicated that 40, 5 % of seroprevalence is reported in South Africa as a whole, with Kwa Zulu-Natal second on the list amongst the provinces at 38.7% (SANDOY, 2009). The high prevalence has led to a rise in children dying due to HIV related causes. This prompted the need

for the prevention of HIV/AIDS in children. More than 90% of children living with HIV are infected during pregnancy; labour, during delivery, or by breastfeeding (WHO, 2006).

1.1.3 Reducing child mortality to curb the epidemic

The millennium development goal for child survival requires countries to reduce child mortality by two thirds before 2015 (UN, 2000), which mainly are due to the burden of paediatric HIV. According to UNAIDS, (2010) globally an estimated 370 000 children per 1000 000 child births (220 000– 520 000) contracted HIV during the perinatal and breastfeeding period, which has reduced compared to 500 000 (320 000– 670 000) transmissions in previous years. This has been credited to the Prevention of Mother-to-Child Transmission of HIV program, as well as improved access to anti-retroviral treatments compared to previous years. A decline is also noted in the recent report from UNAIDS (2010) from 99 per 1 000 live births in 2005 as reported by Rollins (2006), to an estimated 61.9 deaths per 1 000 live births. The decline is not sufficient for South Africa to reach MDG (Millennium Development Goal 4) (2000) by 2015, which amongst other aims, intends to reduce child mortality by two-thirds.

1.1.4 Interventions to reduce transmission rate

The introduction of the Prevention of Mother-to-Child Transmission of HIV program (PMTCT) which aims at reducing the transmission of HIV/AIDS from HIV positive women to their children to improve child and maternal survival, has been a success in some countries. Botswana experienced reduced transmission to less than 3,5% respectively (Stringer, 2009). The results in Botswana, one of the countries in the sub-Saharan developing region has shown that the program has a high potential to improve maternal and child health, thereby reducing transmission to less than 5% which results in reduced child mortality, if implemented properly, and provided all the required interventions are documented.

Documentation of PMTCT activities remains critical to be able to evaluate if all the processes of care has been rendered. As Dohrn (2008) has discovered inconsistent documentation of cd4 cell count and recording of baby NVP(Nevirapine) This program can even be effective in third world countries, if no opportunity is missed by women and children in receiving the processes of care shown by documents. Without any intervention treatment, the risk of Mother-to-Child

Transmission (MTCT) is estimated between 20 to 45% (WHO, 2010). This implies that if there is no treatment given to women and children, transmission will continue to rise, resulting in further child mortality. The program requires that pregnant women attend antenatal clinics to access all the activities required by the program. In European countries, a transmission rate lower than 2% was reported after the successful implementation of the program (Doherty, 2007). The rate at which sub-Saharan Africa utilises antenatal care has improved to above 90% (WHO, 2010). This provides the opportunity of testing pregnant women so that they are able to access antiretroviral prophylaxis (Dual therapy) to reduce the possibility of Mother-to-Child Transmission.

1.1.5 The importance of documentation

The successes of the program rest on the role of the health provider in utilising the available interventions, as well as the quality of health service rendered. Health Systems Research (2002) highlighted adequate staff as the key to improving quality of care. Documenting intervention is one of the crucial elements in ensuring that the quality of health service was rendered throughout the client's pregnancy.

With the revised PMTCT guideline (Dual therapy prophylaxis) which was implemented in South Africa from April 2002, health workers have received training that prepares them and equips them with the knowledge regarding the program to be able to put women on antiretroviral therapy, however, not all women who are eligible are reached by the program (Horwood, 2010). The program was revised for 2010 (DOH: 2010), but the study will focus on the DOH guidelines (2008).

With the multi-step of the program, and the complexity of it occurring at different levels of care (antenatal clinic, maternity section, and post-natal) according to Stringer, (2009) appropriate documentation of the activities for the PMTCT program, effective data collection, including monitoring and evaluation are crucial to show performance. Documentation is an integral part of quality and the ensuring of safe care for patients. In nursing and health care, the patient record is considered a legal document, and a lawsuit can be filed against a health worker who has failed to

document. The continuity of care for the patient relies on what is documented (Barker, 2000), so that any co-worker is able to pick up a chart and understand clearly the status of the patient's condition and the care rendered. With PMTCT, the requirement of the chart review remains an important measure to determine whether the program was implemented as planned.

1.1.6 Core Prevention of Mother-to-Child Transmission of HIV Program activities

In this study, these are thirteen core PMTCT activities that are undertaken during the client's antenatal care through to delivery which should be documented on the patient's records (DOH, 2008). These activities will be regarded as the gold standard in this study for the program.

I. Dual therapy (DT) initiated at Antenatal clinic

A combination of two anti-retroviral prophylactics as therapy offered to HIV positive pregnant women to take during labour. At the time of the study this was given at 28 weeks of gestation.

II. DT taken for more than four weeks

Studies have proven that the longer the duration of the drug intake by pregnant women, the more effective it is. If the women had attended antenatal clinic regularly (at least four times or more), an opportunity for a longer duration of treatment would be provided by the time the women delivered.

III. Dual therapy (sd NVP and AZT) to women

All tested HIV positive women should have received the above two drugs by the time they deliver.

IV. AZT taken three-hourly during labour

Guidelines stress the importance of women receiving AZT at three-hourly intervals while they are in labour until such time as they deliver.

V. Cd4 count taken

It is a requirement that all HIV positive women should have their cd4 cell count taken to determine their eligibility for lifelong Anti-retroviral (triple therapy, if cd4 is equal to or less than a 200 cell count) therapy. The test should be done the same day a client tests positive, to fast-track women for treatment.

VI. Cd4 results documented

After the test has been carried out, the results should be available within a week or two of the taking of the specimen. If the results are not documented, women may miss the opportunity to be started on treatment in time for their own health (ART triple therapy) or for PMTCT (Dual therapy prophylaxis).

VII. Cd4 count below

If the results are 200 or below, a woman should be prepared to start ART triple therapy (3TC, AZT, NVP) within two weeks.

VIII. above 200 cell count

When the results come back, every woman whose cd4 count has been done should have these results documented in the patients' documents. Further management depends on whether the cd4 count is below or above the 200 cell count. If the results are above a 200 cd4 cell count, and the patient was clinically assessed and found to be stage one or two (has signs that do not qualify for lifelong therapy) a woman should continue with dual prophylaxis.

IX. HAART initiation if low cd4 (below 200 cd4 cell count)

If the cd4 is 200 and below, the client should be started on lifelong ART and not on DT within two weeks of testing HIV positive.

X. The World Health Organisation clinical staging (WHO Staging).

All women who tested HIV positive should be clinically assessed to determine eligibility for lifelong Antiretroviral therapy regardless of their cd4 cell count. This criterion lists all the clinical signs and symptoms to choose from in order to assess clients.

XI. Infant feeding counselling at ANC

Women should be offered infant feeding counselling, so that they can make informed choices.

XII. Formula feeding choice

The formula is supplied free of charge from the public hospital, but this is only if the criteria called AFASS have been followed (screening assessing the accessibility, acceptability, feasibility, sustainability and safeness of choosing the method for feeding). This will minimise mixed feeding, and reduce post-natal transmission of HIV through breast milk.

XIII. Breastfeeding.

Choice of feeding should be made by the time of delivery. It should be clearly documented on the patients' records whether breast milk or formula is the method of choice. Women make the choice guided by the health worker.

XIV. NVP to baby within 72 hours

The baby should receive NVP within 72 hours of delivery for MTCT.

XV. DT to baby to be given at home

Children should receive the syrup post-delivery, which mothers should continue to administer at home. The length of the administration of medication, whether 7 days or 4 weeks is determined by the length of DT by the women while pregnant. If the DT was taken for more than 4 weeks by the women, then the babies should be given the medication for 7 days only, but if the DT was taken for less than 4 weeks by the women, then the children should take a daily treatment for 4 weeks.

1.3 Problem statement

Documentation by health workers is critical in the provision of intervention measures. With the multi-steps in the provision of PMTCT activities occurring at different settings in different times, missed opportunities may occur at each step. A study by Rollins (2005) revealed a gap in the

provision of antiretroviral prophylaxis treatment to eligible pregnant women, as well as poor monitoring and evaluation of the program for PMTCT. Rollins also identified that it is not drug availability which led to women not receiving dual prophylaxis (missed opportunities); according to him, the challenge was the gap in the health system, which includes monitoring tools, and documentation of interventions. As outlined in a recent study by Horwood (2010) examined the evaluation of the PMTCT and showed that gaps still exist in the provision of PMTCT.

The saying goes that if it is not documented it is not done. Amongst other studies, a study in Nigeria, Chandra (2009) noted that the assessment of quality through reviews led to improved care. The study also identified poor data recording by health workers as one of the reasons resulting in poor scaling-up of the PMTCT.

It is for this reason that the study will review charts to assess whether the PMTCT program activities are rendered as per the Department of Health guidelines (DOH, 2008).

1. 4 Purpose of the study

The aim of the study was to assess the documentation of the core activities of the Prevention of Mother-to-Child Transmission of HIV program provided to pregnant women in antenatal, maternity and post-natal care at a selected Regional hospital in the Ethekeini District.

1. 5 Study Objectives

1. To describe the processes of the PMTCT activities as documented in patients' clinical records.
2. To assess the performance of the PMTCT activities by providing the proportion of charts with complete documented PMTCT core activities as per revised PMTCT guidelines.
3. To explore the relationship amongst the core activities of the PMTCT as documented in patients' records.

1.6 Research Questions

1. How are the processes of core PMTCT activities documented in patients' records?
2. What is the proportion of charts with documented core PMTCT activities in patients' records?
3. What the relationship between the core activities of PMTCT is as documented in the charts?

1.7 Significance of the study

Based on the challenges of the poor performance of the PMTCT as a result of poor documentation, monitoring and evaluation as documented in the background still remains vital. Horwood (2010) identified gaps in the provision of quality care, leading to increasing child mortality which still remains a challenge (Horwood, 2010). This study will provide a new body of knowledge as to whether core activities for the PMTCT program are provided at the Ethekewini District Regional hospital which will be shown by documentation. The study will add new knowledge in nursing practice on the value of monitoring performance through chart reviews, and whether the current practice has gaps which will require swift interventions.

The results will lead to attaining a better quality of care required to improve the health of people. It will show that clinical information can be used for purposes that go beyond individual patient care, but include chart reviews and process improvement.

The findings as well as recommendation for this study will assist the King Edward V111 hospital management to emphasise importance of documentation whilst drawing up policies that will educate and in-service the health workforce. It will assist in increasing the accountability for health workers to see the need of documentation and the need for nurse managers to monitor closely routine charts audits and feedback on such. This study will help the researchers to see the need and value of conducting the retrospective chart reviews, an action which has not been greatly recognised in nursing research.

Key words: Prevention of Mother-to-Child Transmission of HIV (PMTCT), antenatal clinic, antiretroviral prophylaxis, patient-held maternity record, chart review, child mortality.

1.8 Definition of terms:

The keywords used will be operationalised for the study. The key concepts were adapted from the Department of Health (2008) Prevention of Mother-to-Child Transmission Program guidelines. For this study, the following concepts will be operationalised as indicated below:

1.8.1 Mother-to-Child Transmission of HIV

This is the transmission of HIV from the HIV positive pregnant woman to her baby. This study focuses more on vertical transmission than on post-natal transmission. In this study this will be abbreviated as MTCT, and will be used to mean the same as the DOH (2008) definition.

1.8.2 Infant Mortality Rate

This comprises the rate at which children die before their first birthday.

1.8.3 Antenatal care clinic

In this study, the Antenatal clinic is the clinic that offers antenatal services to women while they are pregnant.

1.8.4 Maternity setting

This will be operationalised to mean the setting or place where the pregnant women go into labour and deliver, after being pregnant.

1.8.5 Prevalence rate

This will be defined as the existing cases of pregnant women living with HIV.

1.8.6 Core completeness

This means that the information system from which the results are derived is appropriately inclusive, representing the complete list of eligible persons or units, and not just a fraction of the list.

1.9 THE THEORETICAL MODEL

Donabedian Structure, Process and Outcome original model

The theoretical model for this study was adapted from Donabedian's Structure, Process, and Outcome. Donabedian's (1966) structure (also called input) - process-outcome framework serves as the foundation for the model of the provision of care of the program for Prevention of Mother-to- Child Transmission of HIV in this study.

According to Donabedian, (1966) "structure" refers to the tools and resources that participants have to accomplish their work. This involves the organisational setting where they work (Donabedian, 1988). This includes the qualifications of personnel, the geographical structure, and the equipment which the facilities use to provide care. It also comprises the manner in which the delivery of the program is organised. For Donabedian, the structure is stable, and influences the care that is provided.

The process in the framework refers to a set of activities that go on within participants. This involves the technical and interpersonal aspect of care (Donabedian, 1966). This includes the social, psychological interaction between clients and participants.

Outcome on the other hand, refers to the "consequences of the process on the health and welfare of clients" (Donabedian, 1966, p. 243). To Donabedian, the outcome means the change in the client's current and future health status. Physical, social and psychological functions comprise the outcome. Also included in this concept are the client's satisfaction, attitude, health-related knowledge, and behavioural change regarded as the most important variables in the outcome.

How the model was adapted to this study

For the purpose of this study, the elements of Donabedian's framework are represented as follows: Structure refers to the documents being available to provide continuity of care, DT to

women as documented, cd4 testing documented, DT to baby documented, the documents of the PMTCT care clearly documented for the PMTCT, the availability of the required drugs. These will contribute to the outcome and performance of nursing care. The errors, omissions in the recording process will affect the outcome (Hoque, 2008).

The study will be reporting on the activities of core PMTCT activities. The process in this study refers to how these activities are performed by the health workers, e.g. Whether cd4 testing was done, the administering of dual therapy, the recording of the interventions after being performed, while all of these activities are to be completely recorded. This also includes the provision of continuum care after the records have been documented.

The outcome is the result of the care rendered, whether all clients receive the complete activities required by the Department of Health, to have been given dual therapy after having tested positive for HIV, documents of these activities on the charts to show that this was performed. After all these actions have been carried out by the antenatal facilities, the documents should show that the care was given. If actions are not recorded, this will mean the care was not provided, therefore any errors or omissions will result in a poor outcome. According to Donabedian, (1988) the choice of measuring structure, process or outcome is determined by the availability of information. This highlights the importance of having information documented to assist in the evaluation, as well as the monitoring of activities of care rendered. The structure measures affect the outcome at the end. This will affect the required care that should have been rendered, therefore women will not receive the antiretroviral prophylaxis which can lead to a long term outcome, that of increasing the chances of the transmission of HIV to the baby. This study does not aim to address the outcome.

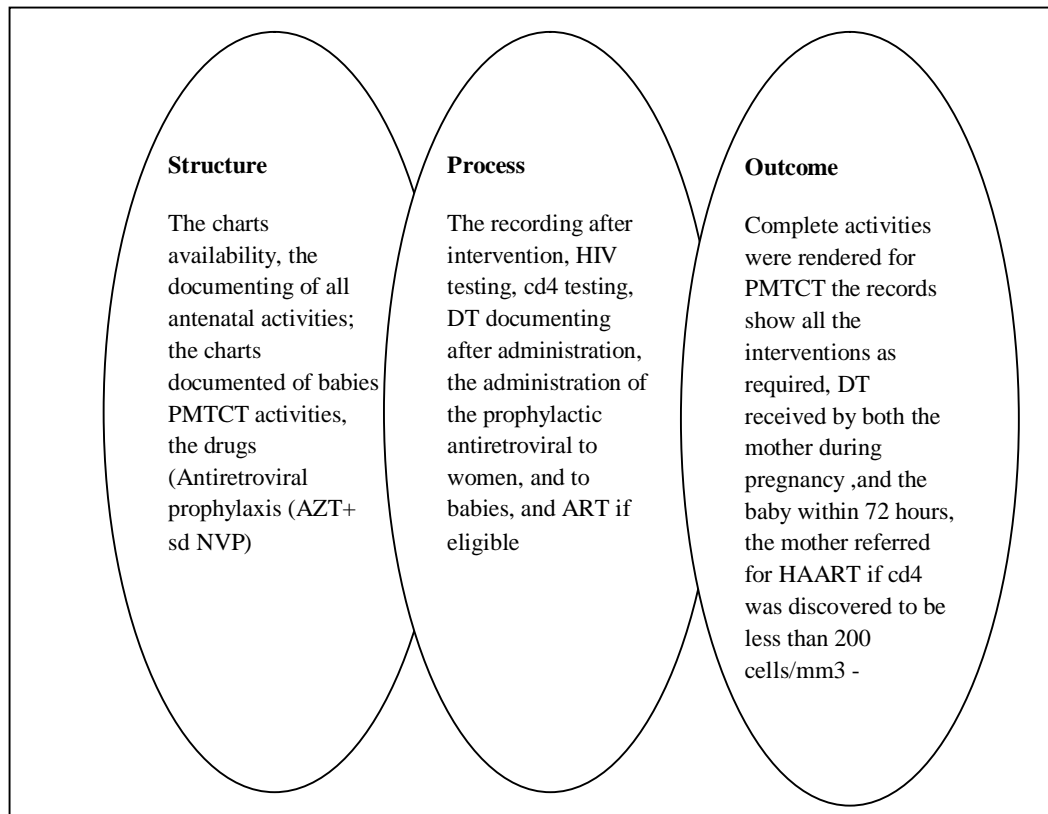


Figure 1: The activities of the PMTCT program in the model

CHAPTER 2

Literature review

2.1 Introduction

The literature presented in this study is related to the Prevention of Mother-to-Child Transmission of HIV Program as per the Revised Policy Guidelines of the Department of Health - South Africa: PMTCT Manual: February 2008 (SADOH, 2008). The literature was obtained through the following databases: Pub-med search, MEDLINE search (1990-2003) - using a combination of terms, and Cochrane systemic review articles. The search was based on the terms -Prevention of Mother-to-Child Transmission of HIV, -completeness of documents, -monitoring and evaluation of program, -documentation, -the use of ARV prophylaxis in PMTCT, the other searches were based on the -current infant mortality rate, -the prevalence rate in pregnant women of South Africa, and -global interventions on PMTCT.

The following sections are presented in this review:

- 2.1 The state of HIV and mortality
- 2.2 The South African situation for PMCT
- 2.3 Interventions: global and local interventions
- 2.4 Monitoring and evaluation
- 2.5 Nursing documentation
- 2.6 Process of the Prevention of Mother-to-Child Transmission

The study was conducted when Dual therapy (NVP and AZT) were provided at 28 weeks in 2009. The new revised PMTCT guidelines (DOH, 2010) were noted and reported on in this literature.

2.1 State of HIV and mortality rate

In the sub-Saharan region, it is estimated that over 90% of new infections among infants and young children occur through Mother-to-Child Transmission (UNAIDS /WHO report, 2008). Without any interventions, between 20 to 45% of babies may be infected. The overall risk can be reduced to less than 2% by a package of evidence-based interventions (UNAIDS 2006). Mother-to-Child Transmission of HIV is the highest mode of HIV transmission amongst children in Southern Africa, and contributes to child mortality (UNAIDS, 2007). South Africa is one of the 12 countries globally with increasing child mortality rates (WHO, 2005). Without intervention, there is a 35% chance of a pregnant mother passing the virus on to her baby during pregnancy, birth, or breastfeeding (UNICEF, 2008). Southern Africa's under-five mortality rate in 2006 was found to be 146 per 1,000 live births (UNICEF, 2008).

In response to the increased child mortality and transmission rate, countries had made commitments based on the United Millennium Development Goals. Amongst others, one of the goals was that of reducing Mother-to-Child Transmission by 2015. About 108 countries across the world, including South Africa, set targets for the prevention of Mother-to-Child Transmission, by 2005, to reduce the proportion of infants infected with HIV by 20% , and by 50% in 2010 (UNGASS, 2001), which was identified as the leading cause of deaths amongst children. Pledges were made by the United Nations Millennium Development Goals (UNMDG, 2000), Targets 4, 5 and 6, which focus on reducing the child and maternal mortality, "Reduce Child Mortality, setting the target: reduce by two-thirds, between 1990 and 2015, to less than 5% mortality rate" (UN, 2000). Each country has developed some interventions based on the UNMDG of 2000, in the PMTCT. South Africa has adopted the National Strategic Plan (2007-2011) which amongst other aims includes that of reducing Mother-to-Child Transmission to less than 5% by 2011 (DOH, 2007). Having said that, the onus is on each country to have systems in place to achieve its target through monitoring of the program performance by conducting reviews of charts to identify gaps. Since the running of the study, the PMTCT program has been revised for both women and babies: ART prophylaxis intervention.

The PMTCT guidelines revision (DOH, 2010) aim to introduce ART prophylaxis early, (at 14 weeks as opposed to 28 weeks of pregnancy in women) and to include the new drug called Truvada (Tenofovir) to be given to women during labour. This will also promote early attendance at Antenatal clinics, where women will be encouraged by the early intervention. Before this, there was only AZT administration at three-hourly intervals, and no intervention of Truvada. Also, babies should be receiving Nevirapine within 72 hours after delivery, as well as the introduction of a daily Nevirapine dose for six weeks, or for the duration of breastfeeding (DOH, 2009).

Most of the preventive measures to reduce Mother-to-Child Transmission of HIV are through the use of Anti-retroviral Prophylaxis drugs and the avoidance of breastfeeding (DOH, 2008). These have been proven in developed countries to reduce the risk of Mother-to-Child Transmission to less than 2% (UNICEF, 2008). In Europe and the United States of America, the Mother-to-Child Transmission rate has been reduced to less than 2% (Newell, 2000). This has been achieved through screening pregnant women for HIV, and identifying the HIV positive women who are attending Antenatal clinics, early initiation of highly active antiretroviral treatment (HAART) while pregnant, delivering by caesarean section, and avoiding breastfeeding.

The PMTCT Program is provided in all the clinics in South Africa. Although the PMTCT of HIV program was implemented, much depends on the documented information by the health workers. Documentation plays a huge role in providing continuity of care to clients. Scarf (1997) saw patients' records as a principal source of information of which the nursing documentation of patient care is an essential part. Pregnant women living with HIV are at high risk of transmitting HIV to their infants during pregnancy, birth, or breastfeeding. Without appropriate care and treatment, more than 50% of newly infected children will die before their second birthday (Luo, 2005). The current transmission rate in South Africa of the Mother-to-Child Transmission is at 21%, after the single dose Nevirapine intervention, whereas it was 12% without any intervention (Rollins, 2008). The National Strategic Plan of South Africa in its strategy for 2007-2011 aims at reducing the Mother-to-Child Transmission rate to less than 5% (DOH, 2007). The WHO report (2008) has shown an improvement in the provision of antiretroviral for prophylaxis, but not to a level that confirms reaching the Millennium Development goals.

The figure 1 below illustrates the improvement in the provision of antiretroviral prophylaxis from 34% in 2007 to 45% in 2008 (WHO Report: 2008), as well as that of children receiving prophylactic treatment from 20% to 32%. The expectation on the run chart below is that if women do receive prophylaxis, the same amount of children should be receiving as exposed to reduce the transmission rate, ideally one line on top of each other. It implies that women receive intervention (45%) more compared to infants (32%) born to the infected women.

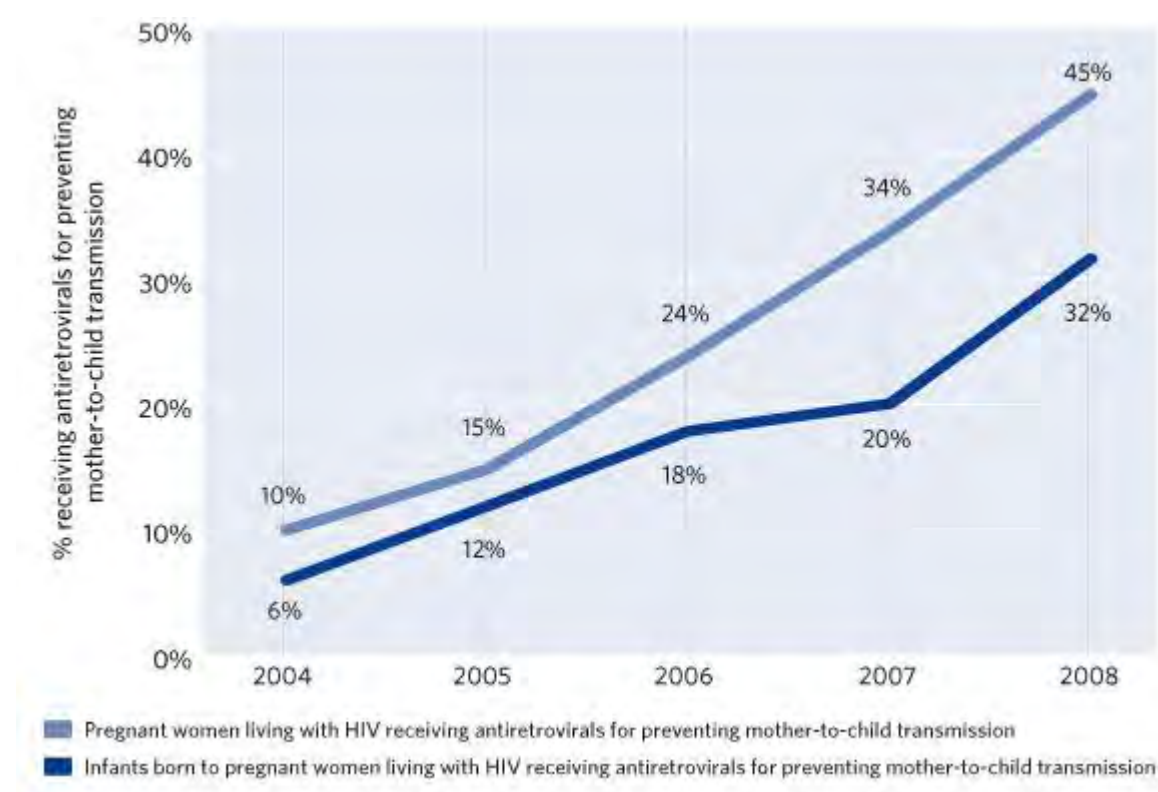


Figure 2: Showing the proportion of pregnant women and infants receiving antiretroviral therapy for prophylaxis

A retrospective record review was conducted of antenatal records for syphilis in women attending the Prince Mshiyeni Memorial hospital in Durban (Mullick, 2005). This examined the compliance with the three doses of syphilis treatment. The study revealed gaps in the recording of care, and that the most critical records were either not completed or incomplete information was recorded. The gaps resulted in challenges in offering the next level of quality care to pregnant women. This study highlighted the need to review records within the department to swiftly expose gaps which required correction.

2.2 The South African Situation context of HIV and interventions

Prevention of Mother-to-Child Transmission of HIV Program in South Africa

This is abbreviated as PMTCT and was introduced in 2001 in South Africa in the Province of KwaZulu-Natal. The King Edward Regional Hospital is situated in this province. The aim of the programme is to reduce the number of HIV infected babies born to HIV positive mothers (DOH, 2008).

Mother-to-Child Transmission of HIV can occur through HIV positive women passing on infection to their unborn babies (vertical transmission), or through breastfeeding (DOH, 2008). South Africa is currently experiencing an overwhelming HIV/AIDS pandemic. In South Africa, it is estimated that 100 000 babies per live births became infected with HIV through Mother-to-Child Transmission (UNICEF, 2004).

The Prevention of Mother-to-Child Transmission of Human immunodeficiency virus (PMTCT), was aiming amongst other things, at reducing the number of infected babies born to HIV positive mothers (National DOH Guidelines, Policy Implementation of PMTCT Programme, 2000). PMTCT involves methods that reduce HIV transmission during pregnancy, labour and delivery, and through breastfeeding.

Initially, the program had only one drug, this being the single dose Nevirapine (sd NVP), which was considered by the World Health Organisation (WHO) as the minimum standard of care for pregnant mothers living with HIV, and which was recommended by the WHO. This was to be taken by the mother when in active labour, and given to the infants within 72 hours after their

delivery. The current transmission rate with sd NVP is 21%, high above the expected 12% , which was the target for single dose Nevirapine in the PMTCT Program (DOH, 2008).

The implementation of the program in 2001 did not transpire without controversy. Treatment Action Campaign (the activists in support of the provision of antiretroviral treatment) was pushing the National Department of Health to commence the PMTCT Program. The National Health Department started by piloting the PMTCT program consisting of Monotherapy (sd NVP). The TAC felt that the pilots in the 18 sites by the NDOH should be converted to a roll-out, not only in the 18 sites, but in all state facilities that could dispense it (Bateman, 2007). Following a court order, the Department of Health had no choice but to implement the program. The TAC won the court order in 2003; therefore the sd NVP PMTCT was spread across all the state facilities, not only the piloted sites. The Minister of Health at the time was Minister Manto Tshabalala Msimang. She was publicly criticised for delaying revising the sd NVP to Dual Therapy, which, according to the TAC spokesperson, Nathan Geffen in 2003 is a scientifically proven method of reducing Mother-to-Child Transmission. On 25 January 2008, the DOH announced a new national protocol for the PMTCT, namely the introduction to Dual Antiretroviral prophylaxis, which consisted of sd NVP plus Zidovudine (AZT). Though the TAC welcomed the revised program, they felt it should have included the Lamivudine (3TC), as recommended by the World Health Organisation for the PMTCT of HIV, and not just the abovementioned two drugs. For the TAC, another shortfall of the NDOH is that pregnant mothers are to be initiated on Anti-Retroviral Therapy, once their cd4 is 200 cells/mm³, or below. The TAC feel this is outside current international best practice, because the WHO recommends a cd4 count of 350 and below (WHO, 2006).

According to scientific evidence, the advantage is to initiate ART at a cd4 count of 350 cells/mm³, and not 200 cells/mm³. The United States and European treatment guidelines recommend that all patients including pregnant mothers start Anti-HIV treatment at a cd4 count of 350 cells/mm³ . This was not the case in South Africa at the time of this study.

In 2007 alone, 330 000 HIV positive pregnant women gave birth in South Africa, with the estimate that 70 000 of their infants were born HIV positive (TAC Report, 2008). WHO

recommends that the full implementation of the revised protocol will reduce the numbers significantly (WHO Report, 2008).

With the use of single dose Nevirapine for the PMTCT programmes, it was later discovered that resistance develops with the use of sd NVP, which can compromise the success of the subsequent treatment of mother and child with ARV in future. A study by Newel (2007) on the prevalence of resistance to NVP in mothers and children after sd NVP exposure to prevent vertical transmission of HIV-1, revealed that there was a high burden of viral resistance in both women and children. The sd NVP is considered a minimum standard of care for mothers living with HIV who are pregnant. The Dual therapy revised new PMTCT program, which consists of Zidovudine (AZT) and Nevirapine (NVP) which is the recommendation by the WHO (World Health Organisation) is considered more effective than the sd NVP (WHO, 2006, Antiretroviral Drugs For Treating Pregnant Women). Initially, the WHO had recommended the sd NVP, but new evidence is available which supports the effectiveness of the Anti-retroviral (ART) in the prevention of MTCT (WHO, 2006).

This was supported by a study done in Khayelitsha, Cape Town, South Africa, which aimed at estimating the efficacy of the PMTCT program in Khayelitsha, and providing details of the antiretroviral regimens received by mothers and infants. The results revealed that the majority of pregnant women in Khayelitsha accept HIV testing during pregnancy, and are prepared to join the program. This acceptance of testing is the key to the effectiveness of the PMTCT program (Abdullah et al, 2001). In developing countries like South Africa, on average, less than 10% of women receive even the most basic PMTCT services, (Stop AIDS in children campaign) therefore access to the PMTCT services remain low.

2.3 Child Mortality

Human Immunodeficiency Syndrome (HIV) and Acquired Immunodeficiency Syndrome (AIDS) is an epidemic in South Africa. Sub-Saharan countries are the worst affected by the pandemic (WHO, 2006). South Africa is one of the sub-Saharan countries which is most affected by deaths caused by HIV/AIDS. In 2004, it was estimated that 10.5 million children younger than five years died across the world due to preventable diseases, with the majority of deaths

occurring in the poorest countries (UNAIDS, 2006). In December 2007, 33.2 million people worldwide were living with HIV, with 2,5 million people being new infections, and 2.1 million dying of AIDS (UNICEF, 2008).

One of the main causes of death for children younger than five includes HIV/AIDS which contributes 40% (MRC, 2000) to the overall deaths. An estimated 420 000 children were newly infected in 2007 (UNICEF, 2008). Without intervention, it is estimated that half of these children will die before their second birthday (UNICEF, 2008). In South Africa, according to the UNAIDS report, around 5,7 million South Africans were living with HIV at the end of 2007 (UNAIDS/WHO, 2008). This includes 280 000 children below 15 years of age. In the South African National HIV Survey (2005) which sampled a proportional cross-section of South African society (15,851 agreed to test), the HIV prevalence rate in men was 8, 2% (6, 342 males), while the prevalence rate in females was 13, 3% (9, 509). These figures show the epidemic in the country of South Africa, with females being the most affected group (UNAIDS, 2006).

In October 2008, Statistics South Africa reported on mortality and causes of death in South Africa, 2006. It revealed that 91% of the annual number of deaths between the years 1997-2006 was registered, with 14,783 deaths due to HIV (SatsSA, 2006). These figures were seen as underestimates, because most of the deaths were not classified as HIV related. This means that most of the deaths are not classified as HIV related, but are classified as caused by diseases like, pneumonia, etc.

Among the number of deaths, WHO estimated that among the countries of the sub-Saharan region, over 90% of HIV infections amongst children occur through Mother-to-Child Transmission of HIV (MTCT), which is transmitting the HIV infection from the pregnant positive mother to her unborn infant, in this way contributing to child mortality (UNAIDS, 2006). There is still no cure for HIV; prevention is the main approach to reducing the spread of HIV, especially the prevention of Mother-to-Child Transmission of HIV. A report by Professor Rollins (Rollins, 2007) on the National AIDS Conference mentioned the increasing child mortality in South Africa. In a study conducted in Durban, among 2, 470 infants (6 weeks of age) who attended up to 11 different immunisation clinics around KwaZulu-Natal, it was revealed that

7 percent of all these infants were already infected by the time they reached the clinic. This, according to Rollins, equals the 20,8 vertical transmission rate. Since more than 90% of HIV infected pregnant women attend ante-natal clinics, Rollins felt that these women could be reached with preventive drugs, like the ART prophylaxis, which is Dual Therapy in South Africa (single dose Nevirapine with Zidovudine).

The PMTCT service delivery in South Africa varies a great deal, with some provinces outperforming others, like the province of the Western Cape which has managed to reduce its transmission rate to less than 5%. Prevalence studies have been done in South Africa (DOH, 2007) which estimates the number of South Africans who have HIV. One study by the Department of Health, the National HIV and syphilis sero-prevalence survey in 2007, examined the Antenatal clinics data and used it to estimate HIV prevalence amongst pregnant women and Antenatal clinic attendees across all nine provinces of South Africa. Results showed that in South Africa, 28% of pregnant women were living with HIV in 2007 (DOH, 2007). The province with the highest prevalence is KwaZulu-Natal at 38.7% (NDOH, 2009) in which it is the province to which the hospital under study falls.

2.4 Global interventions to reduce MTCT and scaling-up of PMTCT

According to UNICEF (2008), the HIV epidemic is a major threat to child survival in sub-Saharan Africa. Almost 90% of global MTCT occur in this region. Southern Africa's under-five mortality rate rose from 125 per 1 000 live births in 1990, to 146 per 1,000 live births in 2006 (UNAIDS, 2008). More than 400 000 children under 15 were newly infected with the virus in 2007. Without intervention, there is a 35 % chance that a pregnant woman will pass the virus to her baby during pregnancy, birth, or through breastfeeding.

In 2006, about 39,5 % million people were living with HIV worldwide, with 17,7 million being women, and 2,3 million being children younger than 15 years (UNGASS, 2006).

A journal article on the Barriers to Access Prevention of Mother to Child Transmission for HIV positive women in a well-resourced setting in Vietnam, showed low coverage of the PMTCT services (Shetty, K et al, 2008) .It also investigated the access of HIV infected pregnant women to PMTCT services in the capital city of Hanoi. The HIV positive women, who were enrolled,

were consulted, in-depth interviews were conducted, and they were asked about their experiences in accessing PMTCT services. This study identified gaps in the PMTCT services. Women reported being limited by a lack of knowledge and information due to poor counselling. It also revealed that HIV testing was done too late for optimal interventions. Only 44 % and 20% of the women had received minimal and comprehensive PMTCT services as revealed by the study results. The study managed to identify the barriers to accessing PMTCT services.

The UNGASS Declaration on HIV and AIDS, 2001 set goals of reducing the proportion of infants infected with HIV by 20 % by 2005, and by 50% in 2010, by ensuring that about 80% of pregnant women have access to information, counselling and other HIV prevention services, like PMTCT, increasing the availability and providing access for HIV infected women and their babies to effective treatment to reduce MTCT.

An effective PMTCT program is needed in order to achieve the UNGASS goal. This study reports on the documenting of the PMTCT activities through the reviewing of charts retrospectively, where the PMTCT has been revised.

In another study on PMTCT, "From research to reality" by Sherman (2004), the efficacy of a PMTCT program in a routine service setting was assessed. The study utilised retrospective data obtained from the hospital records. The study revealed the low HIV transmission rate of 8, 7%. The subjects were pregnant women known to be HIV positive who delivered at a hospital in Johannesburg. Of the 8,221 deliveries, 1,234 occurred in women known to be HIV infected. This transmission rate confirmed the efficacy of PMTCT. They identified the gap in record-keeping, and felt that it is important that the record-keeping facilitate ongoing monitoring.

A study on the PMTCT of HIV in resource-limited settings was carried out by Spensley et al. (1999) at the University of North Carolina, Washington DC, based on the Elizabeth Glaser Paediatric Aids Foundation, in the developing world to reduce perinatal acquired HIV infection. The study reviewed six-and-a-half years of PMTCT programs of HIV. The method was for each PMTCT facility to record patients' data in Antenatal clinics and labour and delivery settings regarding counselling, testing, HIV status, and ARV prophylaxis, and to submit the data to foundation staff. The results of the study revealed that 92% of the women who received

antenatal care had been counselled, and 82,8% of those counselled had accepted testing. Among those identified as HIV positive, 75% received ART prophylaxis (which was then sd NVP), and among their infants, 45,6% received prophylaxis. The results show that providing patients with ART prophylaxis improves program efficiency, as long as the program can be viewed as an essential part of the continuum of care.

In a qualitative study of PMTCT in Khayelitsha, Cape Town, South Africa, gaps in information on PMTCT were identified. The study recommended that accurate information is needed about PMTCT, including the feeding options and the risks during pregnancy (Chopra, 2000).

A significant gap remains between global policy commitments to reduce Mother-to-Child Transmission of HIV, and access to PMTCT interventions in resource-limited settings like South Africa.

The WHO recommends that using triple therapy (a combination of three antiretroviral drugs) by mothers and infants has been shown to reduce the risk of HIV transmission, rather than using one drug (sd NVP) (WHO, 2008). In European countries the transmission has been reduced to less than 2% (WHO, 2008), but in resource-limited countries, the Dual therapy (AZT and sd NVP) has proved to be effective (Alcorn, 2008).

A report by UNAIDS (2006) showed that in 2005, less than 10% of HIV positive pregnant women had access to PMTCT services worldwide. This implies that a large number of pregnant women who required these services did not receive them. With the high burden of HIV in the Province, efforts are needed to address the issue of missed opportunities, as women report to facilities, and at least more than 90% (Stringer, 2009) attend routine antenatal services. A study by Rollins (2006) on HIV prevalence rates amongst six-week-old infants in South Africa found that HIV infected women and infants do not access HIV programs like the PMTCT, due to poor identification and an inadequate referral system. The studies revealed the rate of vertical transmission at six weeks among HIV exposed babies to be 20.8 % (Rollins, 2006). In Rollins' opinion, to monitor the effectiveness and impact of PMTCT program, the screening of infants at immunisation clinics is necessary.

According to the WHO Guidelines, the regimen currently recommended for preventing Mother-to-Child Transmission in a resource-limited setting like South Africa, is a combination of zidovudine AZT and single dose Nevirapine. These were found to be more effective, and less likely to lead to drug resistance, as was reported with single dose Nevirapine (sd NVP) alone (WHO, 2008). According to the WHO, the women should begin taking AZT at 28 weeks of pregnancy.

In a study on retrospective chart review on the feedback on clinical experience of nurses on recording, Hardy (2000) revealed that there are flaws in recording, and that there is a lack of prioritised interventions. The study also identified missing information that should have been recorded. Currell (2003) looked at the nursing record system and its effect on nursing practice and healthcare outcomes. The Prevention of Mother-to-Child Transmission of HIV program is one of the interventions that rely solely on the documents compiled by the health workers to provide continuity of care.

One trial carried out in Zambia (2001) on breastfeeding revealed that there is a problem with disclosure of status to partners, or families. In most African cultures, it is expected that mothers should breastfeed their babies and women who aren't breastfeeding are viewed with suspicion. This is a big problem here in South Africa too, (UNAIDS,2009) where mothers choose one feeding option, then, when they go home their practices don't permit the choice that they made earlier and they therefore alter their decisions, opting for the other method, or mixed feeding.

The information that is provided by the health workers to guide mothers in making informed decisions regarding feeding choices is fraught with challenges. The WHO recommended the use of AFASS criteria. The choice of feeding for the mother should be based on these criteria. The formula powdered milk is being provided by the Department of Health (DOH, 2008) for mothers who meet the criteria, and those who don't meet the criteria have to breastfeed the baby exclusively for six months (WHO, 2006).

While the guidelines by the WHO underline the importance of scaling-up efforts to improve exclusive breastfeeding rates for all children to meet the Millennium development Goals of

reducing child mortality (WHO, 2009), it still remains a challenge in a society faced with stigma and disclosure issues.

The WHO also recommends that, for HIV positive women, exclusive breastfeeding is encouraged for the first six months of infant's life, unless the replacement feeding is:

- Acceptable
- Feasible
- Affordable
- Sustainable and Safe

The women have to choose the most appropriate feeding option for their babies, but they need support to make informed decisions, in order to choose and adhere to the best option for their situation (WHO, Geneva, 2009).

2.4.1 The United Nations Millennium Development Goals: 2000

The Millennium Development Goals were agreed and adopted at the United Nations Millennium Summit in September 2000 (UN, 2000). A total of 189 member states of the United Nations pledged to achieve the goals within the timeframe. This encompasses eight bound development goals, which seek to address the issues of poverty, education, gender, equality, health, the environment, and global partnership for development to be achieved by year 2015.

Some of the goals set were:

Goal 4:

Reduce Child Mortality, setting the target: reduce it by two-thirds, between 1990 and 2015, to a rate of less than 5%.

Goal 5:

To improve maternal health.

Goal 6:

To combat HIV/AIDS, Malaria, and other diseases.

In order to reduce child mortality, and achieve Millennium development goal 4, the following recommendations were made:

- Clear documentation of information on HIV, PMTCT, and Anti- Retroviral Prophylaxis should exist in the charts.
- The PMTCT should be up-scaled to prevent further HIV infections, including the treatment of pregnant women who need ART.
- Early identification of mothers needing the ART prophylaxis.
- Promotion of exclusive breastfeeding in all Antenatal clinics and health care facilities.

Longer courses of drugs, which involve daily doses for several weeks were found to be more effective in Preventing Mother-to-Child Transmission of HIV (WHO, 2006). These are less likely to cause drug resistance. The adjustment by the National Department of Health (National Guidelines, February 2008) for resource-constrained settings like South Africa, stresses the added benefit of beginning AZT at week 28 of gestation (DOH, 2008). This will hopefully lead to a further reduction of the transmission rate, which is at 21% currently (Evaluation report on the PMTCT Programme in 2005) to at least less than 5% with the Dual Therapy (National Strategic Plan, 2007-2012), but will also ensure that a smaller proportion of women present for delivery, having received more than four weeks of AZT therapy (WHO, 2008; Strategic approaches to the Prevention of HIV Infection in infants: report of a WHO meeting, 2003). A revised PMTCT program may help South Africa to achieve the Millennium Development Goals by reducing child and maternal mortality. This is also because it doesn't concentrate on the baby alone, but also focuses on the mother. King Edward is a District hospital which has its own Antenatal clinic, and also sees clients from feeder clinics which don't do deliveries, or women with complicated pregnancies. The hospital communicates with the Antenatal clinics through the

records of the pregnant positive women who come to the clinic with Antenatal cards which should contain all the information about the women, including the PMTCT information.

2.4 Access to Anti-retroviral drugs

2.5.1 Global perspective Access

In 2005, it was found that only 15% of HIV infected pregnant women received preventive drugs (UNGASS, 2001). Botswana, one of the developing countries in the sub-Saharan region has managed to lower the rate of MTCT of HIV to less than 4%, along with 15 other developed countries (UNAIDS, 2007) despite systematic bottlenecks, like a human resource crisis.

Data from the 2005 report card on PMTCT of HIV Care and treatment (WHO and UNICEF, 2004) found that in 2004, 7 % of HIV positive pregnant women were given Artø, while 5% of HIV exposed babies received the ARV prophylaxis. In 2005, 11% of positive pregnant women were given Arts, while 8% of HIV exposed infants received the ARV prophylaxis.

In 2005, the G8 leaders of different countries agreed to work with the WHO, UNAIDS, and other international bodies, to develop and implement ãa package for HIV prevention, treatment and care, aiming at universal access to treatment for all those who need it, by 2010ö. The use of ARV as an intervention to öreduce the risk of MTCT of HIV has become an affordable optionö as stressed by Smith (2003, p. 121) in her thesis on öSome obstacles for the HIV MTCT prevention programmeö. According to Smith, (2003, p.101) öIn order to ensure that programs support delivery of PMTCT interventions, it is critical to identify the current and envisaged obstacles that could hinder the national initiative of MTCT interventionsö. Since it is clear that MTCT contributes to child mortality, the obstacles to interventions cannot be afforded.

The findings of another qualitative study done in Khayelitsha, Cape Town (Chopra et al, 2000) on infant feeding practices emphasised the need for accurate information about MTCT, which includes risk during pregnancy, child birth and breast feeding.

United Political Declaration on HIV and AIDS, June 2006

Member states committed to ensuring that pregnant women have access to and receive antenatal care, information, counselling and other HIV services. This aimed at increasing the availability of and access to effective treatment for women living with HIV and their infants, to reduce MTCT. A further aim was to ensure effective interventions for women living with HIV.

ABUJA Declaration on HIV and AIDS, Tuberculosis and other related infectious diseases, 2006.

In the Abuja Declaration, Heads of State and Governments committed to achieving the following targets: That at least 80% of pregnant women have access to the Prevention of Mother-to-Child Transmission.

Also, that 80% of those in need, especially women and children, have access to HIV and AIDS treatment, including ART, as well as care and support.

A comprehensive research audit of Durban's four Regional hospitals showed that, despite infants accounting for the most paediatric deaths (63%), 75% of all deaths had no information on the provision of the PMTCT. Dr Harry Moultrie (2007) Clinician at Chris Hani Baragwaneth Hospital) told the Indaba, at the Aids Conference 2007 that there is a severe lack of communication between the Antenatal Care, the Hospital, and the immunisation clinic, which meant that no one has any idea which children have HIV, and which ones ought to receive the co-trimoxazole prophylaxis. Both Dr Moultrie and Professor Nigel Rollins (Head of the Paediatric and Child Health at the University of KwaZulu-Natal) have shown how badly the Health Care system is failing mothers and children. Professor Rollins' results at the Aids Conference, and his research findings revealed a high number of HIV positive pregnant mothers at their six week visit to the clinic, and the non-existence of HIV tracking between the Antenatal Care check-up at clinics and hospitals.

Another study carried out by Professor N Rollins (2006), which examined the current system efficiency with sd NVP, two tier prophylaxis in KwaZulu-Natal province observed a 92% attendance of antenatal care clinics. This implies that women do present at antenatal clinics to access antenatal care.

The attainment of the UNGASS target of reducing HIV infections by 50% by 2010 necessitates that 80% of all pregnant women accessing care receive PMTCT services. In 2005, only 7 of the 71 countries were on track to meet this target. However, PMTCT coverage increased from 7% in 2004 (58 countries) to 11% in 2005 (71 countries) (UNGASS, 2006). In 2005, 8% of all infants born to HIV positive mothers received antiretroviral prophylaxis for PMTCT, up from 5% in 2004, though only 4% received co-trimoxazole. 11% of HIV positive children in need received antiretroviral treatment in 2005. In 31 countries that had data, 28% of the women who received an antiretroviral for PMTCT also reported receiving antiretroviral treatment for their own health. Achieving the UNGASS target is possible, but it needs health systems to be strengthened more. In 2006, UNGASS reported that at least 8 countries exceeded the 40 % ARV prophylaxis uptake mark which is required to achieve the 2005 PMTCT target of UNGASS on HIV/AIDS.

2.5.2 South African Perspective

A study in Durban region, by Naidoo et al. (2007) which researched the under-five mortality rate in the Durban hospitals, reflected the failures of access to the PMTCT (South African Aids Conference, June 2007). It revealed that there are more than 65% of child deaths in hospital associated with HIV. This shows that more energy needs to be injected into the health system.

A study done at the McCord Hospital, a semi-private hospital in Durban, South Africa, by Dr Steve Knight (2008) on the effectiveness of the PMTCT program, indicated that a very high percentage of mothers received prophylaxis, 97%, and 98% of the babies received prophylaxis. This shows the successes of the program in a developing country (SAMJ, June 2008). Amongst other factors contributing to this performance, were the effective monitoring and evaluation of the data that was available.

The other crucial core PMTCT which is overlooked, yet which contributes to the transmission of HIV is the choice of feeding. Breast milk is another method of acquiring Mother-to-Child Transmission of HIV. About 10 to 20 % of infants born to HIV positive mothers may acquire the HIV infection (UNAIDS, 2008). Although formula feeding is certainly the correct choice for some infected women who meet all the criteria according to the WHO guidelines, exclusive

breastfeeding for six months for the majority of the women infected who are poor, reflects the balance between the advantaged and the disadvantaged (UNAIDS, 2008).

2.6 Monitoring and Evaluation

This part will highlight the impact of documentation on quality and on the provision of continuity of care in PMTCT. It will also highlight the importance of retrospective chart review, as well as effectiveness of monitoring coverage of programs using documents

In his evaluation of the PMTCT Programme in his 2005 Surveillance Study, Rollins (2006) found that the impact of the program depended on the degree of inequities in the health system, meaning that providing sd NVP alone was not sufficient to improve the outcomes for both mothers and babies. This was later expanded from Monotherapy, sd NVP, due to the fear of resistance to a single drug, into the Dual therapy, which the National Department of Health has approved, and the current WHO Recommendation (WHO, 2006) consisting of a combination regimen of Zidovudine (AZT) to all women with a cd4 cell count greater than 200 cells/mm³ from 28 weeks gestation, and sd NVP (National Department of Health, February 2008). The amended PMTCT protocol shows that this is prioritised as indicated in the South African National Strategic Plan for HIV/AIDS 2007-2011, aimed at reducing the Mother-to-Child Transmission rates to no more than 5%. The South African HIV Survey (2005) revealed that 10,8 of all South Africans over 2 years old were living with HIV in 2005. KwaZulu-Natal alone was on top with 16.5% prevalence figures compared to the Western Cape with 1,9%.

2.6.1 Importance of documentation

Nursing documentation continues to draw criticism from professional, community, and regulatory organisations because of incomplete, sub-standard charting practices (Howse et al, 1990). Documentation is a fundamental nursing responsibility with professional, legal, and financial implications. Charting systems have, however, been consolidated to minimise the amount of irrelevant data and time spent on documentation. There is a concern that nurses may

be less able or willing to document in ways that reflect the holistic nature of their practice and work. Furthermore, questions arise as to whether the clinical record is the best medium for an accurate account of nursing activities and holistic concerns.

2.6.2 Nursing Documentation perspective

Much has been written on the content and shortcomings of nursing documentation.

Documentation has evolved into a nursing practice strategy to monitor and influence health care outcomes. Still, barriers to effective documentation have been noted in acute care environments. There are three studies that have specifically investigated these barriers.

Renfro (1990) reported on the relationship between nurses' attitudes, subjective norms (or the influence of others), and behavioural intentions toward documentation. Gathering data on 108 nurses from three different southern hospitals, the researchers concluded that subjective norms, rather than attitudes have the greatest effect on a nurse's intention to document optimally. They recommended communication of high ideals and expectations to the staff nurses from important others as ways to enhance optimal documentation (Renfro et al., 1990).

Tapp (1990) studied the degree to which nurses value documentation, including inhibitors and facilitators to this process. She interviewed 14 nurses from a western VA facility, and found that complicated forms and unclear language contributed to poor documentation. This research concluded that nurses lack professional identity and language, as demonstrated by the inconsistent documented evidence of care.

An audit of charts by Stimpfel (2007) identified numerous important information items missing from most of the charts audited. The missing documents were crucial to provide continuity of care to the clients, like, medication allergy being left blank, past medical histories, etc. For her, the medical documents are seen as important in preventing malpractice litigation, and can be used by the health personnel for defence of malpractice lawsuits (Stimpfel, 2007). Clinical Records help in planning for patient care, and provide for continuity in information about patients' medical treatment (Stimpfel, 2007) which should be of high quality.

A study by Leape et al. (2004) which examined the reasons for errors, found that most of the errors resulted from multiple system failures, and staff shortages. Since the care rendered did not occur at the same facility, the medical documents give health care members a way of communication with each other. If some of the information is not documented, it results in blocking the communication, and will interfere with the care the client will receive.

The PMTCT activities occur mainly through Antenatal services; therefore, documenting from the Antenatal care (ANC) is critical for the success of the program. The documented interventions received by clients at ANCs guide the intervention at the next level, which is usually the hospital where the woman delivers. When there are no documents, actions are not considered to have been effected. Complete and consistent documentation is needed to provide consistent high quality of care. Documenting on charts serves as proof that the practices were carried out. When doing the reviews, an auditor relies solely on the documents. Monitoring the program at a facility level helps to identify the gaps which can be corrected sooner. The Western Cape district has localised monitoring and evaluation systems which assist in the assessment of programs, e.g. PMTCT , thus monitoring gaps and checking whether the right intervention is provided.

Documenting on the client card after health worker intervention is an important powerful legal document that helps even the health worker when faced with legal issues. Bjorvell, a PhD student in Sweden saw the benefits of documentation as the improvement of the structured communication between the health professionals and also as ensuring continuity of individually planned patient care. According to the WHO (2007), the patient record should include distinct and clear nursing documentation, since it contains each patient's individual needs. Improving nursing documentation is important. Incomplete recording by the health workers indicates that the intervention by the next health worker who consults the client will be poor, and further investigation will be needed to judge whether or not the care that was given is less. For effective assessment of the PMTCT program, complete documentation of the practice, to see whether all the core activities were performed as per the Department of Health guidelines is required.

A study by Henry (2005) in Georgetown, Guyana in South Africa considered the factors that influenced women's uptake of PMTCT interventions. The study identified documentation as the

key to PMTCT service provision. The study assessed why health workers did/didn't document complete recommended core PMTCT interventions to prevent vertical transmission of HIV. The biggest obstacle to the provision of ARV prophylaxis was the Antenatal care card system which is used to communicate to maternity staff the HIV status determined during Antenatal care, and every other intervention. The card is a client-held record which the client should bring to the maternity section, as most antenatal clinics do not conduct deliveries, but refer clients to the next level.

The United Nations (2000) Millennium Development Goals have recommended that in order to reduce child mortality and achieve MDG 4, clear documentation of information on HIV/PMTCT/Antiretroviral prophylaxis must be recorded on the charts. To the UN, this can increase the scaling-up of PMTCT to prevent further infections. The United Nations considers the records crucial in monitoring the program performance to assess how well the program is proceeding.

2.6.3 Importance of Monitoring and Evaluation

The evaluation of the program in 2002 (DOH) across the 18 sites reported that 56% of the antenatal attendees were tested, with a prevalence of 30%, while only 55% of these received sd NVP, and 99% of HIV exposed newborns received Nevirapine (Doherty, 2005). According to UNAIDS report (2008), in 2007, 60% of HIV positive pregnant women had received ARV prophylaxis in sub-Saharan Africa. Of these, 39% were from South Africa, while 71% were in Europe. Another study by Knight (2005) at McCord hospital revealed that the hospital had low transmission rates given the integrated approach, and had managed to provide AZT to mothers and babies (75% of the women). A study at Prince Mshiyeni Memorial hospital (Mullick, 2004) with a retrospective chart review examined the treatment for syphilis in antenatal care, looking at compliance with the three doses. The study revealed that, of the 18 128 records that were reviewed, almost two-thirds of the women who completed their treatment, many were missing information, e.g. the gestational age. Recording data was found to be the key to monitoring

performance, yet limitations existed in terms of the availability of the data on the maternity records.

An audit of the high infant mortality in Durban hospitals illustrates the delivery gap remaining for PMTCT and paediatric ART programs (Moodley, 2007). Women were delivering without being put on sd NVP. A report by Blackstock (2008) in a study done at King Edward Hospital, revealed that the amount of women who attended the labour ward who were already taking HIV treatment was significantly lower. Half of the women who tested positive were found to have been recorded as having received sd NVP (Doherty, 2007). This gap can be closed if women are put on ART prophylaxis as per the guideline, and this treatment is documented in patient-held charts. Good documentation reveals good patient care, so, by reviewing charts, patient care can be improved through identifying gaps, and providing ideas to correct bottlenecks.

Countries like Botswana and Brazil have managed to provide PMTCT services to most of their pregnant women. Botswana has reduced Mother-to-Child Transmission to less than 2% (UNAIDS 2005).

A Cochrane search was done on Anti-retroviral for reducing the risk of MTCT of HIV infection in South Africa, Cape Town. The objective was to determine the extent of Anti-retroviral aimed at decreasing the risk of MTCT of HIV infection, and also, whether they achieve a decrease in the transmission risk, and the effect these interventions have on maternal and infant mortality and morbidity. The first trial began in 1991, and assessed Zidovudine versus a placebo. These studies revealed that AZT was more effective than the placebo. After these results, there were modifications of the dosage and duration of the drugs. Regarding the other studies on ARV vs. placebos in the breastfeeding population, three studies revealed that Zidovudine given to mothers from 36 to 38 week gestation, during labour, and for 7 days after delivery significantly reduced HIV infection at 4 weeks (efficacy 32%).

2.7 Process of Prevention of Mother-to-Child Transmission

This section outlines the process of PMTCT as provided in each area of maternal care, from antenatal care, labour and delivery services as well as post-natal care. Each area of maternal care

for PMTCT is critical to happen, multiple activities in each step provided in different settings (from antenatal services through to post-natal service provision to mother and baby).

- **Ante natal Care:**

Pregnant women presenting for antenatal care should receive Voluntary Counselling and Testing for HIV. Women who agree to be tested and are discovered to be HIV positive, should be WHO clinically staged, as well as subjected to cd4 count testing, and all this should be documented on the Antenatal chart. Antiretroviral prophylaxis, Dual therapy, which contains Zidovudine (AZT), and sd Nevirapine should be taken by all pregnant HIV positive women. The sd NVP 200mg is given to the pregnant mother to keep, so she should take it when she is in active labour, but the AZT is given from 28 weeks gestation period onwards. The AZT dose is 300mg twice daily, until she is in labour. If results for the cd4 count are 200 or below, (the count usually comes back within a week or more, depending on the facility's turn-around time) the woman should then be switched from DT to Anti-retroviral (Highly Active Anti-retroviral Therapy-HAART), from the ARV initiation site, which is not usually the Antenatal clinic, but the hospital. The initiation of HAART should take place after a client has done three classes called Literacy classes, which are readiness classes that promote compliance. The feeding option is discussed with the woman so that she can make an informed choice based on WHO AFASS criteria.

- **Onset of labour**

Women presenting with labour records are checked into the labour ward, from the ANC card used while at ANC, if the client is on the PMTCT program. If the records don't show the PMTCT information, the woman is considered to have an unknown status. She is then asked whether she took the sd NVP 200 mg before coming to the hospital. If she did not, she will be given this drug from the hospital supply with AZT 300mg immediately, and three-hourly doses of AZT thereafter until she delivers. This will be recorded in the maternity records.

- **Post delivery**

The infant receives sd NVP 2mg/kg within 72 hours after delivery. The infant will then receive AZT 4mg/kg twice a day for 7 days if the mother had received AZT for more than 4 weeks. If

the woman received AZT for less than 4 weeks, the infant will receive AZT 4mg/kg twice daily for 28 days. This 28 day dosage of AZT to the infant applies if the woman was on HAART for less than 4 weeks with a low cd4 count, or WHO clinical stage 4 was recorded on the Antenatal card. When the woman is discharged, she takes with her the AZT for the baby for prevention of transmission. Post-natal care for the woman and her infant is done at the local clinic which the study didn't cover.

2.8 Conclusion

This chapter highlighted the prevalence of HIV, the current status of the PMTCT program, the importance of and issues surrounding documentation. The key areas that needed to be focused on in order to improve access to anti-retroviral treatment as well as prophylaxis, to improve child and maternal child survival are documented. the global as well as the South African perspective of the study question. It showed that drugs were never the issue, but that there are gaps in the provision of intervention for the program which lead to Mother-to-Child Transmission. It also highlighted the importance of documenting the intervention for quality of care to clients and proper continuum of care.

CHAPTER 3

RESEARCH METHODOLOGY

4. Introduction to the methods

Methodology, according to Cresswell (2009), is an approach to enquiry providing specific directions for procedures in a research design. It helps to focus the inquiry on the research design, in trying to find answers. This chapter will explain and describe the research design used in the study, the setting, population and sampling technique used to obtain the sampled patients' records. The data collection process, data extraction tool, data analysis, data management and ethical considerations are also presented in this chapter.

5. Research Approach

This research study was based on the Positivist paradigm. Under this worldview, the quantitative approach is applicable. The philosophers subscribing to this paradigm make assumptions that the facts and truth will be uncovered through numbers, and can be objectively observed by a careful statistical measure of relationships whilst recording observations. The Positivist's findings of the results (Polit and Beck, 2008) will not be influenced by the researcher. Objective observation of the phenomena, whilst trying not to interfere with observations. The paradigm emphasises observation and reason as a means of understanding human behaviour, thus it is used to generate knowledge. The paradigm will help in an accurate description of the guidelines, aiming at explaining events.

The positivistic view is suitable for this study as it reports objectively, in numbers, rather than words on the relationship observed between quantitative variables, and provides a description of what observations can be discerned in the relationship amongst the variables. This part will be presented quantitatively; a quantitative approach is therefore suitable for this study.

3. 3 Research Design

A non-experimental retrospective descriptive exploratory design informs the study. This study aims at providing a description of how the core activities of the PMTCT are carried out, presenting and discovering the relationship amongst the variables. For Cresswell(2009),it allows

observation and documenting aspect of situation as it naturally occurs, without manipulation. The use of retrospective records is suitable for the study as it will indicate with clarity whether the program activities are implemented as planned (Hess, 2004).

3.4 Research Setting

The research was carried out at a Regional Hospital in South Africa, KwaZulu-Natal province. The hospital is one of the largest hospitals in the South of Durban. It is a 922-bedded hospital and is situated in Ward 33 in Ethekewini district. It is based in an urban setting, and is government-funded, including a rural and semi-rural setting. The hospital covers a wide catchment area with an estimated 500 deliveries per month (DHIS, 2010). This hospital is also a teaching hospital of the University of KwaZulu-Natal's Nelson R Mandela Medical School, and has a Nursing College for Advanced Midwives (KEH Database). It is a public service with a free service offered to pregnant women.

3.5 Study population

The study population according to Brink (2006) is defined as the entire group of people or objects that are of interest to the researcher, or that meet the criteria the researcher is interested in studying. The total number of deliveries in the hospital is estimated at 500 per month (DHIS, 2010). The sample population was all the patient records that meet the inclusion criteria for the study.

3.5.1 Inclusion Criteria

The selection of inclusion criteria was based on the study objectives, and the questions that the study wanted to answer. All charts of patients who delivered between the periods 01 April to 30 July 2009 were considered for selection. The inclusion criteria for the study were as follows:

- i. HIV positive clients who were pregnant. The interest for the study is on the Prevention of Mother-to-Child Transmission, which applies to HIV tested positive clients.
- ii. Booked cases with four or more Antenatal Clinic visits. This was chosen to allow equal opportunities for the activities to have been carried out by the antenatal clinics.

iii. Public sector facilities.

The public health sector was chosen because they were offering a package for Prevention of Mother-to-Child Transmission of HIV, as described by the Department of Health guidelines (2008).

iv. Had been issued with client-held/patient-held records while pregnant (records of antenatal clinics).

v. Delivered in the facility and not at home. This variable was chosen based on the PMTCT interventions that are only available in the delivery setting and which should not have been available at home.

vi. Not already on Highly Active Antiretroviral therapy (HAART). Clients who are already on HAART (Highly Active Antiretroviral) do not follow the same activities as those who are newly tested and are not on treatment.

3.5.2 Exclusion criteria

The exclusion criteria are all the characteristics which are not listed in the inclusion criteria above.

3.6 Sampling procedure

3.6.1 Sample selection

According to Brink (2006) a sample is a part or fraction of a whole, or a sub-set of a larger set, selected by the researcher to participate in a research project. Sampling refers to the selection of materials so that the selected group is representative of the population the researcher is interested in (Creswell, 2009). The sampling in retrospective chart review refers to the method by which records are selected from the targeted population (Cresswell, 2009) which in this instance meant all of the charts of pregnant women delivered in the hospital between the period 01 April 2009 to 30 July 2009 at the Medical Records department were included for sampling. There were 1800 (N=1800) deliveries during the period between 01 April 2009 and 30 July 2009 (DHIS, 2009) at King Edward V111 Hospital. Of these deliveries, 7% was considered an adequate

sample size for the study. This is based on a previous study by Doherty (2008), and on the type of research used, namely, a descriptive study.

A simple random sampling was used to select the charts from the period of interest as mentioned above. A simple random sampling according to Brink (2006), allows everyone the opportunity to be selected, which permits a representative sample. The registered numbers as opposed to the names of pregnant women were used to draw the sample. From the list of registered numbers, patient records were selected based on inclusion criteria. Then simple random selection to avoid bias. From the 1800 charts that were selected only 130 charts met the criteria. This was due to the inclusion criteria that the researcher was interested in, e.g., the HIV status, whether any antenatal clinic was attended more than four times or not, or not at all, and how many bookings there were. To control for the sampling bias, only the characteristics for the study in the inclusion criteria were used to select the sample.

3.6.2 Estimating the sample size

The hospital has approximately 400 to 500 deliveries per month (DHIS: 2010). All the charts of previously pregnant women who had delivered at the King Edward V111 hospital during the period 01 April 2009 to 30 July 2009 comprised of 1800 deliveries in total. Based on this number, selection criteria of eligible charts were based on inclusion and exclusion criteria. A total of 130 charts met the set criteria to be included in the study, therefore considered sample size for the study. The rationale for this sample size is that the study aims at providing a description of the process of prevention of mother to child transmission. This sample is adequate to answer the research question, and that it represent charts that met the criteria for selection.

3.6.3 Data collection instrument

A data extraction tool (Appendix 3) was developed for this study to be used for data collection. The extraction tool consisted of the demographic variables, which included the age, the marital status, the employment status, type of delivery, and the time taken from booking in to testing, the baby's weight, and the number of staff on duty. These binary variables were used, based on the

previous studies that had used them to discover relationships. Part two of the extraction tool had all the variables of the Prevention of Mother-to-Child Transmission of HIV. This was used, based on the Department of Health's guidelines (2008) on which this study is based, to indicate which activities were to be included, and regarded as of importance in the coverage of an effective PMTCT program.

3.7 Data collection Procedure

Permission to use the charts was obtained from the hospital Chief Executive Officer for King Edward Hospital. A request for permission letter from the Chief Executive Officer was submitted to the Medical Records department where the patient records are kept for filing. The copy of the consent from the Chief Executive Officer was kept at the Medical Records department for filing.

Data was collected, guided by the standard data abstraction tool (Appendix 3) to inform the data collection process which had been developed for the study to extract data from the patient records containing all the variables to be collected, by examining the documented activities from the time the women had attended antenatal clinic. The researcher extracted the data. The data collection included the following variables as Part One of the extraction tool: demographic variables (age, marital status, employment status, birth weight and type of delivery - as outlined in the table of demographics, Appendix 1, Part 1 of extraction tool). The core PMTCT activities were the second set of variables which was developed, based on the PMTCT guidelines (DOH, 2008) and previous studies done (Horwood, 2010) which outlined the activities needed for prevention of Mother-to-Child Transmission of HIV, and identify the key activities as outlined in the table of variables (Appendix 1, Part 2) .

A convenient time to conduct the extraction was requested from the Medical records team, which turned out to be between 14h00 to 16h00 pm at the Medical Records department, at King Edward Hospital. Mondays, Wednesdays and Fridays were dedicated for extraction (three times a week). A total of ten charts were reviewed a day. This was the request of the Medical Records manager, due to staff shortages.

3.8 Reliability and Validity of the study

3.8.1 Inter-rater reliability:

To ensure inter-rater reliability, the data extraction tool was piloted to test whether the same results would be achieved with repeated use. According to Yawn (2005), information on the inter-rater reliability is seldom reported. The same standard tool was used for both charts. The inter-rater reliability is measured as a percentage of agreement when two or more abstractors collect from the same chart (Allison, 2000). This was achieved by using five charts and using two raters. The raters included all the categories of Data Abstraction Tool Two from demographics, two variables from Part 2 of the extraction tool which look at the PMTCT activities, and lastly, the PMTCT information location. The coefficient from the two raters revealed the need for refinement and the addition of at least two variables that looked at the relationship to answer the research question. The correlation coefficient was -1, and was not in agreement; therefore the tool had to be refined.

Results for raters

- i. Dual therapy to mother at Antenatal clinic
- ii. Cd4 testing for mother

The percentage difference between the two raters was 5%, where for dual therapy one chart hadn't recorded Dual therapy at antenatal care, while the other did not have records. In both charts, the second rater, the cd4 was recorded to have been taken, but one hadn't captured results. The difference between the two was not due to the tool not being able to capture information, but was the result of poor performance as the study aimed at ensuring that charts documented the activities.

3.8.2 Content validity

This is an assessment of how well the instrument represents all the different components of the variable to be measured (Brink, 2006). To ensure that all components were measured, the three objectives for the study were taken into consideration in ensuring that all components are well represented.

Table 3.1. Confirming the content validity of the tool:

Objective	How it was met
1. To describe the processes of PMTCT activities as documented in the charts	Part B , all the activities that should be carried out are described (thirteen core PMTCT activities)
2. To assess the performance of PMTCT activities by providing the proportion of charts with complete documented PMTCT core activities as per revised PMTCT guidelines.	Part A and B
3. To explore the relationship amongst the core activities of PMTCT as documented in charts	Part A (8 demographics), B (13 activities) and C (legality of the charts) of the extraction tool answers the objective

3.9 Data extraction and Data management

The standard data extraction tool was used as the gold standard for consistency in data recording, and only the researcher conducted the extraction. For quality assurance purposes, the data collection process was assessed once in three days. The quality assurance included checking for the three variables responses in the tool, to assess whether the tool was collecting what it intended to collect, with the same wording of the variables. An extraction tool was standardised for all of the 130 charts data extraction. To improve the extraction process, the researcher used

an exemplary chart showing the relevant information to be used as a reference for abstraction which was displayed in the room used for extraction. The extracted data would not be used other than for the purpose of the research. Only the researcher and the research supervisor would have the access code for data access. Data will be discarded after five years.

3.9.1 Missing charts

No charts were found missing. This reduced the bias that might have been caused by the missing files.

3.9.2 Missing data

Data that was missing was managed as ~~not done~~. This is because it is critical for every client to have recorded activities of PMTCT from the Antenatal care facility, to provide a continuum of care to the delivery site. If this was missing, it was deemed not to have been done.

3.9.3 Measurement error

The data extraction was piloted on five charts to ensure that the instrument (data extraction tool) gathered the information that was to be collected. The pilot resulted in a positive outcome, with all the variables of interest covered, as well as the demographic data.

3.10 Ethical Consideration

The research was conducted in an ethical manner. The record review did not record nor link to identifiers, i.e., the names or the identity documents of the records were not collected in the study but the study simply extracted information required for the research. Permission to review records at the King Edward hospital was obtained from the Hospital Manager (Annexure 1 and Annexure 2).

Information was provided to the hospital Chief Executive Officer, which detailed the reason why the study needed to be conducted. The records used for data extraction were guided by the extraction tool, and were not used for anything other than that. There was a fair selection of participants; the selection was based on reasons directly related to the study by using the inclusion criteria.

Confidentiality was ensured by not mentioning the patients' names. They remained anonymous. This was achieved by coding the patients' charts; therefore the data for the participants would not be linked to their names. The study may be published, but it will not use personal identifiers. Ethics clearance was sought from the Biomedical Research Ethics Committee before the study was conducted, and permission to conduct the study and consent was obtained from the Hospital, pertaining to permission to use the medical documents of pregnant positive women who had delivered in that hospital. Consent was not sought from the pregnant women, as only their charts were used. Personal identifiers were stored in a separate location for confidentiality.

3.11 Dissemination of findings

The findings of this study will be published through the University of KwaZulu-Natal library, in consultation with the supervisor. A copy of the report will also be submitted to the hospital Chief Executive Officer as agreed.

3.12 Data Analysis

For Polit (2008), data analysis is a process which a researcher coherently organises and synthesises. The data was analysed based on the research question, and objectives. A description of demographic characteristics will first be provided, which will be followed by the description of the variables, and activities of interest which are considered the core activities for the Prevention of Mother to Child transmission of HIV. Non parametric tests will be used in data analysis. The use of non parametric tests namely Pearson's Chi square, Fischer's exact, Kruskal Wallis was used to discover the relationship amongst the study variables.

Data Analysis was done using computer program SPSS (Statistical Package for Social Sciences) (Version 15.0, SPSS Inc., Chicago, IL) as well as Microsoft excel to display graphs and proportions.

3.13 Conclusion

This chapter covered the methodology used to guide the study; the instrument used to collect data, and included the ethical aspects on protection of the participants for the study, the control of the threat to internal validity as well as how the results will be disseminated.

CHAPTER 4

Data Analysis and Presentation of Results

The chapter will present the analysis of data of the retrospective review of patients records conducted at the selected regional hospital. A description of demographic characteristics will first be provided, which will be followed by the description of the variables, or activities of interest which are considered the core activities for the Prevention of Mother to Child transmission of HIV. The use of non parametric tests namely Pearson's Chi square, Fischer's exact, Kruskal Wallis-was used to discover the relationship amongst the study variables. Each chart assesses whether all the core activities of PMTCT is documented which will be shown by the documents on charts. A decision was made that if the charts do not have the documented activity, that will be taken as not done. This is based on the study done (Town-send et al: 2007), which stresses the importance of documentation by the health workers to assist in the provision of continuum of care to clients.

4.1 Introduction

All the 130 charts met the inclusion criteria thus considered for analysis. Data was analysed based on data collected from the extraction tool developed for the study guided by the PMTCT key activities (DOH: 2008) from the patients records. Analysis was done using computer program SPSS (Statistical Package for Social Sciences) (Version 15.0, SPSS Inc., Chicago, IL) as well as Microsoft excel.

The Chi square is the most widely used statistical test in nursing research (Brink: 2006), used to compare set of data, in the form of frequencies. The performance of these statistical tests is to discover the relationship between the core PMTCT activities amongst themselves, as well as the relationship of the activities with the demographic data. Proportions, frequency tables, and graphs (bar graphs, pie charts) will also provide the description whether PMTCT is provided in the services. A decision will be made based on clinical significance of the results. The aim of the

study was to assess whether core PMTCT activities are provided the hospital of Kwa-Zulu Natal, Durban as documented in the charts.

A description of demographic characteristics will first be provided, which will be followed by the description of the variables used.

4.2 DEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE

A total of eight demographic variables were used in the study, namely: age, marital status, employment status, type of delivery, time taken from booking to testing, parity, baby birth weight, staff on duty. These variables were selected based on the previous studies that considered these important in discovering the relationships with the activities of Prevention of Mother to Child transmission of HIV program Horwood (2010)

Table 4.1: Sample Characteristics

Characteristic	Frequency	Percentage
Age group		
13 years to 19 years	36	28%
20 years to 26 years	41	32%
27 years to 32	37	28%
33 years to 38	11	8%
39 years and above	5	4%
Mean = 24.8		
SD = 7.07		

Mode = 19 Range= 14 ó 47 Median = 23 years		
Marital Status Single Married Divorced Widowed	97 32 1 0	75% 24% 1% 0%
Booking to Testing At first visit After first visit	39 91	30% 70%
Employment Status Employed Not employed	30 100	23% 77%

Parity		
1 st Pregnancy	51	39%
More than once	79	61%
Staff on duty		
Less than 10 RN	101	78%
More than 10	29	22%
Mode of Delivery		
Normal vaginal delivery	74	57%
Caesarean Section	56	43%
Birth weight		
Above 1,5 kg	82	63%
Below 1,5 kg	48	37%

4.2.1 AGE DISTRIBUTION

The sample reflects the age distribution of women that delivered in the Regional hospital as documented on patient's records. The youngest participant was 14 years and the oldest was 47 years of age. The mean age was 24.8 years, standard deviation = 7.07 with a mode of 19 years. When age was grouped, the majority of participants fell within the category of 20 to 26 years of age, n= 41(32 %), followed by n= 37(28%) within the 27 to 32 years and n= 36 (28%) total

falling within the age group of 13 to 19 years respectively (see table 4.1). It is evident that women that were pregnant at the time of study were ranging between this age group. Twelve women fell within the age category of 33-38 years of age $n=11(8\%)$, whilst the participants in the category of 38 years and older were $n= 4(3\%)$. Majority of participants were 19 years old (i.e. $n= 14 (11\%)$, whilst only 1 (%) participant was 47 years of age.

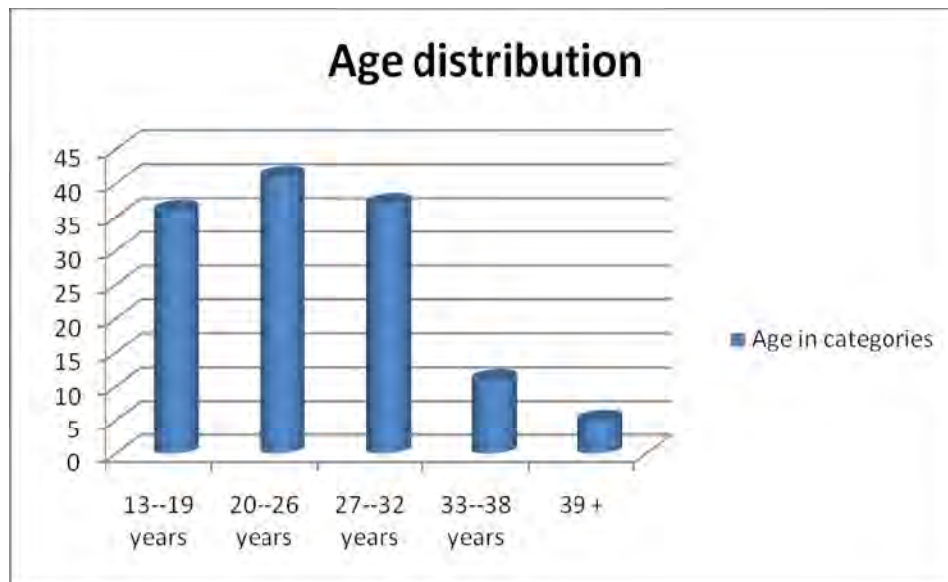


Figure 4.1: Age distribution of participants

4.2.2 Marital status

Marital status was categorised into four, namely single, married, widowed, and divorced. All reviewed charts had documented marital status. Of the charts reviewed, the majority had $n=97 (75\%)$ participant single, followed by $n=32 (24\%)$ documented to be married. Only $n=1 (0.8\%)$ was a widower whilst no one was reported to be divorced as per documents.

4.2.2.1 Marital status and age

The minimum age of clients that were reported single $n=97 (75\%)$ was ranging between 14 to 35 years, median was 22. Of the $n=32(24\%)$ participants that were married, the minimum age was 19, maximum of 47 years, with a median age of 37. This implies that most of the sample was made up of young single women.

On investigating the relationship between age and the marital status using the Kruskal Wallis non parametric test, no significant relationship was established between these variables (Kruskal-Wallis H value= 28.23, d f= 1, p= 0.234). This result suggests that the participant's age had no relationship with regards to her marital status in this study. Although a significant number of charts reviewed were those of single women between ages 14 and 35 years, which may indicate high prevalence of HIV in this age group in women whose charts were eligible for inclusion in the study.

Table 4.2. Comparing means between marital status and age range

Marital Status	N	%	Age Range	Median age	Mean rank
Single	97	74.6%	14-35 years	22.00	53.40
Married	32	24.6%	19-47years	31.50	100.36
Widowed	1	0.8%	37-37years	37.00	123.0
Divorced	0	-	-	-	-

4.2.3 Employment status

This variable was recorded employed or not employed in the charts; therefore it was reported in the study as the binary variable. The documents could not specify what type of employment. A total of n=30(23%) participants were employed, with n=100(77%) without employment. This demonstrates that only a quarter of women delivering in this hospital have employment.

4.2.3.1 Employment status and marital status

A cross-tabulation of marital status and employment revealed that more than two thirds of the sample were single and unemployed (n= 85, 65.4%), in relation to only n=15 (12%) of married women who were unemployed. Table 4.2 displays the results of the cross-tabulation. When employment status and marital status was assessed using a Pearson Chi Square test showed a

significant relationship between these variables ($\chi^2 = 25.87$, $df = 2$, $p = 0.000$). These results suggest that employment status is related to a participant's marital status.

Table 4.3: Employment status and marital status cross tabulation

Marital status	Employed	Not employed	Total
Single	12 (9%)	85(65%)	97(75%)
Married	17(13%)	15(12%)	32(24%)
Widowed	1(0.8%)	0(0%)	1(0.8%)

4.2.4 Type of delivery and administration of Nevirapine to the baby

This binary variable of whether the delivery type was Caesarean section or by normal vaginal deliveries variable was chosen because some babies may have not received Nevirapine dose (prophylaxis), because the child was delivered with complications. In the public health sector, a caesarean delivery is only performed when there is an indication. (Moodley: 2005). The normal vaginal deliveries were $n=74(57\%)$, whilst participants delivered by a caesarean section were $n=56(43\%)$. This entails that in this study, participants delivered normally were slightly more than those delivered by a caesarean section.

On further exploration between the mode of delivery and the administration of Nevirapine using a Fishers Exact non-parametric test, there was no significant relationship established (Fishers exact value= 2.492, $df = 1$, $p = 0.114$). This is an encouraging finding which suggests that the administration of the NVP is not affected by the mode of delivery.

4.2.4.1 Baby birth weight and type of delivery

This variable birth weight was used as a proxy measure to estimate whether low birth weight (below 1,5kg) and normal birth weight (equal and above 1,5 kg) relates to the type of delivery for women. About $n=82(63\%)$ of babies had the birth weight of 1,5 kg and above whilst $n=48(37\%)$ had the weight below 1.5 kg. This implies that most babies had the birth weight of

1,5 kg and above respectively. The number born with normal weight outweighs the babies born with low birth weight by n=34(26%).

On exploration of the relationship between the babies birth weight and the type of delivery using a Chi square test, there was no significant relationship established (χ^2 value=0.487, d f=1, p=0.272), implying that a child's birth weight is not affected by the mode of delivery (either normal vaginal delivery or caesarean section) of a woman.

Table 4.4 : Birth weight (below or above 1, 5 kg) and type of delivery (Caesarean section and Normal vaginal delivery).

Type of delivery	Birth weight		Total
	above 1,5kg	Below 1,5kg	
Normal Vaginal Delivery	50(38%)	24(18%)	74(57%)
Caesarean Section	32(25%)	24(18%)	56(43%)
Total	82(63%)	48(37%)	130(100%)

4.2.5 Parity and Nevirapine to pregnant women

This binary variable assessed whether the current pregnancy was the first pregnancy or not the first pregnancy. About n=50(38%) participants reported to be pregnant for the first time, whilst n=80 (62%) was not the first pregnancy. This implies that more than half of the participants were not pregnant for the first time in this study. This variable will be used to investigate the

relationship between the administration of Nevirapine to the women and the parity. On application of Chi square, a non significant test result was obtained ($\chi^2 = 6,923$, DF=1, $p=0.009$) which suggest a non significant relationship between the participant's parity and the administration of Nevirapine to a woman.

4.3 Activities of PMTCT

To assess the performance of PMTCT, fifteen activities were identified as the core activities that will inform that the women and children received the antiretroviral prophylaxis as per DOH (2008). This entails that if the program is implemented well, each patient document should have all the activities documented. Given the fact that every activity or intervention to prevent mother to child transmission is important, some charts were found to have gaps on important areas. This may mean that there were gaps in the provision of quality care for prevention of mother to child transmission of HIV. The list of the activities were as follows:

- I. Dual therapy (DT) initiated at Antenatal clinic
- II. DT taken more than four weeks
- III. Single dose Nevirapine taken in labour
- IV. AZT 3 hourly taken in labour
- V. Cd4 count taken
- VI. Cd4 results documented
- VII. Cd4 count Below 200
 - VIII. Above 200 cell count
- IX. HAART initiated during pregnancy
- X. World Health Organisation clinical assessment (WHO Staging)
- XI Infant feeding counselling

XII. Formula feeding choice

XIII. Breastfeeding choice

XIV. AZT to baby within 72 hours

XV. DT to baby to be given at home

4.3.1 Dual therapy initiation to pregnant women

About n=98(75%) of charts showed that dual therapy was initiated while pregnant with n=43(33%) had it taken for more than four weeks. These results suggest that there is an improvement in the coverage of dual therapy initiation to pregnant women, which is contrast with a study by Doherty (2009) which showed reduced uptake at 57% of DT at antenatal care.

About n=91(70%) had a single dose Nevirapine taken in labour. Participants documented to taking AZT three hourly were n=81(62%) respectively, whilst n=91(70%) of women documented to have taken single dose Nevirapine (sd NVP) in labour. The descriptive findings of this variable suggest that pregnant women were 75% more likely to receive Dual therapy while pregnant.

4.3.2 Dual therapy initiation to baby

A total of n=105(80%) of babies born to HIV positive women received nevirapine post delivery whilst n=95(73%) received AZT within 72 hours after delivery as required by the Department of Health program guidelines. This study showed much improvement when compared to the study by Doherty (2009) which showed 15% of nevirapine to babies. The results suggest that babies are 80% more likely to receive dual therapy when born to HIV positive women in this study.

4.3.2.1 Relationship between Dual therapy to women and Dual therapy to babies documented

A total of n=98(75%) of sd Nevirapine given to mothers while n=105(80%) sd Nevirapine was recorded as administered to babies. This indicate the 5% difference between the baby NVP and the mother NVP. Although it seems like there is improvement in the administration of NVP to babies, compared to Doherty (2009) study of 15%, but the 20% is too large the proportion for the

babies that were missed. Newell (2007), had stressed that one life lost is too many, if the opportunity for administration are missed. This entails that these babies maybe at increased risk of transmitting the virus from their mothers if they didn't receive antiretroviral intervention prophylaxis. Interestingly, there were no set of twins in the charts that were reviewed; hence it was not in the exclusion criteria. On exploring the relationship between the dual therapy to women and a dual therapy to babies applying Fischer's exact test (Fischer's exact value= 0.19, $df=1$, $p= 0.66$), there was no significant relationship established between DT given to women, and the DT given to babies, this is of concern on light of the guidelines (DOH: 2008) , a difference as indicated by the fisher exact test suggests that not all mothers and or babies are receiving the dual therapy as is indicated

4.3.3 CD4 Recording

4.3.3.1 Relationship between CD4 taken against cd4 cell count results documented

A total of $n=78(60\%)$ had cd4 taken, while $n=52(40\%)$ of eligible positive women were not taken cd4 count. Of the participants taken cd4 cell count, only $n=45(35\%)$ had their results documented. A cd4 cell count is the requirement that all HIV positive women to have been taken same day of testing for HIV (Doherty : 2009). This enables women to be able to assess for eligibility for lifelong antiretroviral therapy (ART) when their cd4 count is equal or less than 200 cell count (DOH: 2008), which help them to improve their own health. Having a cd4 count that is less than 200, poses risk of transmission from the pregnant woman to her unborn child (Dhayendre: 2007). This study result is in contrast with the study by Horwood (2010) which discovered much improved uptake 78% of cd4 taken. The documentation of results or availability is still a gap in this study (35%) compared to Horwood study which showed improvement by half (55%).

A Fischer's exact test exploring the relationship between the cd4 taken and the results documented revealed no significant relationship (Fischer's exact value = 19.23, $df=1$, $p= 0.028$) This indicates the likelihood of a disparity of a client having their cd4 test performed and not receiving results for the cd4 test.

4.3.3.2 Booking to testing against cd4 count taken

About $n=52(40\%)$ of women who were booked for their first antenatal visit were tested for HIV on the same day of booking compared to $n=78(60\%)$ who were tested on repeat visits. One of the exclusion criteria has been that women should have at least attended the antenatal clinic four times or more (this was done to control for clients who may have booked late and would have not been able to access antenatal care early to receive the package). This reveals that there still is a gap in clients being tested at the same day of booking. Although the testing is voluntary, which means a person chooses to be tested after having pre test counselled; there was no record of the test being offered to clients and whether they refused the test. The delay in testing worsens the cd4 resulting which should be taken the same day of testing HIV positive (out of the $n=78(60\%)$ done cd4, only $n=39(30\%)$ of them were done same day of testing positive.

A non significant test was obtained when applying a non-parametric test (Fischer's exact= 0.39, $d f=1$, $p= 0.335$). The results suggest that there was no relationship between the time the participant book for antenatal care and testing for cd4 cell count, this is of concern in light of the PMTCT guideline which indicates that (a cd4 test should be done the first day a participant test positive.

4.3.4 HAART initiation during pregnancy

4.3.4.1 Relationship between Cd4 results <200 mmol/l and HAART initiation

About $n=18(14\%)$ had a cd4 cell count of less than 200 mmol /l. Of the clients with low cd4 cell count, $n=10(55\%)$ were initiated on Highly Active Antiretroviral Therapy while pregnant (eligibility as determined by the level of cd4, if equal or less than 200 cell count or WHO clinical staging). With the majority of cd4 results not documented (only 35% available from the 60% taken), there may be participants who have low cd4 count, but that is not known due to unavailability of results.

On exploration of the relationship testing, Fischer's exact yielded a significant relationship (Fischer's exact= 20.80, $d f=1$, $p=0.000$) proving the significant difference between the women who are initiated onto HAART and the level of cd4.

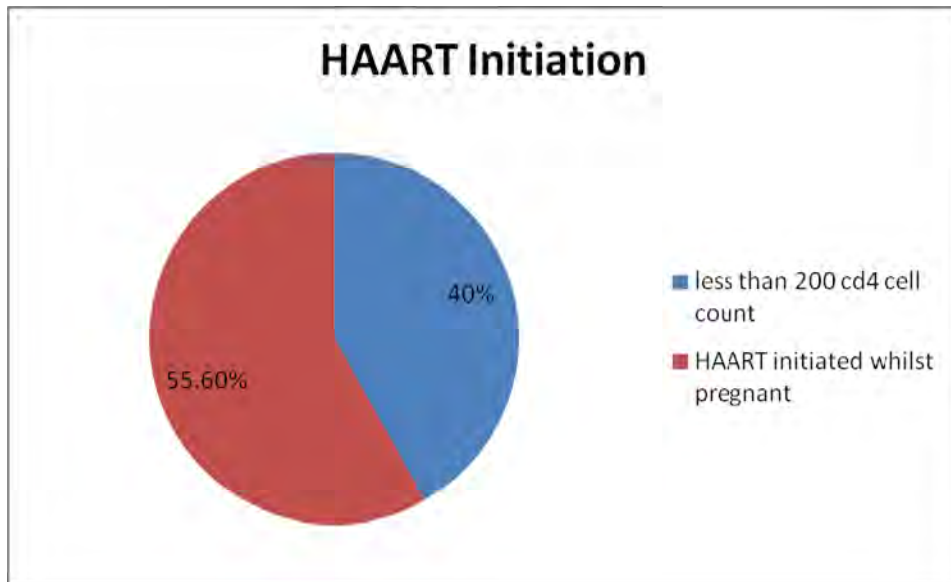


Figure 4.2 : showing HAART initiation against less than 200 cd4 cell count

Despite cd4 cell count as the eligibility criteria to qualify for ART, WHO clinical staging is another form of determining whether a person qualify for ART (WHO: 2004). According to this criterion, cd4 cell count is not the only criterion to access for ART eligibility (Chopra: 2009). Of n= 9(7%) patient records had World Health Organisation staging recorded (see table 4.5).

Table 4.5: Core PMTCT Activities

Variable- core activity	No. of charts with documented activity	Percentage
DT initiated at ANC	98	75%
DT taken more than 4 weeks	43	33%
Sd NVP taken in labour	91	70%
AZT 3 hourly in labour	81	62%
Cd4 count taken	78	60%
Cd4 count results documented	45	35%
Cd4 count <200 cell count n=45	18	40%
Cd4 count >200 cell count n=45	27	60%
HAART initiated during pregnancy (of those eligible-) n=18	10	56%
WHO stage 3 or 4	9	7%
DT to the baby n	105	80%
Feeding counselling received	60	46%
Opted for breast feeding	26	20%
Opted for formula	63	48%
AZT given to baby within 72 hrs	95	73%
Easy access of PMTCT information	36	28%

4.4 Documentation of key activities: n=15

The total cardinal activities (15 activities) were chosen based on the Department of Health (2008) guidelines. These were considered to be the core activity that informs the program for

Prevention Of Mother to Child Transmission of HIV/AIDS. Having assessed each variable (see table 6), the proportion at which each was documented as done differs in all the activities. This section will then assess further on how many charts had activities documented. The activity documentation was divided into three groups that is 0 to 5 activities; 6 to 10 activities and 11 to 15 activities. On exploring each file, there was no chart with all fifteen core activities documented. Table 4.6 indicates that majority of the charts n=107(82%) had between 6 to 10 core activities documented, whilst n=12(9%) with 0 to 5 activities, and n=11(9%) had 11 to 15 activities. This indicates that not all the required activities for PMTCT were performed as documented on the sampled charts. As the pregnancy progresses the opportunities are missed in each step of the PMTCT activity intervention.

Table 4.6 : Documentation of activities

Documented activities in range N= 15	Total no. of patient records within the range N=130	Percentage
0 to 5 activities documented	12	9 %
6 to 10 activities documented	107	82 %
11 to 15 activities documented	11	9%

On demonstrating the comparison of the documented activities, each chart was given a score based on the key activities of PMTCT. The maximum activities documented was 12. The median charts with documented activities was 28 (i.e. 22% of the sampled files) with at least 8 activities documented; the lowest charts had 4 of the core PMTCT activities documented n=3(2.3%).

The top five commonly documented activities that were most frequently reported are presented in table 4.7. Majority of the charts had documented DT to baby initiated n=10(80%), DT initiation at ANC followed with n=98(75%) of charts with this core activity.

The list on commonly reported activities ranked in order of mostly reported.

Table: 4.7. Showing the top five commonly reported activities

Core activity	Frequency
1. Dual therapy (DT) given to baby	105(80%)
2. Dual therapy initiation at ANC	98(75%)
3. Single dose Nevirapine (sd NVP) taken by women in labour	91(70%)
4. AZT three hourly to woman in labour	81(62%)
5. CD4 blood taken	78(60%)

While these were documented, and were considered the core activities for PMTCT, no activity was reported more than 80% of the time. The Dual Therapy to baby n= 105(80%) is the crucial activity for PMTCT, but it was evidenced to work well when women had received the Dual Therapy initiated at antenatal clinic, which is documented less by 5% compared with the DT.

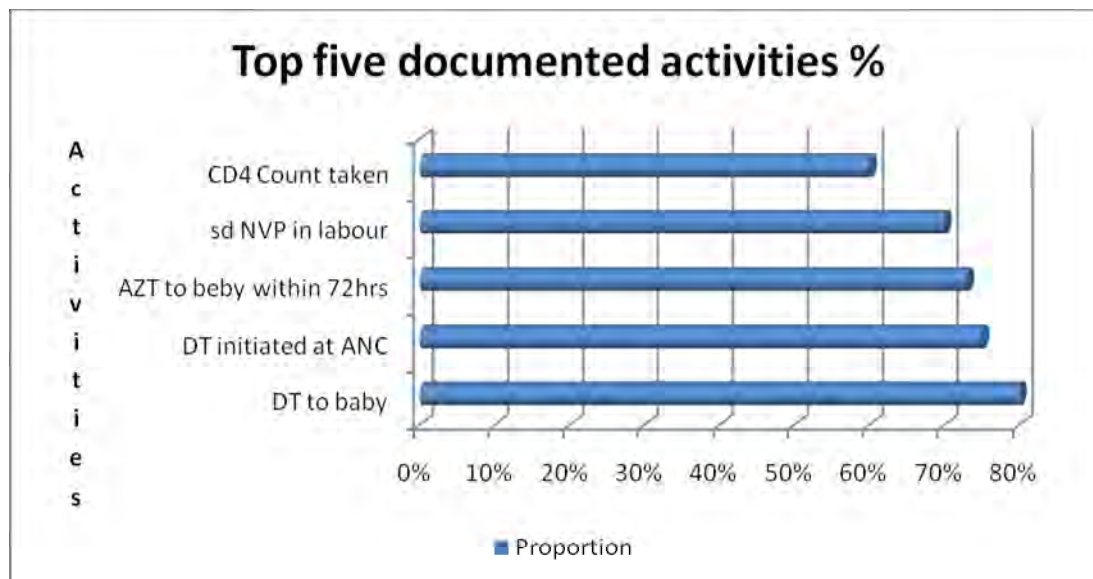


Figure 4.3 : Top five activities documented

The least documented activities was WHO clinical staging with n= 9(7%) charts, followed by dual therapy taken more than four weeks, n=43(33). These are some of the crucial activities that should be performed in all the tested positive women while pregnant to minimise the risk of transmission. The bottom five activities documented, arranged from the least documented were as follows:

1. World Health Organisation clinical staging (7%) documented

To assess whether women is clinically eligible to start HAART even in the absence of cd4 results. Each tested positive women is required to have gone through the assessment

2. Dual therapy taken more than 4 weeks (33%)

3. Feeding counselling received (46%)

The feeding counselling choices should be decided on while pregnant, and has been identified as contributing to postnatal HIV/AIDS transmission (UNICEF: 2000).

4. Cd4 result documented (35%)

HAART for pregnant women rely on whether the cd4 count is equal or below 200 to qualify for treatment.

5. HAART initiation to eligible women (56%)

For women with low cd4 count, or WHO stage 3 or 4, it is the requirements that (WHO: 2008)

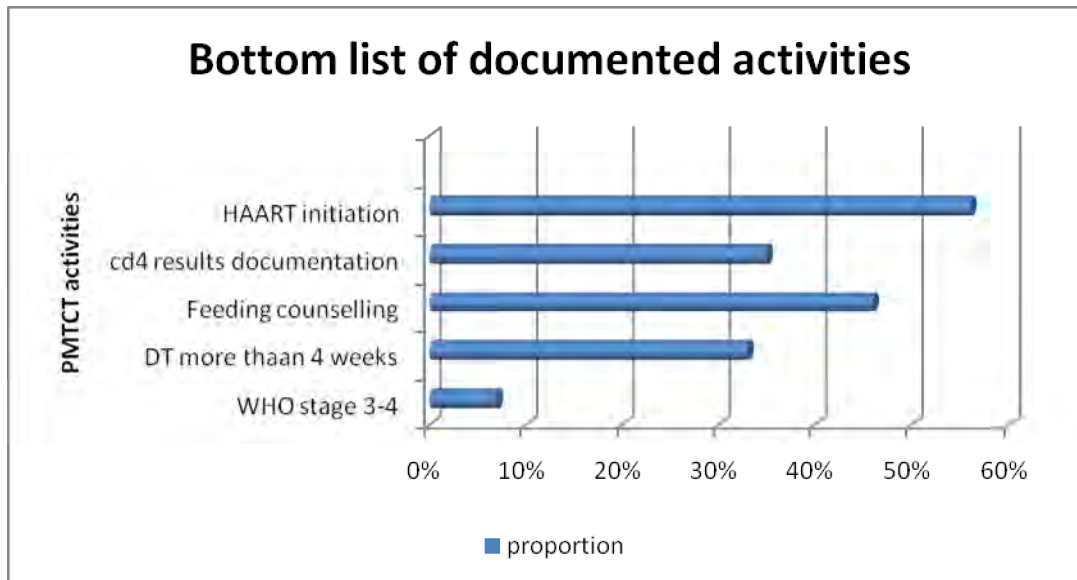


Figure 4.4 : Displaying the bottom list of activities documented

4.5 Relationship amongst the key activities of PMTCT

Table 4.1 demonstrate the upper and lower limit to which the activities can fall within even when applied elsewhere, with the percentage of charts with the number of the activities documented. The figure explains the confidence interval to guide the process of generalisation based on the sample. The charts with the most documented activities were n=28 (21.5 %) charts with at least 7 of the 15 core activities documented resulting in the confidence interval of lower limit and upper limit (0.1446 1.285) respectively, indicating that in the true population from which the sample was drawn, one can have a 95% certainty that this will occur.

Table 4.8 : Percentage of documented activities and related confidence intervals

No. of activities documented N=15	Frequency no. of charts with activities N=130	Percentage of chart	CI for the % of charts
4	3	2.3%	0.0026 0.049
5	9	6.9%	0.0256 0.113
6	13	10%	0.0036 0.217
7	28	21.5%	0.1446 1.285
8	24	18.5%	0.1186 0.252
9	22	16.9%	0.1056 0.233
10	20	15.4%	0.0926 0.216
11	6	4.6%	0.0096 0.082
12	5	3.8%	0.0056 0.071

From the table 4.1, it shows that no chart had all the 15 activities documented. Instead the maximum was 12(n=15). The median charts with documented activities was n=24(18%) charts with at least n=8(53%) activities, and the most charts had n=7(22%) activities which was n=28(22%) charts. The lowest had n=4(27%) PMTCT activities documented, a total of n=3(2%) charts.

4.5.1 Cd4 results against cd4 done

About n=78(60%) of women were done cd4 count, and only n=45 (35%) had documented results. A significance test result when Fischer's exact test performed revealed (Fischer's exact value= 37.69, d f =1, p=0.000). The results indicate that there is a significant difference between cd4 done and the availability of results. This imply that it is likely that not all participants done cd4 receive result

4.5.2 Feeding choice against employment status

A total of n=60(46%) received feeding counselling to make informed choice, whilst n=70(54%) were recorded as not counselled on infant feeding. To determine the relationship, Pearson's Chi

square revealed the non significance difference result (χ^2 = value of 37.692, d f=1, p=0.29). The result suggest that there is no significant relationship between the choices that women make and their employment status, therefore the choices of infant feeding made is not influenced by the employment status in this study.

4.5.3 Infant feeding counselling and the choice of infant feeding

The choice of infant feeding was either formula feeding or breast feeding, there for was made binary variable. The majority of participants chose formula feeding n=63(48%) to breast feeding n=26(20%), when only n=60(46%) participants received infant feeding counselling to make informed choice. It implies that a total of n=70(54%) participants were not offered infant feeding counselling whilst n=41(32%) is not known what method of feeding was chosen .On exploring the relationship of the two variables, the Fischer's exact test revealed (Fischer's exact value= 0.123, df=1, p=0.000) , explaining the significant differences in the choices made by women .With the new recommendations from WHO(2010) it made it clear on the importance of providing counselling for infant feeding to reduce the mixed feeding resulting in transmission of HIV/AIDS through post natal care.

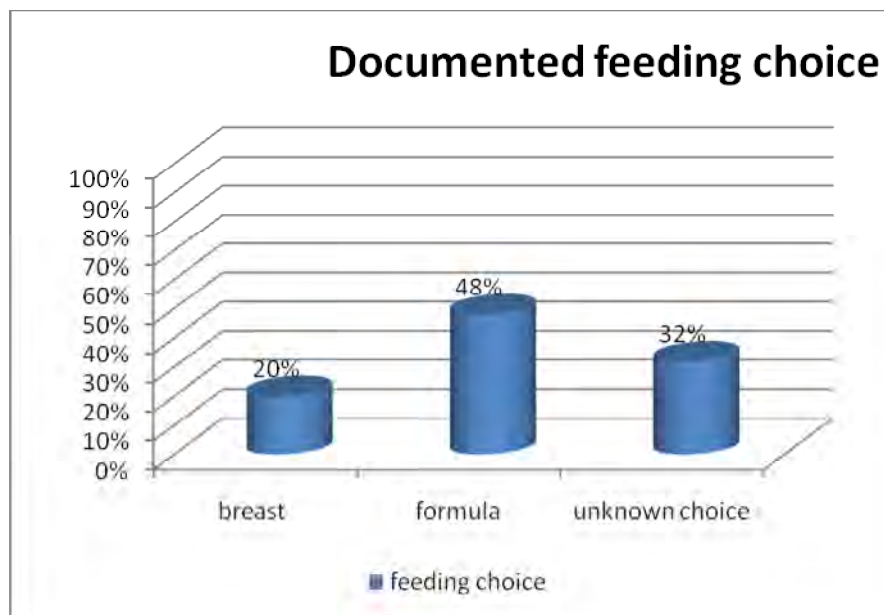


Figure 4.5: The figure demonstrate the feeding choice documented as chosen by participants

4.5.4 Breast feeding choice against age

The women who are younger tend to not choose breast feeding method. This may be due to the influence of each other or stigma associated with breastfeeding options. What was observed is the high number of 19 year olds $n=11(8\%)$ of whom only $n=3(2\%)$ chose to breast feed. When comparing the breastfeeding option by women to age, the test statistic Fischer's exact revealed (Fischer's exact value= 46.85, $df=1$, $p= 0.000$), which indicate the highly significant relationship between the choice of breast feeding and the age of women. That entails that the decision on breast feeding choice is influenced by age.

4.6 Conclusion

The results indicate that gaps still exist in provision and documentation of PMTCT activities, and that the demographic information contributes partly in the outcome of PMTCT. In age category, noted is the majority of the participants who were between the 20 to 26 years category (32%), with the category 39 years and above (4%) the minority. The majority of the participants were unemployed (77%) noticeable, the majority who were unemployed were single participants (85%). These results suggest the relationship between the employment status and the marital status ($p=0.000$).

Dual therapy initiation at antenatal clinic is improving compared to previous studies (75%) although the 25% missed opportunity can be avoided. Most interesting result is that of Nevirapine to babies and mode of delivery. The results suggested that the administration of Nevirapine to babies is not affected by the mode of delivery of a pregnant women ($p=0.114$). This implies in this study that whether the deliver mode is normal vaginal delivery or by caesarean section, this will not change whether the baby will receive Nevirapine or not.

It also shows that the testing for cd4 counts is still a gap, where 60% of the cd4 were done, and only 35% results were documented. This highlights the poor documentation of intervention, for quality of care and for continuity of care in the next level of care. It cannot be over emphasised that unless it is documented, it is not done. The late testing for cd4 count may impact on the turn

around time for results, and initiation of eligible women onto lifelong Highly Active Antiretroviral therapy (HAART). Studies had proven that with low cd4 count (when the study was begun the cd4 was 200 mmol/l, the new guidelines allow 350 mmol/l eligibility access for ART.

With only 46% infant feeding counselling done, the choice for infant feeding may be incorrect as no informed decision was made to support women, and to reduce the post natal transmission of HIV. With the new World Health Organisation Guidelines, the expectation is that women should make an informed choice, with an added benefit, Antiretroviral (Nevirapine) to the baby to improve child health survival. Extensive counselling for women on making informed decision about what to feed their babies is therefore crucial.

It is the requirement by World Health Organisation that all HIV positive women be clinically staged to determine eligibility for ART. With the new PMTCT guidelines that had been revised to enable women to access prophylactic ART with cd4 less than 350 (DOH:2009), as opposed to 200 cd4 in the previous program (DOH:2008), it is needed that women are staged more so in cases where the cd4 count is not available enabling women to HAART.

Minimize waiting times for ART to help women to assess treatment for their own health as well as for their babies. It is important that women who has low cd4 counts or WHO stage 3/4 to access ART as they carry a risk of transmitting the virus to their unborn babies (weak immune system). This is also important to measure the effectiveness of the PMTCT program

Evidence had shown that there is increased number of chances of transmission from a client with low cd4 count (McKellar, 2007)) as well as who has been assessed clinically as stage 3 or 4. This means that all measures need to be taken to get all necessary steps right so that by the time of delivery women received adequate care to assist in reduction of transmission. Most happen due to women who qualified for HAART, but were not initiated on time.

The following chapter will then discuss major results, the recommendation as well as limitation and conclusion.

Chapter 5

Discussion of major results, recommendations, limitation and conclusion

5.1 Introduction

The chapter will discuss the major results following the data analysis after the chart review study conducted that described the performance of PMTCT activities as documented. It will provide the design and methodology utilized in data collection, then discuss the recommendation and limitation of the study

5.2 Discussion of major results

5.2.1 CD4 testing and cd4 results documentation

The PMTCT service recommended by DOH (2008) includes investigation for cd4 when tested HIV positive, while also staging of clients, which then determines the Antiretroviral Therapy eligibility of clients. Stringer (2009) had shown that low cd4 increases the chances of transmission of HIV due to high viral load. There had been slight improvement in taking of cd4 cell counts to HIV positive women (60%) as opposed to 57% in a study by Doherty (2009) yet it is expected according to the guidelines(DOH:2008) that cd4 should be done same day a client test positive and to all women found to be positive. With only 60% of participants recorded to have been taken cd4, indicates that 40 % (n130) were missed the opportunity to assess the level of cd4 to access treatment for their own health and for their children. a significant difference proved the association in the results and documentation ($p=0.000$). Horwood (2010) in the study to evaluate PMTCT, had shown that 78% of women were reported to have done cd4 count, but 33% had the results recorded, which support this study that there is poor uptake of cd4 as well as unavailability of the cd4 results after it was taken.

According to Tonwe-Gold (2007), early identification by cd4 results shown by availability of results and HAART initiation prior to delivery is essential for preventing the transmission from the mother to her child (MTCT). Considering the unavailability of cd4 results, it is possible that more women may have low cd4 (equal or less than 200) if only their results were available.

With the new Department of Health guidelines for PMTCT (2010), it is recommended that women should receive antiretroviral with at least 350 cd4 cell counts, which has improved from the previous 2008 (cd4 of 200 cell count) DOH guidelines to allow women to access treatment early.

The delay in results delay clients in accessing lifelong therapy, HAART since World Health Organisation staging is poorly documented as well with only 9 /130(7%) were clinically assessed, yet the World Health Organisation had recommended that all HIV positive tested clients should be clinically staged to determine HAART eligibility, and not only relying on cd4 results. A low cd4 count was associated with high viral load thereby increasing the chances for mother to child transmission.

5.2.2 HAART initiation whilst pregnant

The study revealed the gap in HAART initiation to eligible pregnant women, and gap in cd4 results availability. Amongst the inclusion criteria, one of them was that of attendance to ANC four times and more. This shows that woman presented themselves at least four times that they had the opportunity to had undergone PMTCT interventions.

A total of 18/130(18%) participants had low cd4 (equal and less than 200 cd4. of the n=18 participants. About 10 (55%) were initiated onto HAART. With Kwa Zulu Natal being one of the Provinces with highest HIV antenatal sero-prevalence at 38.7 (NDOH: 2009), the PMTCT program will bear results once all the processes of care and activities are provided to all women found to be HIV infected to be able to meet the NSP target (DOH: 2007) of reducing MTCT to less than 5% by 2011) as well as documentation of processes on patients records

The study highlights the fact that there are still gaps in the documentation of core PMTCT activities that if not performed may have negative outcome to a child or women. This is made worst by poor recording of the simple PMTCT activities yet complicated by occurring at different levels, resulting in failure to provide continuum of care by the next level.

5.2.3 Antiretroviral prophylaxis initiation (Dual prophylaxis= Nevirapine and Zidovudine-AZT)

It is recommended that pregnant women who are tested HIV positive but not yet eligible for life long therapy of ART, should receive the ART prophylactic drugs (Zidovudine and Nevirapine called Dual therapy prophylaxis) for prevention of transmission of HIV from mother to child at the time of study the criterion was that the prophylaxis should be started from 28 weeks of pregnancy (DOH:2008), yet the new PMTCT guidelines (DOH :2010) had made recommendation fro the prophylaxis to be started from 14 weeks of pregnancy. The prophylaxis had proved that if implemented well at 28 weeks, it can reduce transmission to less than 5% (Chopra : 2009).

A total of n=98 (75%) of women had received nevirapine at antenatal clinic, which is lower than Horwood (2010) study which had found that 91% received nevirapine at antenatal clinic, whilst n=91(70%) taken nevirapine in labour. This highlight the quality gaps in the provision of services. With 98 participants receiving dual therapy, the remaining n=32(35%) may seems like the small number, but this counts to the number of exposed children that may be infected due to missed opportunity, whilst their mothers had attended antenatal care for more than four times (eligibility criteria for this study). The opportunity was there, but women are missed. With increasing child mortality in the developing countries like South Africa, interventions that have proven to work in the same resource limited settings like Khayelitsha from Western Cape, succeeded in reducing vertical transmission in 2007, to less than 3.5% (Doherty :2007). This suggest that PMTCT can reach all mothers who need service and count down to United Nations Millennium development goals (by 2015 reducing MTCT to less than 5%) and National Strategic plan (SADOH:2007) to reduce transmission of HIV from mother to child to less than 5% by 201.

5.2.4 Infant feeding Practises

Besides vertical transmission of HIV, infant feeding is one of the methods that may contributes to post natal transmission of HIV. Although the focus is not much on this method of transmission, but it has been noted that breast feeding can contribute to transmission. A total of

n=60 (46%) of participants that received infant feeding counselling according to records. Of the 46% that received infant feeding counselling, n=26(20%) chose to breast feed whilst n=34 (26%) had chosen formula feeding. With the new World Health Organisation recommendation for infant feeding (WHO: 2009), includes the use of antiretroviral interventions to babies (Nevirapine syrup) while babies are breast fed, in reducing the transmission at post natal period. With the new recommendation , it is strongly emphasised the importance of counselling to make informed choice to improve HIV free survival oh HIV exposed infants , thus improving the HIV infected women. With the DOH guidelines (2009), the formula was provided free of charge to women who are found to be positive and chose to formula feed. While in the new upcoming recommendation by World Health Organisation (2010) guidelines which have not yet finalised by the South African Department of Health , it is hoped that women should consider breast feeding as the first choice (Coutsoudis : 2009), in the low resourced countries like South Africa.

The rationale for counselling has always been to ensure that the correct method is chosen, information is provided for women to make a choice to avoid the post natal transmission of HIV.

5.2.5 Accessing PMTCT information

Access to information about activities of PMTCT was challenging to extract with only n=36(28%) documents, had the PMTCT activities centrally located for easy access , to ease intervention, the rest n=94(72%) was located all over the chart, that was time consuming for continuum of care. This may result in health worker having to miss this crucial information in the health care system that always is short staffed in the maternity section. The low initiation rate also poses a concern for pregnant women's health. All charts for women with low cd4 had documented that the women was referred for ART, yet no initiation was done as per documents. This can be attributed to the disintegrated services, This was noted through the recording stated that clients to be referred for initiation to the next site, by not providing the package of services in one facility as most clinics do not offer ART on site. Long waiting times for counselling on adherence to HAART drug regimen was noted in documents.

The low uptake of HAART in pregnancy is a concern. Considering that most clients couldn't have the results, it may have been that more qualify for HAART, has it be that their results are

unknown. The studies done had revealed that there is increased transmission with low cd4 count. Provincial DOH (2008) has made a memorandum that since women that are pregnant are a priority, they should be initiated within two weeks of discovering their status. In other developed countries like Europe , pregnant women found to be HIV positive are put on Triple therapy ARV to reduce transmission, to which they have succeeded in reducing it to less than 2% (UNAIDS:2008) .

The poor availability of cd4 results , 60% taken, with only 35% results available in documents is a concern for maternal and child survival, which implies that pregnant women will not receive the expected quality of care that should be rendered to them, thereby missing the opportunity for children born to these women. The unavailable results may be low cd4 cell count that requires that women undergo advanced treatment, as opposed to prophylaxis Dual therapy. Documentation translates to practise, if it is not documented, it is not done. With the complexity of the PMTCT program occurring in different settings, the documents serve as the communication tool to all the levels of care, with the interventions documented to guide the next intervention. The cd4 cell count is the key eligibility criteria as well as WHO clinical staging that determines whether lifelong antiretroviral should be prescribed for women. With only 9/130 (7%) of charts with staging recorded, whilst cd4 uptake is poor, women are lost which may increase the chances to transmission.

The gaps identified will be evident more in the follow up of clients for testing of babies born to HIV positive women. The importance of clear documentation of activities couldn't be over emphasise by the fact that the services are rendered at different levels of care (Ante natal care, labour ward, as well as post natal care)

If South Africa is to succeed in meeting the MDG goals (Millennium Development Goals (goal 5- which stresses the prevention of HIV), and that of National Strategic Plan (NSP: 2007-2011-2013, that of reducing MTCT from 21% to less than 5% by 2015 , the country has to ensure that all the necessary interventions for the priority program (PMTCT) should be clearly documented and performed.

5.3 CONCLUSION AND RECOMMENDATION

Recommendations

Despite the burden posed by HIV pandemic, documentation of vital steps for access to intervention strategy (PMTCT AND HAART) remains poor. This is despite the established PMTCT ART programs, the majority of women are missed which may result in poor outcome such as child mortality, that represents failure of the program. The chapter will provide recommendations that will cover the following: the nursing education, recommendation for clinical practise, for research as well as the recommendation for nursing management.

5.3.1 Recommendation for Nursing Education

South Africa has good health policies and guidelines; however the country must ensure that these policies and guidelines are translated into practise. Support should be offered to the health workers especially nurses, to ensure that guidelines are adhered to, and that the nursing curriculum emphasising the importance of documentation more especially by the nurses, and ensures that necessary measures are taken to ensure accountability of the health workers in documenting their practise. A need to ensure that monitoring and evaluation tools are available to monitor the progress of the program

5.3.2 Recommendation for clinical practise

Quality of care should be rendered to every client to ensure that health promotion, prevention of diseases that contributes to child transmission of HIV. Proper documentation by health workers to facilitate ongoing continuum of care, and assisting with the evaluation of the program which remains the challenge. This involves accountability on the part of health workers and providing quality of care. A need for accountability, must also realize that documenting the practice has and will always be the only way of ensuring that the right intervention is received, as if not recorded it is not done.

5.3.3 Recommendation for future research

A large study that will follow up to see whether DT resulted in prevention of mother to child transmission. The follow up for children to assess whether mother to child transmission was reduced, a prospective study that will follow up more so, the HIV exposed children (children born to HIV positive women) to see the transmissions averted. Chart reviews research in nursing is poorly done. More chart review studies should be encouraged, to identify gaps for prompt action.

5.3.4 Recommendation for nursing management

The study had revealed gaps in the provision of Prevention of Mother to Child transmission program. Documents revealing missed opportunities for women who did not receive care as outlined in the PMTCT guideline (DOH: 2008). The onus is on nurse managers in the institutions to ensure that the guidelines are adhered to, and emphasize the importance of documentation. Through routine charts audits, the gaps can be identified swift, and actions taken to correct gaps. The managers should ensure that the health workforce are skilled and know the guidelines and protocols to guide the practise, and necessary measures in terms of accountability, to be taken for not adhering to the required practise that may lead to poor quality of care rendered to patients.

5.4 Study Limitations

Limitation to the study include that the chart review didn't track post natal recording of babies' charts for documentation of HIV exposure to make a follow up at the clinic, whether postnatal care was recorded in Road To Health Card. This will help to communicate the need for an HIV test for a child.

Although Chart reviews reveal lot of gaps, it may have excluded some information which have been missed, but also this is the strength of the study to reinforce documentation of interventions. It is ethically needed to document the intervention to clients.

The sample size was not powered but was calculated based on the previous studies done, which may not be adequate for this study. Another study needed which will explore the reasons why

cd4 results are always missing, a need to investigate further. A qualitative study, that will prospectively explore and investigate the reasons for poor documentation is needed.

5.4.1 Selection bias

A choice of public hospital only may have led to selection bias as the results may not be generalised to the private setting. Mothers who do not attend antenatal care, and deliver at home were excluded. Having a researcher extracting data may result in selection bias.

5.4.2 Information bias

The study relies on data collected for routine monitoring, which may result in errors in written records.

5.5 Strength of the study

The use of already collected data, routine data, by using patients medical records strengthen the study, as was collected independent of the study.

Less exposed to internal validity since the study focused on clinical charts review.

Less information bias as it relied on primary clinical records.

5.6 Summary and Conclusion

The study provided with new knowledge and insight whether the Prevention of Mother to Child transmission of HIV program activities are documented as performed in different settings shown by patient records.

It had made it clear that all the package of activities is crucial and interdependent. All of the activities should be performed for effective PMTCT program that will help improve the child and maternal survival of participants. It has brought to light that although the activities are performed, but not to an acceptable level for most of the Sub Saharan countries like South Africa, which has the highest HIV disease burden. Also that the target for Millennium Development goals can be achieved if all the small multi step, multi-setting activities which may be considered small, can be achieved at an acceptable quality standard of care.

Although the study had limitations, but this study will help to bring in the new knowledge which will assist in the evaluation of the program for effectiveness thus highlight the need for documentation and routine chart reviews.

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Appendix One: Data Extraction Tool

CHART REVIEW STANDARD SHEET : DATA EXTRACTION TOOL
A Retrospective Clinical Chart Review study on the core PMTCT activities at a Regional hospital in Durban,Kwa Zulu Natal
This data must be extracted from all charts selected for the study.

PART ONE		
Identifying data		
1. Hospital-----		
2. Unit-----		
3. Record Number-----		
DEMOGRAPHIC DATA		
1. Age :		
2. Marital status : i. single ii. Married iii. Divorced iv. widowed		
3. Employment status : i. Employed ii. Unemployed		
4. Testing for cd4 : i. At first visit ii. Tested later		
5. Type of delivery : i. Normal vaginal delivery ii. Caesarean section		
6. Parity : i. First pregnancy ii. More than one		
7. Baby's birth weight : i. 1.5 kg and above ii. Below 1.5 kg		
PART TWO		
Key Activities of PMTCT		
Is the HIV status of the patient clearly documented	Yes:	No
Dual therapy (Antiretroviral prophylaxis)		
To the pregnant mother		
Was Dual Therapy initiated at Antenatal clinic		
Was DT taken more than 4 weeks by pregnant woman		

Appendix Two : Ethical Clearance for the study from the Ethics Committee



RESEARCH OFFICE
Biomedical Research Ethics Administration
Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

Website: <http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx>

03 December 2010

Ms Hloisile Ngidi
School of Nursing Howard College Building
University of KwaZulu- Natal

PROTOCOL: A retrospective clinical chart review study on the core PMTCT activities at a Regional hospital in Durban, KwaZulu-Natal. REF: BE240/09.

Dear Ms Ngidi

EXPEDITED APPLICATION

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application dated 26 October 2009.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 29 November 2010 to queries raised on 26 January 2010 have been noted by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given full ethics approval and may begin as from 03 December 2010.

This approval is valid for one year from 03 December 2010. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

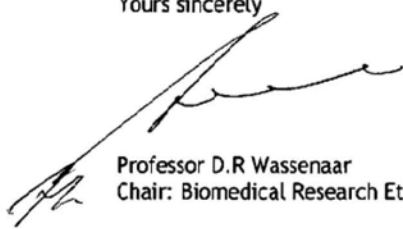
Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2004), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at <http://research.ukzn.ac.za/ResearchEthics11415.aspx>.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** at a full sitting of the Biomedical Research Ethics Committee meeting to be held on **08 February 2011**.

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

A handwritten signature in black ink, appearing to be 'D.R. Wassenaar', written over a horizontal line.

Professor D.R Wassenaar
Chair: Biomedical Research Ethics Committee

Appendix Three: Letter requesting permission from King Edward V111 Hospital

3 B Bass Place

Newlands East

4037

19 February 2010

The Hospital Manager

Kind Edward V111 Hospital

Private Bag x 07

Congella

Dear Sir/Madam

APPLICATION FOR PERMISSION TO CONDUCT A RESEARCH STUDY

Research Topic : A retrospective clinical chart review study on the core PMTCT activities at a Regional hospital in Durban, Kwa Zulu Natal.

I wish to request permission to conduct a research project at King Edward V111 hospital.

I am a 34 year old female who is currently studying Masters in Nursing Research óCoursework. Part of the requirement for my studies requires that I conduct a Research project in the area of my interest. I am currently not involved in any research at King Edward hospital.

The project is about review of pregnant women's charts, looking at documentation from when they attended clinic to when they deliver at hospital. It looks at the provision of PMTCT activities whether they were conducted, through records. The study is not intended to disturb the functions of the hospital since it will be the reviews of charts which will be conducted by the researcher herself and not the personnel. The reviews will be done retrospectively, only the charts documents will be used when clients have been discharged.

I declare that no funding has been sort to conduct this research.

I hope my request to be successful

Thank you

Researcher : Miss Hlolisile Ngidi

Work: 031 260 4648

Cell: 076 317 9187

Research Supervisor: Mrs J. Naidoo

Work : 031 260 2499

Appendix Four : Letter of permission to conduct the study from King Edward V111 Hospital

PERMISSION TO CONDUCT A RESEARCH STUDY/TRIAL

This must be completed and submitted to the Medical Superintendent/s / Hospital Manager/s for signature.

For King Edward VIII Hospital (KEH) and Inkosi Albert Luthuli Central Hospital (IALCH) studies please submit the document together with the following:

1. Research proposal and protocol.
2. Letter giving provisional ethical approval.
3. Details of other research presently being performed by yourself if in the employ of KEH, (individually or as a collaborator).
4. Details of any financial or human resource implications to KEH, including all laboratory tests, EEGs, X-rays, use of nurses, etc. (See Addendum 1)
5. Declaration of all funding applications / grants, please supply substantiating documentation.
6. Complete the attached KEH Form - "Research Details"

Once the document has been signed it should be returned to Mrs Patricia Ngwenya: Biomedical Research Ethics Administrator, Room N40, Govan Mbeki Building, Westville Campus, University of KwaZulu Natal.

To: Chief Medical Superintendent / Hospital Manager

Permission is requested to conduct the above research study at the hospital/s indicated below:

Site 1 address:

King Edward VIII
Hospital

Investigator/s:

Principal: Dr H M Agem

Co-Investigator: _____

Co-Investigator: _____

Signature of Chief Medical Superintendent / Hospital Manager:

[Signature] **HOSPITAL MANAGER**
KING EDWARD VIII HOSPITAL

Date: 1/9/2010

Site 2 address:

Investigator/s

Principal: _____

Co-Investigator: _____

Co-Investigator: _____

Signature of Chief Medical Superintendent / Hospital Manager:

Date: _____

NB: Medical Superintendent/s / Hospital Manager/s to send a copy of this document to Natalia

Appendix Five : Letter of Approval from the King Edward V111 Hospital



KING EDWARD VIII HOSPITAL
Private Bag X02, CONGELLA 4013
Corner of François & Sydney Road
Tel : 031-3603853, Fax: 031-2061457
Email: rejoyce.khuzwayo@kznhealth.gov.za
www.kznhealth.gov.za

Enq.: Miss. R. Khuzwayo
Ref.: KE 2/7/1/ (06/2010)
Research Programming

25 February 2010

Ms. Hlohlile Ngidi
School of Nursing Howard College Building
UNIVERSITY OF KWAZULU-NATAL

Dear Ms. Ngidi

Protocol : A retrospective clinical chart review study on the core PMTCT activities at a Regional Hospital in Durban

Your request to conduct research at King Edward VIII Hospital has been approved.


Please ensure the following:-

- * That King Edward VIII Hospital receives full acknowledgment in the study on all publications and reports and also kindly present a copy of the publication or report on completion.
- * Before commencement:
 - * Discuss your research project with our relevant Directorate Managers
 - * Sign an indemnity form at Room 8, CEO's Complex, Admin. Block.

The Management of King Edward VIII Hospital reserves the right to terminate the permission for the study should circumstances so dictate.


Yours faithfully

SUPPORTED / NOT SUPPORTED


DR. O.S.B. BALOYI
MEDICAL MANAGER

25/2/2010
DATE

APPROVED / NOT APPROVED


MR. M. BHEKISWAYO
CHIEF EXECUTIVE OFFICER

1/3/2010
DATE

uMnyango Wezempho : Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope