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MASTERS MINI-THESIS

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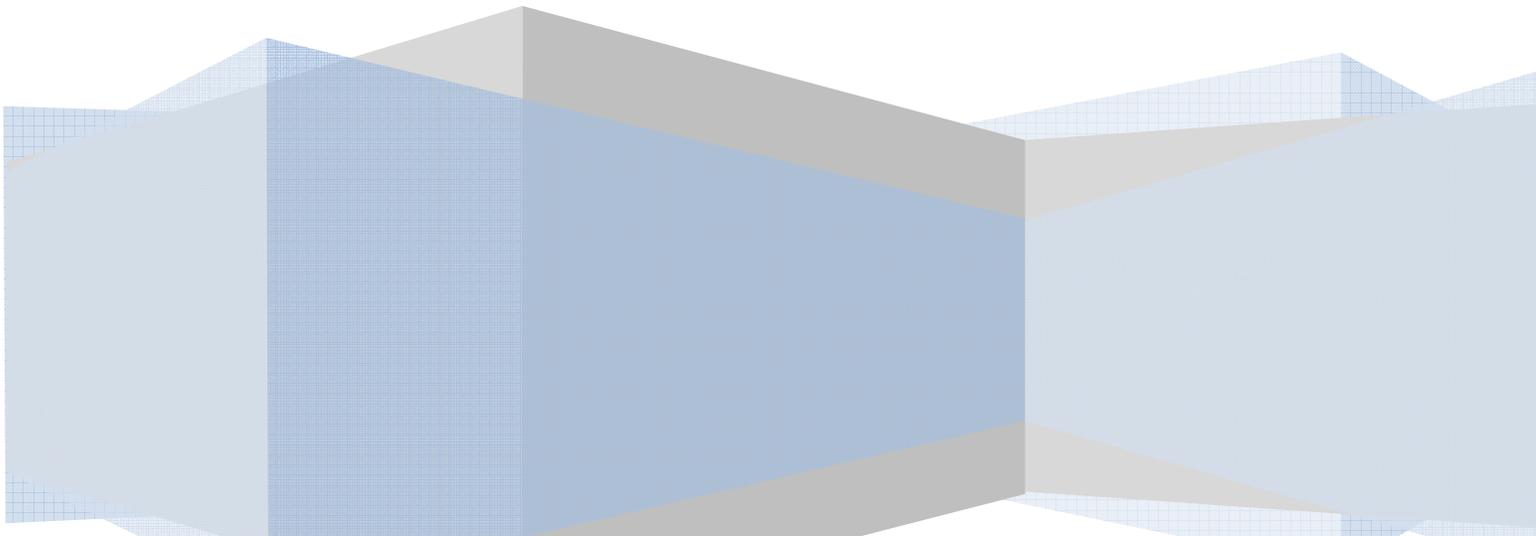
School : School of Public Health (SoPH)

Title of Thesis : The operational effectiveness of a single dose Nevirapine prevention of mother to child transmission of HIV/AIDS programme in Khomas region, Namibia.

Date : May 2010

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DEDICATION

I dedicate this work in memory of my late beloved mother “Ba Ellen Namasiku Mukuni” who wished to see this event, however, did not live to this day.



CERTIFICATION

I hereby certify that Mrs. Gloria Mutimbwa Siseho in the School of Public Health, Faculty of Community and Health Sciences, University of the Western Cape carried out this work.

GLORIA MUTIMBWA SISEHO



ASSOCIATE PROFESSOR: DR DEBRA JACKSON

DATE

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ACRONYMS & ABBREVIATIONS

AFASS	Acceptability, Feasibility, Affordability, Sustainability and Safety of avoiding all breastfeeding
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal care
ARV	Antiretroviral
AZT	Zidovudine (antiretroviral medication)
ANC	Antenatal Care
CI	Confidence Interval
DBS	Dried Blood Spot
DNA PCR	Deoxyribonucleic acid Polymerase Chain Reaction
EBF	Exclusive Breast feeding
EFF	Exclusive Formula Feeding
ELISA	Enzyme-linked Immunosorbent Assay
EID	Early Infant Diagnosis
HIV	Human Immuno-deficiency Virus
IATT	International level, an Interagency Task Team
L&D	Labour and Delivery
MTCT	Mother to child transmission
MoHSS	Ministry of Health and Social Services
NDoH	National Department of Health
PCR	Polymerase Chain Reaction
PHC	Primary Health Care
PMTCT	Prevention of mother- to- child transmission of HIV

SoPH	School of Public Health, University of the Western Cape
UNAIDS	United Nation Agency for International Development.
UNICEF	United Nations Children’s Fund
UNGASS	United Nations General Assembly, Special Session
UWC	University of the Western Cape
VCT	Voluntary Counseling and Testing
WHO	World Health Organization



DEFINITION OF KEY WORDS

Prevention of Mother To Child Transmission (PMTCT) Mother-to-child transmission: transmission of HIV from a HIV-positive woman to her child during pregnancy, delivery or breastfeeding. The phrase is used because the immediate source of the virus is the mother, and does not entail fault on the mother.

Human Immuno Deficiency Virus (HIV): This is the virus that causes AIDS.

Acquired Immuno Deficiency Syndrome (AIDS): this is a disease as a result of Human Immuno Deficiency Virus.

Single Dose Nevirapine (SDN): is one of the single drug regimen used as a prophylaxis administered to mother–infant pairs to prevention HIV transmission from an infected mother to her baby.

Women: are all females of reproductive age between 15 – 49 years.

Infant: refers to any person from birth to 12 months of age.

Antenatal Care (ANC): is a service given to a pregnant woman from first trimester of first week of conception until the last day of giving birth.

Pregnancy: is the period of conception between first weeks of confirmation of pregnancy by a test until 40 weeks or last day of pregnancy just before the baby is born.

Delivery: in this case refers to the time when the woman is in labour until the baby is born.

DNA-PCR: is a virological test to detect virological particles and not HIV antibodies. This test helps to estimate the HIV prevalence among this age population.

ABSTRACT

Objective: The study **aim** was to measure the operational effectiveness of a single dose Nevirapine for PMTCT programme among infants aged six weeks in Khomas region of Namibia.

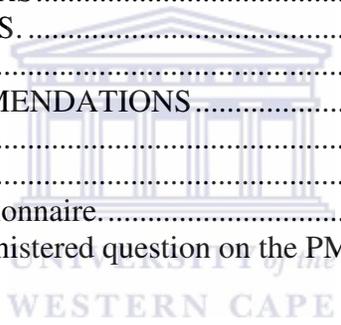
Methods: This was a retrospective record review quantitative study based on a descriptive approach. The record review aimed at measuring operational effectiveness through the distribution of certain variables among HIV exposed infants including the socio economic variables such as age, sex and the breast feeding practices of their mothers. A total of 451 HIV positive mothers and their infant pairs` record registers were reviewed in two hospitals of Khomas region, Namibia.

Results: A total of 451 PMTCT mothers` records for the year 2007 (median age 29 years) were reviewed in the Katutura and Windhoek Central hospitals of Namibia.. The HIV prevalence among infants aged six weeks or more out of the total 167 tested was 5% (95% CI, 0.9 -3.7). **Conclusion:** The findings from this study shows that although the rate of PMTCT in tested infants was low, registers for maternity and infant follow up are extremely poorly completed with the vast amounts of missing information making it difficult to assess programme effectiveness and monitor programme outcomes. PMTCT programme registers and routine monitoring and evaluation data need to be strengthened. .

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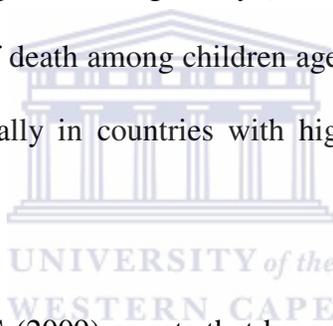


CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND

By the end of 2007, an estimated 2.1 million children younger than 15 years of age were living with HIV and 90% of these children were infected through mother-to-child transmission of HIV. In the same year, 290 000 children younger than 15 years of age died of HIV-related causes (WHO, UNICEF & UNAIDS, 2008). Sub-Saharan Africa, of which Namibia is part, accounts for about 90% of all children living with HIV globally (WHO *et al*, 2008). In East and Southern Africa, HIV is the leading cause of death among children aged five and below. It is affecting the general health of children, especially in countries with high burdens of HIV (Stringer *et al*, 2009).



The WHO, UNICEF and UNAIDS (2009) asserts that beyond the goal of ensuring an HIV and AIDS-free generation and global action to prevent the mother-to-child transmission of HIV directly supports achieving the Millennium Development Goals (MDG) 4, 5 and 6. The MDG 4 target is to reduce by two thirds the mortality rate of children younger than five years. The WHO, UNICEF and UNAIDS further state the need to reduce by three quarters the maternal mortality ratio (MDG 5), and halting and beginning to reverse the spread of HIV/AIDS (MDG 6) by 2015. According to African Network for the Care of Children by AIDS (ANECCA, 2004), HIV/AIDS accounts for 7.7% of mortality worldwide in children under five years of age, while AIDS already accounts for a rise of more than 19% in infant mortality and a 36% rise in under-five mortality.

The WHO, UNICEF and UNAIDS (2009) state that the use of antiretroviral drugs to prevent HIV transmission is emerging as a potential new set of interventions for prevention. Antiretroviral drugs, combined with HIV testing of pregnant women and appropriate infant feeding practices, are already being used to prevent HIV transmission from pregnant women to their children. Guidance also exists on the use of antiretroviral drugs for post-exposure prophylaxis, and research is on going on their use for pre-exposure prophylaxis. The same report continues to provide observational evidence that antiretroviral therapy may reduce the sexual transmission of HIV in generalized epidemics, especially among discordant couples (WHO *et al*, 2009).

The Global HIV Prevention Working Group (2006) asserts that HIV rates continue to be disturbingly elevated with more than four million people infected annually. The authors state that for women, despite the availability of effective existing interventions, only “one in five people” in the high risk groups have access to effective interventions. As a result, many existing approaches continue to be difficult to access for women (Global HIV Prevention Working Group, 2006:1).

The progress report, towards universal access: scaling up priority HIV/AIDS interventions in the health sector (WHO *et al*, 2009) reports a continuously increasing number of women, infants and children living with HIV every year, and that the HIV epidemic continues to radically affect their health, livelihood and survival across regions. The report further estimated the number of women living with HIV to have increased from 14.1 million in 2001 to 15.5 million by 2007. The authors state that in sub-Saharan Africa, women now account for almost 60% of the adults living

with HIV, although in other regions women continue to represent less than half of all people living with HIV. While globally the percentage of adult women aged 15 years and older among people living with HIV has stayed steady at 50% for the past 10 years (WHO *et al*, 2009); they further describe HIV as the primary cause of mortality among women of reproductive age worldwide.

HIV can affect mortality both directly and indirectly; and contributes to deteriorating pregnancy outcomes as an underlying cause of maternal death. A study from Zimbabwe found that HIV accounted for 27% of reported maternal deaths in 2006 (WHO, UNICEF & UNAIDS, 2008; WHO *et al*, 2009).

Actions to reduce the burden of HIV and AIDS among children and women have been placed high on the agenda by a number of multilateral and bilateral agencies, including UNAIDS, Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the President's Emergency Plan for AIDS Relief (PEPFAR) (WHO *et al*, 2009).

1.2 STUDY SETTING

In Namibia the Prevention of Mother-to Child Transmission (PMTCT) services contribute to the risk reduction of HIV transmission during pregnancy, childbirth or breast-feeding. These services were rapidly rolled out to all 34 district and 4 public (2 regional and 2 national) referral hospitals by the end of 2007 (Ministry of Health and Social Services (MoHSS), 2008). In this study, the focus was on two national referral hospitals (1 tertiary and 1 national referral hospital) in Namibia of which one was a pilot site when the programme was introduced in 2002.

With an estimated total population of 2 million people, the 2006 and 2008 national HIV sentinel surveys report that Namibia recorded 19.9% and 17.8% antenatal care HIV prevalence in 2006 and 2008, respectively (MoHSS, 2008). According to the MoHSS (2008) estimates and projections of the impact of HIV/AIDS in Namibia, adult HIV prevalence is estimated at 15.4% during 2008/09. It is also estimated that approximately 204 000 people are living with HIV, with 14 000 new infections annually. Out of the total new infections (39 new infections occur every day) 44% are among the 15-24 years age group, of which 77% are women and 9% are children under the age of 15 years (MoHSS, 2008). According to the MoHSS 2008/09 PMTCT annual report, the PMTCT programme recorded 9 600 HIV positive pregnant women during the year 2008/09 (MoHSS, 2008/09). In view of the above, it is estimated that HIV/AIDS contributes about 55% of the total 15 5000 orphans in the country (MoHSS, 2008).

The Namibia MoHSS annual reports state that the PMTCT programme was introduced in 2002 in two hospitals and has since been expanded throughout the country (MoHSS, 2007/08). The 2006 MoHSS sentinel sero-survey report argues that about 1 in 5 pregnant women are infected with HIV (MoHSS, 2006). In addition, the antenatal care (ANC) surveillance is currently a key data source for all HIV estimates in the country. The ANC surveillance data provides inputs for the models which estimate and project the following: national HIV prevalence; HIV incidence; estimated number of people living with HIV; ART estimated needs; and estimates of pregnant women who are living with HIV. It is thus essential for programme planning, budgeting and evaluation (MoHSS, 2008).

The 2006 sentinel survey report states, a total of 7 422 pregnant women attending antenatal care services participated in the survey from 29 health districts out of the 34 (MoHSS, 2006). However, in 2008, all 34 health districts participated and a total of 8 174 pregnant women attending antenatal care services were included in the survey. Over the years, the highest age-specific prevalence was observed among the age group 30-34 years, and this prevalence among the adult group continuous to increase. On the other hand, in the younger age groups of 15-19 and 20-24 years, HIV decreased from 11% to 5.1% and 22% to 13.9% respectively between 2002 and 2008 (MoHSS, 2008).

The Namibia national HIV sentinel survey reports maintain that during the sentinel surveillance, the MoHSS follows a standardized methodology recommended by the WHO as the most suitable way for countries to monitor the trends of HIV in different geographical areas. The report asserts that HIV testing is completed on blood samples collected from pregnant women attending antenatal care clinics. Blood samples are stripped of any personal identifying information prior to HIV testing so there is no way that the HIV status of particular women can become known during this process. This prevents the possibility of stigma against her (MoHSS, 2006; MoHSS, 2008).

The 2008 national HIV sentinel survey report in Namibia notes that Katutura State Hospital, which is one of the two referral hospitals in the country where this study took place, recorded a high prevalence (21.7% and 21.7%) in both 2006 and 2008, respectively compared to the national figures; while Windhoek Central Hospital recorded 9.1% and 4.7% respectively (MoHSS, 2008).

According to the 2009 MoHSS PMTCT annual report, the early infant diagnosis (EID) programme started towards the end of 2005 at 1 pilot site in Katutura State Hospital in Windhoek. The EID programme has been rolled out from the beginning of 2006 and has now been scaled up to cover the whole country. Since March 2009, 202 out of 335 health facilities in Namibia were submitting dried blood spot (DBS) samples, of which 256 are ANC sites. The report further reasons that HIV polymerase chain reaction (PCR) is available for all HIV-exposed children from six weeks of age, and for symptomatic children less than 18 months old. The PCR is repeated two months after weaning if child is breastfed, and if initial PCR is negative. It is a standard guideline that initial PCR positive result is confirmed with a rapid test or enzyme-linked immunosorbent assay (ELISA) at 18 months old. Also, by the end of May 2009, 98% of all specimens submitted for PCR were dried blood spots (DBS) (MoHSS, 2008/09). In this regard, the Namibia 2008 PMTCT annual report recorded an increase in the number of DNA-PCR tests over the year from 3 678 in 2006 to 8 532 in 2007. A further increase was observed in 2008 to 10 179 (MoHSS, 2008/09).

Generally, life-saving interventions are now available to prevent mother-to-child transmission and to prolong the survival of people living with HIV/AIDS, such as antiretroviral (ARV) drugs, and advice regarding breast-feeding. Therefore, the role of testing children for HIV in this programme is to ensure that infants testing positive are referred and/or put onto ARV therapies. Before this study, there was no data regarding the HIV prevalence among infants born to HIV positive mothers, as no assessment had been done in the country to evaluate the operational effectiveness of single-dose Nevirapine (Sd-NVP) for the prevention of mother-to-child transmission of HIV.

In Namibia, antenatal care is a service that is provided to pregnant women from 12 weeks until delivery (36 to 40 weeks). Women come mainly from the surrounding areas of the health facility, but any other pregnant women not from the vicinity are normally welcome. This is because some women come to town or urban areas because Nevirapine therapy is mostly available in urban facility settings, and in Khomas region there were only two national referral hospitals that were providing PMTCT/ANC services during the study period. The 2007 PMTCT annual report, states Khomas region had 8 190 deliveries during 2006/07. Among these, 6 444 (79%) delivered with known HIV status, with 1 168 of these HIV positive. Of the HIV positive women, 932 (80%) were given ARV prophylaxis and 1 010 (86%) infants received Nevirapine within 72 hours after birth (MoHSS, 2007).

In these facilities, the services include:

- Group and individual voluntary pre-test counselling, and post-test counselling
- Provision of Sd-NVP prophylaxis to eligible women
- Sd-NVP syrup to infants born to HIV positive mothers

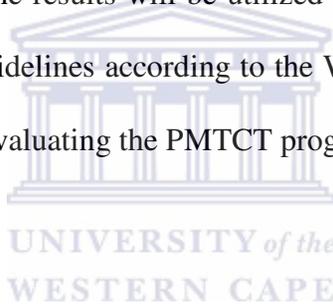
In addition, if their CD4 count is found to be below 250, women are referred to antiretroviral therapy (ART) sites for further management, in addition to normal antenatal care follow-up till delivery. Pregnant women who report to the maternity ward or a health facility and have never been tested for HIV, are routinely offered voluntary pre-test counselling.

1.3 RATIONALE

It is important to recognize that 15% of new HIV infections each year are caused by mother-to-child transmission and that the elimination of HIV infection in infants and young children would serve to accelerate global HIV prevention efforts (Chopra & Coveney, 2006).

It is for this reason that the researcher was motivated to conduct a study in this area because the 2007 incumbent Permanent Secretary of the Ministry of Health refused to sign the revised PMTCT guidelines in 2007 citing, among other reasons, that there was no evidence as to whether the regimen of Sd-NVP was ineffective for the PMTCT programme. He emphasized he wanted scientific evidence to evaluate the PMTCT programme. The researcher was the officer responsible for PMTCT within the MoHSS and decided to conduct an evaluation using available PMTCT records.

The study was carried out to evaluate the effectiveness of the Sd-NVP PMTCT programme in the Khomas region of Namibia. The results will be utilized to support the newly recommended regimen in the revised PMTCT guidelines according to the WHO guidelines. In addition, it will act as a means of monitoring and evaluating the PMTCT programme in the study sites. .



1.3.1 METHODOLOGY

The retrospective, descriptive record review approach was chosen because it is short and simple. It also has the potential to identify developments over time, though in this case the description of the effectiveness of Sd-NVP PMTCT HIV programme using assessed variables was only for a one year period, January to December 2007. The researcher purposely chose to review the records only, and not interview the care givers and health workers, as that would be time-consuming, expensive and require many days away from work during data collection, analysis and report writing.

CHAPTER TWO

LITERATURE REVIEW

2.1 GLOBAL HIV INFECTION AMONG WOMEN AND CHILDREN

In countries with a high load of HIV infection, AIDS is reported to be the principal cause of deaths and illness among women of reproductive age. Since more than 10% of all new infection is accounted in children, every day, more than 1400 children under the age of 15 years become infected with HIV. The period when infants born to women living with HIV become infected is during pregnancy, labour and delivery or postpartum through breast feeding (World Health Organisation (WHO), UNICEF & IATT, 2009).

The WHO (2009) progress report, towards universal access: scaling up priority HIV/AIDS interventions in the health sector; depicts that the number of children younger than 15 years old living with HIV increased from 1.6 million in 2001 to 2.0 million in 2007. While the number of women living with HIV increased from 14.1 million in 2001 to 15.5 million in 2007 (WHO *et al*, 2009). However, the number of newly infected children has been reducing since 2003, most likely due to the global stabilization of HIV prevalence among women and increasing coverage of programmes to prevent mother-to-child transmission. The same report states that children accounted for 14% of HIV-related deaths; 6% of children were living with HIV; and 17% were new infections worldwide (WHO *et al*, 2009).

WHO, UNICEF & IATT (2009), guidance on global scale-up of the prevention of mother-to-child transmission of HIV: towards universal access for women, infants and young children and eliminating HIV and AIDS among children report that worldwide in the year 2006, 2.3 million

children younger than 15 years and 17.7 million women were living with HIV (WHO, UNICEF & IATT, 2009).

2.2 HIV AMONG INFANTS AND PREGNANT WOMEN IN SUB-SAHARAN AFRICA

The burden of paediatric AIDS disease is due to: high rates of maternal HIV infection; high birth rates; lack of access to currently available and feasible interventions; and the widespread practice of prolonged breast-feeding. HIV/AIDS continues to be the major cause of infant and childhood mortality and morbidity in Africa (African Network for the Care of Children by AIDS, 2004).

In low and middle income countries, approximately 1.4 million pregnant women who were living with HIV gave birth. Out of the total pregnant women who gave birth, ninety one (91%) of them were living in Sub Saharan Africa (WHO *et al*, 2009).

The burden of HIV is disproportionately felt by women and children. An estimated 540 000 children were reported to have new HIV infections in 2005 alone, with about 90% of these occurring in sub-Saharan Africa. The common modes of HIV transmission from mother-to-child occur during pregnancy, labour and delivery, or during breast-feeding. Of the 20-45% overall risk of HIV transmission from mother-to-child, 15-30% occurs during the antenatal and perinatal period, and 5-20% is through breast-feeding by an infected mother. It is also reported that the overall risk of mother-to-child transmission can be reduced to below 2% when antiretroviral (ARV) prophylaxis interventions are given to women during pregnancy and labour and to the infant in the first weeks of life and breast-feeding is avoided (WHO, 2006).

In most HIV affected countries in Sub-Saharan Africa, 60% and more of all new HIV infections is among women, infants and young children (WHO, UNICEF & IATT, 2009).

2.3 INTENSIFYING HIV SERVICES FOR WOMEN AND CHILDREN

The WHO *et al* (2009) assert that national political commitments to expand HIV prevention, treatment and care services for women and children have increased in recent years. Temmerman *et al* (2003) suggest that interventions for mother-to-child transmission of HIV such as antiretroviral therapy during pregnancy, formula feeding and elective caesarean section are within reach for most women in the developed world, but are not readily accessible for underprivileged, resource-limited countries.

However, according to the guidance on global scale-up of the prevention of mother-to-child transmission of HIV: towards universal access for women, infants and young children and eliminating HIV and AIDS among children, the PMTCT target of the United Nation General Assembly Special Session on HIV/AIDS to exceed 40% antiretroviral prophylaxis uptake by 2005 was achieved by only eight countries during 2006 (WHO, UNICEF & IATT, 2009).

In the year 2008, 70 low- and middle-income countries had recognized a national scale-up plan with population-based targets to prevent mother-to-child transmission of HIV; up from 34 in 2005. During the same period, 54 low- and middle-income countries had national plans integrating population-based targets to scale up paediatric HIV services in 2008, as compared with 19 in 2005 (WHO *et al*, 2009). HIV testing and counselling among pregnant women is increasing with the expansion of provider-initiated approaches in healthcare settings. In 2008,

21% of pregnant women giving birth in low- and middle-income countries received an HIV test; up from 15% in 2007. Whereas in sub-Saharan Africa, the corresponding percentage improved from 17% to 28%, with especially high rates of increase in countries in Eastern and Southern Africa. In addition, the percentage of HIV positive pregnant women who received antiretroviral therapy to prevent HIV transmission to their children, increased from 35% in 2007 to 45% in 2008. In 2008, approximately one-third (34%) of pregnant women who tested HIV positive were assessed, either clinically or by CD4 cell count, for eligibility to receive antiretroviral therapy for their own health (WHO *et al*, 2009).

At an international level, the Inter-agency Task Team (IATT) on Prevention of HIV Infection in Pregnant Women, Mothers and their Children, brings together international partners that execute on preventing mother-to-child-transmission of HIV and providing children with HIV treatment, care and support. During 2007, the IATT suggested specific targets and coverage levels of core interventions to guide national programmes as they expand interventions to address HIV among women and children. Recommended targets and coverage levels are as follows:

- At least 80% of all pregnant women attending antenatal care are provided with information on preventing mother-to-child transmission of HIV.
- At least 80% of all pregnant women attending antenatal care are tested for HIV, including those previously confirmed to be living with HIV.
- At least 80% of pregnant women living with HIV receive antiretroviral prophylaxis or antiretroviral therapy to reduce the risk of mother-to-child transmission.
- At least 80% of eligible pregnant women living with HIV receive antiretroviral therapy for their own health.

- At least 80% of pregnant women living with HIV receive infant feeding counselling and support at the first infant follow-up visit.
- At least 80% of women living with HIV are successfully referred and enrolled in comprehensive longitudinal care and treatment.
- At least 80% of infants born to women living with HIV receive a virological HIV test within two months of birth.
- At least 80% of infants and children living with HIV and in need receive co-trimoxazole prophylaxis and/or antiretroviral therapy.

(WHO *et al*, 2009: 90-91).

In view of the above targets, it is clear that the IATT is committed to the scaling up and reduction of mother-to-child transmission of HIV during perinatal and peripartum periods. Community outreach and support structures should also be seen as key among the efforts aimed at reducing mother-to-child transmission of HIV, especially in diminishing stigma associated with formula feeding; disclosure of HIV status; and adherence to treatment, care and support programmes.

Therefore, according to WHO *et al* (2009), the implementation of a comprehensive strategic approach aimed at preventing infants and children from HIV infection is one of the United Nations General Assembly, Special Session (UNGASS) recommendations. The UNGASS recommendations complement the United Nations Millennium Development Goals and the goal of universal access to comprehensive prevention programmes, treatment, care and support. The WHO further outlines four main components under the prevention of mother-to-child

transmission of HIV, and affirms that all signatories to the United Nations recommendations to reduce HIV by 50% by the year 2010 among women and children should make the following priority areas of their PMTCT programmes:

- primary prevention of HIV infection among women of childbearing age;
- preventing unintended pregnancies among women living with HIV;
- preventing HIV transmission from women living with HIV to their infants, and
- providing appropriate treatment, care and support to mothers living with HIV and their children and families (WHO *et al*, 2009: 93).

When assessing progress in paediatric care, the WHO notes an increase in health facilities providing paediatric antiretroviral therapy in low- and middle-income countries by around 80% from 2007 to 2008. Similarly, children getting antiretroviral therapy increased from 197 000 in 2007 to about 275 700 in 2008, attaining 38% of the 730 000 children estimated to be in need of antiretroviral therapy in low- and middle-income countries. They also state that augmented efforts are needed to expand access to HIV care and treatment services for children, because in 2008 only 8% of infants born to pregnant women with HIV initiated co-trimoxazole by two months of age (WHO *et al*, 2009).

In conclusion, HIV among infants can be eliminated through the focused implementation of the four components of a PMTCT programme, and together with strong political will, HIV trends can be averted even in resource-limited settings.

2.4 OPERATIONAL STUDIES OF SINGLE-DOSE NEVIRAPINE (Sd-NVP) IN AFRICA

A systematic review of randomized controlled trials of any antiretroviral regimen aimed at decreasing the risk of mother-to-child transmission of HIV infection compared with placebo or no treatment, which was aimed at determining the extent to which antiretroviral regimens decrease the risk of mother-to-child transmission of HIV infection was reported by Volmink *et al*, (2007). . The study looked at what effect these interventions have on maternal and infant mortality and morbidity within the 16 reviewed countries. The study results revealed that where mothers were routinely receiving ZDV in the third trimester of pregnancy and infants were receiving one week of ZDV therapy, a single dose of Nevirapine given to mothers in labour and to their infants soon after birth compared with a single dose of Nevirapine given only to mothers, resulted in HIV infection rates that were not significantly different at birth and 6 months. The results further show that the reduction in risk of HIV infection or death at 6 months was marginally significant (Efficacy 45.00%; 95% CI - 4.00 to 94.00). In antiretroviral regimens using different drugs and durations of treatment in breast-feeding populations, a single dose of NVP given to mothers at the onset of labour plus a single dose of NVP given to their infants immediately after birth ('HIVNET 012 regimen'), compared with ZDV given to mothers during labour and to their infants for a week after birth, resulted in lower HIV infection rates at 4-8 weeks. (Volmink *et al*, 2007).

In order to ensure success in the control of the HIV/AIDS epidemic it is crucial to view the prevention of mother-to-child transmission of HIV as one of the key strategies (Ahoua *et al*, 2009). Beyond clinical trials operational research indicates effectiveness of routine PMTCT

programmes. Researchers in a prospective cohort study of mothers and infants in South Africa found that the mother's best chance of receiving Nevirapine (NVP) was associated with her socio-economic status. In addition, better counselling increased the chances of mothers receiving NVP. The study also found that the time the infant received Nevirapine was not associated with HIV transmission, but found that early transmission rates was associated with maternal viral load and low birth weight (Colvin *et al*, 2006).

A cross-sectional study on the effectiveness of the first district-wide programme for the prevention of mother-to-child transmission of HIV in South Africa by Coetzee *et al* (2005), found that 23% of the infants were delivered by caesarean section, and less than 1% of women reported giving mixed feeding between 1 and 18 days after delivery. Of the total 535 infants who were tested for HIV, 47 (8.8%) were HIV-positive. The study also reported that women aged 25 years and older were more likely to transmit HIV to their infants. In Cameroon, Welty *et al* (2005), conducted a prospective study into the integration of prevention of mother-to-child transmission into routine antenatal care. The results found that age, marital status, positive syphilis serology, low gravity, young age at first sexual intercourse, and a number of sex partners reported in the last three months, was powerfully related to HIV-1 infection in multivariate investigations.

In Uganda, a study was conducted by Magoni *et al* (2004), which looked at modes of infant feeding and HIV infection in children in a programme for prevention of mother-to-child transmission. The study found that exclusive breast-feeding (EBF) and mixed feeding (MF) carried a significantly higher risk of HIV transmission than the exclusive formula-feeding (EFF)

group. This difference was found among infants who received Sd-NVP after delivery. But when comparing different feeding options, the transmission was found to be lower in the formula-fed infants than when compared to the EBF and MF infants. The study also found HIV transmission to happen mostly during the first week of delivery.

The authors of a study on the feasibility of preventing mother-to-child transmission of HIV using peer counsellors in Zimbabwe, state that out of a total 1 986 pregnant women infected with HIV at a hospital site, 35% (691) received Sd-NVP tablets at the onset of labour, while 615 (31%) of the exposed infants received their dosage of Sd-NVP within 72hours after birth. They also assessed the response of mother-infant pairs at six weeks post delivery for those who delivered at the clinic, and found only 396 (54.5%) out of the 727 HIV-infected women went back to the clinic for the six-week follow-up visits. The authors concluded that it is feasible to implement an Sd-NVP-based PMTCT programme with the use of peer counsellors (Shetty *et al*, 2008).

There are a number of studies that mention the effectiveness of Sd-NVP for PMTCT programmes. Among them is the study on the high frequency of rapid immunological progression in African infants infected in the era of perinatal HIV prophylaxis by Mphatswe *et al* (2007) in KwaZulu Natal, South Africa. This study tested HIV-exposed infants on day 1 and 28 to detect the intrauterine (IU) and intrapartum (IP) infection. The authors report that Sd-NVP reduced mother-to-child transmission through an effect on IP transmission, and that mother-to-child transmission that did take place, despite the Sd-NVP, occurred in about two-thirds during IU. They also reported that IP infected infants were born to mothers with extremely elevated viral loads. As a result, 85% of these infants meet the WHO standard to be put on ART within

six months, because of quick disease progression. Jackson *et al* (2007) in their prospective cohort study on operational effectiveness and 36-week HIV-free survival in the South African programme to prevent mother-to-child transmission of HIV-1, also found that maternal viral load augmented the risk of HIV transmission and/or death by about 1.5 times among infants. The Jackson study also found that there was marginal significance risk in adjusted analysis ($p = 0.058-0.093$) among premature infants becoming HIV positive or dying.

The results from the Temmerman *et al* (2003) observational study on mother-to-child HIV transmission in resource poor settings, supports Mphatswe *et al* (2007) view on the effectiveness of Sd-NVP. Temmerman *et al* also state that Sd-NVP lowered mother-to-child transmission of HIV-1 by 47% at the age of 14-16 weeks in breast-feeding mothers in Coast Provisional General Hospital in Mombasa, Kenya. A later study in Mombasa also found that more than 30% of women who attended the health discussions during antenatal care did not receive personalized pre-test counselling and half of the women who were informed that they were HIV-seropositive did not arrive for Sd-NVP at 34 weeks of gestation. An evaluation of a five-year programme to prevent mother-to-child transmission of HIV infection in northern Uganda, found that 16% of women were on ART; 7% were not given prophylaxis or treatment at the time of delivery; and 50% of the women enrolled on the PMTCT programme were eligible for ART (Ahoua *et al*, 2009).

A further example of the prevention of mother-to-child transmission of HIV in Africa is the Nevirapine-based programme in Lusaka, Zambia. In looking at the successes and challenges in scaling up this programme, Stringer *et al* (2003), found risk reduction of 41% (95% CI, 74-273) for those mother-infant pairs who received and were observed with Sd-NVP during intrapartum

and postpartum. In a study by Martinson *et al* (2009), of women exposed to Sd-NVP in successive pregnancies, and looking at effectiveness and non nucleoside reverse transcriptase inhibitor resistance, a prevalence of 11.1% of HIV-1 was detected among infants and 4.2% among those exposed for the first time. Martinson *et al* also state that Sd-NVP efficacy can be weakened by previous exposure to Sd-NVP. In a different study at Coronation Women and Children Hospital (CWCH) Johannesburg, South Africa, results of a descriptive study over a 13-month period using retrospective data and prospective data found 26/300 (8.7%) HIV transmission rate in the six-week DNA-PCR testing results (Sherman *et al*, 2004).

An anonymous, unlinked HIV prevalence testing study conducted on dried blood spot (DBS) samples from all infants attending six-week immunization clinics at seven primary health care clinics offering PMTCT by the University of KwaZulu Natal, South Africa, found a vertical transmission rate (VTR) of 15.0% among mothers who reported to have taken Sd-NVP for PMTCT and 30.5% VTR among infants who were detected with antibodies but whose mothers reported being uninfected by HIV (Rollins *et al*, 2007).

In a retrospective study conducted between the year 2000 and 2005 to evaluate the PMTCT programme in Northern Uganda, researchers' analyzed information of all mother-infant pairs enrolled in the PMTCT programme. Among the main findings from the study was the high number of lost to follow-up, that is those that had unknown HIV status at 18 months and who had missed their appointment schedules for two months. Out of the total 30 536 women sampled, 62% received counselling and HIV testing, 1 037/19 017 (5%) were HIV-positive, while 507/1 037 (50%) agreed to enroll in the PMTCT programme. At delivery, 227 (69.4%)

women received intrapartum Sd-NVP, 17 (5.2%) received sc-AZT, 23 (7%) did not take any prophylaxis and 52 (15.9%) had been on ART for a median time of 6.7 months (IQR 2.0 - 15.4) prior to delivery. Of those who received ART or intrapartum Sd-NVP (n=302), 205 (67.9%), were compliant while 92 (30.5%) were not compliant with the PMTCT protocol. About 83.4% of infants who received Sd-NVP were given according to PMTCT protocol; the remainder were either moderate or non-compliant. Of the 353 infants alive, 47 (13.3%) were exclusively breastfed, 96 (27.2%) received replacement feeding and 210 (59.5%) were mixed-fed. Median age at start of weaning was 6 months (IQR 4–6), irrespective of the type of feeding (p=0.15). Overall, 367 children had been tested for HIV. The cumulative HIV transmission rate was 8.3% (24/288, 95% CI 5.6–12.2) among infants tested, and 15.5% (57/367, 95% CI 12.2–19.6) when probable HIV related deaths were included (Ahoua *et al*, 2009).

In the Ahoua *et al* (2009) study they further described that transmission rates that did not differ by type of feeding (19.2%, 10.5% and 18.1% for exclusive breast-feeding, replacement feeding and mixed feeding, respectively; Pearson χ^2 test, p=0.20). However, lost to follow-up of mother–infant pairs was a substantial problem in this study. Overall, 303/567 (53.4%) mother–infant pairs had been LFU after a median time of 1 month (IQR 0–5). Of the 197 pairs successfully traced, 45 (22.8%) had been LFU after PMTCT enrolment, 2 (1%) between enrolment and delivery, 42 (21.3%) after delivery and 108 (54.8%) during follow-up. The main reasons for dropping out were the mothers’ lack of understanding of the importance of follow-up (29.9%) and infant death (27.4%). In this study, the authors assert that more than 5 in 10 mother-infant pairs were lost to follow up. The recorded percentage of hospital delivery was high.

In an assessment that was conducted on the efficacy of a prevention of mother-to-child transmission programme in a routine setting in comparison to a research environment at Coronation Women and Children Hospital (CWCH) in Johannesburg, South Africa, the authors argue that “A single dose of NVP administered to the mother at the onset of labour and to the infant within 72 hours of birth significantly reduces MTCT of HIV” (Sherman *et al*, 2004: 291). This statement is supported by a study on the effectiveness of repeat Sd-NVP for prevention of mother-to-child transmission of HIV-1 in repeat pregnancies in Uganda conducted by McConnell *et al* (2007), who conclude that Sd-NVP given to mother–infant pairs within the PMTCT programmes are effective in reducing the early transmission of HIV in operational settings. McConnell *et al* further mention that Sd-NVP is widely used to prevent mother-to-child HIV transmission in resource-limited settings. In the Lusaka, Zambia study on the prevention of mother-to-child transmission of HIV in Africa, findings revealed that Sd-NVP has been discovered to prevent almost half of HIV infection during intrapartum and neonatal periods in Zambia, in spite of limited resources in public sectors (Stringer *et al*, 2003).

A study on the effectiveness of repeat Sd-NVP for the prevention of mother-to-child transmission of HIV-1 in repeat pregnancies in Uganda, in which prospective data were collected from pregnant women who were Sd-NVP exposed or unexposed before delivery, revealed that in the retrospective cohort, the infection rates were 11.3% and 16.7% for 104 infants of NVP-exposed and NVP-unexposed mothers, respectively ($P = 0.41$). While in the prospective cohort, among 103 infants of NVP-exposed and NVP-unexposed mothers, the 12-month infant HIV-infection rates were 20.5% and 18.7% ($P = 0.81$) and HIV-free survival rates were 74.4% and 78.1% ($P = 0.66$), respectively. The study concluded that there was no difference in the risk of

HIV infection in infants born to women who had been exposed, or not exposed, to Sd-NVP (McConnell *et al*, (2007). The above findings by McConnel *et al* are to an extent in agreement with the WHO international guidelines to offer Sd-NVP to HIV-infected pregnant women, regardless of previous Sd-NVP exposure, when more complex prophylaxis regimens are not available (WHO, 2006).

In summary, the studies show that Sd-NVP is effective but that this effectiveness can be nullified by subsequent exposure to mixed breast-feeding and poor quality PMTCT services.

2.5 EFFECTIVENESS OF SINGLE-DOSE NEVIRAPINE (Sd-NVP) VERSUS A COMBINATION OF AZT.

At the time of this study, Namibia was using an Sd-NVP regimen for PMTCT; however, combination regimens are more efficacious than single-drug regimens (WHO *et al*, 2009). In a study done in Cameroon on integrating the prevention of mother-to-child HIV transmission into routine antenatal care, it was noted that more than two thirds of the HIV-infected population reside in sub-Saharan African communities, where the benefits of extending the recent breakthrough in prevention of MTCT to most infected women remains a tremendous challenge. In such settings, short-course antiretroviral prophylaxis regimens with Zidovudine or Nevirapine or with two drugs (Zidovudine and Lamivudine) in resource-limited settings can reduce HIV infections (Welty *et al*, 2005).

The systematic review of the efficacy of antiretroviral therapies for reducing the risk of mother-to-child transmission of HIV infection states that Nevirapine monotherapy given to mothers and infants as a single dose reduced the risk of vertical transmission compared with an intrapartum

and postpartum regimen of Zidovudine (RR 0.60, 95% CI: 0.41-0.87). Zidovudine plus Lamivudine was effective in reducing the risk of maternal-child transmission of HIV (RR 0.63, 95% CI: 0.45-0.90), However, adding Zidovudine to Sd-NVP in infants was not more effective than Nevirapine alone (pooled RR 0.88, 95% CI: 0.47-1.63). Neither did they find any significant difference between Zidovudine plus Lamivudine and Nevirapine. While on the other hand, in mothers already receiving Zidovudine prophylaxis, and adding a single dose of Nevirapine to mothers during labour and giving the same drug to infants, may further decrease the risk of vertical transmission and infant death (Suksomboon *et al*, 2007).

The World Health Organization (WHO) in its document on recommendation for a public health approach on antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: towards universal access reports that longer regimens starting earlier in pregnancy are more efficacious than shorter regimens. WHO further reports that the transmission rates are lower when AZT is given to women from 28 weeks of pregnancy and to infants for six weeks. In conclusion, longer regimen is highly efficacious and achieves lower rates of MTCT than with either AZT or Sd-NVP alone (WHO, 2006).

A randomized study was conducted among infants born to HIV-positive mothers who received Sd-NVP alone, or combined with AZT after delivery. The study findings revealed the rate of transmission at 6-8 weeks was 15.3% in infants who received Nevirapine and Zidovudine, and 20.9% in those infants who received Nevirapine only. At the same time those infants who were negative at birth and received Nevirapine and Zidovudine, the test at 6-8 weeks showed an

infection rate of (51) 12.1%, and for those who received Nevirapine only had a p-value of 0.03, giving a protective efficacy of 36% respectively (Taha *et al*, 2003).

Another study conducted on the cost effectiveness of Sd-NVP for mother and infants to decrease vertical HIV-1 transmission in sub-Saharan Africa, found that the single-dose regimen given to mother and neonates in the intrapartum period and soon after birth is more cost effective compared to the multidose regimen. The authors also argue that more lives can be saved given investment in mother-to-child transmission for PMTCT programmes, in high HIV prevalence areas (Marseille *et al*, 1999).

Similarly, a study conducted in Pune, India, on mother-to-child transmission of HIV among women who chose not to exclusively breast-feed their infants, found that single-dose NVP or a short course of AZT, are effective in reducing MTCT in an Indian setting (Gupta *et al*, 2007). In summary, Zidovudine alone or in combination with Lamivudine and Nevirapine monotherapy is effective for the prevention of mother-to-child transmission of HIV. These therapies may also be beneficial in reducing the risk of infant death (Suksomboon *et al*, 2007; WHO, 2006).

2.6 RISK FACTORS FOR PERINATAL TRANSMISSION

According to the progress report on towards universal access: scaling up priority HIV/AIDS interventions in the health sector by WHO *et al* (2009), mother to child transmission of HIV is responsible for more than 90% of children living with HIV (WHO *et al*, 2009).

A study on monitoring the effectiveness of programmes to prevent mother-to-child transmission in lower income countries, available on the WHO website, states in its findings that multiple studies have shown that high maternal HIV plasma viral load, low maternal CD4+ lymphocyte cell count, vaginal birth and breast-feeding are the main central risk factors for perinatal HIV transmission. The study also reasons that many women have no access to life-saving measures aimed at reducing HIV transmission, such as the ARV regimen, elective caesareans, secure options to breast-feeding, or access to basic antenatal services (Stringer *et al*, 2009).

Another study on the risk factors for perinatal transmission of human immunodeficiency virus type 1 in women treated with zidovudine. Pediatric AIDS Clinical Trials Group Study 185 Team by the Pediatric, Adolescent and Maternal AIDS Branch, National Institute of Child Health and Human Development, in the USA found similar risk factors to the above. The methodology that was used was to examine the 480 women and their infants, all of whom received zidovudine, the effects of maternal, obstetrical, and infant-related characteristics and maternal virologic and immunologic variables on the risk of perinatal transmission of HIV-1. The women and infants were participating in a phase 3 trial of passive immunoprophylaxis for the prevention of perinatal transmission. This study found that reduced maternal CD4+ lymphocyte counts at base line; diminished maternal HIV p24 antibody levels at base line and delivery; augmented maternal

HIV-1 titer at base line and delivery; increased maternal HIV-1 RNA levels at base line and delivery; and the presence of chorioamnionitis at delivery were associated with perinatal transmission. Within the same study, the 107 women who had undetectable levels at delivery or the 84 women who had HIV-1 levels below the limit of detection (500 copies per milliliter) at base line were found to have no HIV-1 perinatal transmission. The study therefore concluded that the health of the women can be enhanced and the risk of perinatal transmission reduced through the administration of antiretroviral therapy that lessens the HIV-1 RNA level to below 500 copies per milliliter (Mofenson *et al*, 1999).

In a study on prevention of perinatal HIV transmission during pregnancy by the division of infectious diseases, at Bronx-Lebanon hospital in New York, United States of America found that vertical HIV transmission is best predicted by maternal plasma HIV viral load. Primary HIV infection in a pregnant women is at increased rate of transmission when the plasma viral loads are at their peak. Regardless of zidovudine use, HIV plasma viral loads of <1000 copies/mL has no or little HIV transmission (Joseph, McGowan, Sanjiv & Shah, 2000).

2.7 METHODS OF EVALUATING PMTCT PROGRAMMES

The WHO, UNICEF and UNAIDS (Draft, 03/2000)) state that the monitoring and evaluation of PMTCT programmes should be viewed as a decision-oriented instrument, and closely linked with decision-making whether at the operational or strategic level. They also reason that because participation in the process of monitoring and evaluation often brings a better understanding of

the activities, the process of carrying out monitoring and evaluation activities is as important as the drawing conclusions (WHO, UNICEF and UNAIDS, Draft, 03/2000).

While in a study on prevention of mother to child transmission of HIV in Africa: success and challenges in scaling up a Nevirapine program in Lusaka, Zambia, authors asserts that cross-sectional or retrospective data can also be used to establish PMTCT of HIV effectiveness. Since they have advantages of being simple, short study time frame and are best suited to gather population based results. Measuring of trends over time, changes in programme uptake, drugs regimens and general cause of death can be easily ascertained with retrospective approach. The authors concluded by proposing Demographic Health Surveys (DHS) as a model that can be used to assess PMTCT programmes. As it captures, various areas of the PMTCT cascade such as fertility rates, sero-sentinel surveys, number of sexual partners, infant feeding practices, maternal and infant, and child morbidity and mortality rates (Stranger *et al*, 2009).

Puoane and Alexander (2006:89-90) describe the following different types of evaluation studies:

Evaluation assessment - *This is an evaluation conducted before a formal evaluation, aimed at assessing the readiness of the programme to be evaluated, and where its findings are used to inform the scope and rationale of a formal evaluation.*

Baseline evaluation (front end analysis) - *This is an evaluation, background scan and viability assessment, usually done before the programme implementation starts. It is carried out to assist in the preparation and growth of the programme. This type of evaluation takes into account a “needs assessment” and the practicability of the programme implementation.*

Formative evaluation – *This evaluation tracks the progress made during programme implementation and since it is method orientated, it provides direction to the programme activities.*

Midterm evaluation - *This type of evaluation assesses the success and usefulness of the programme when it is half way through the intended implementation phase.*

Impact or outcome evaluation – *This evaluation is useful in deciding the extension of the programme. It gauges the products of the programme and measures its success against its significance.*

Summative evaluation – *This is an evaluation that uses its findings to assist in deciding whether to continue or end a programme, and is usually done at the end of the project.*

Evaluation of evaluation – *This evaluation is used for funding purposes, research and to guide policy makers. Re-analysis of evaluation data, meta-analysis of several evaluations and external reviews of evaluations are some of the processes involved.*

In view of the above, the commonly used evaluation methods by different institutions to assess their programmes are baseline surveys, midterm evaluations for long-term projects and evaluations of the evaluation by external evaluators to assess programmes. It is also asserted that cross-sectional or retrospective data can also be used during the monitoring of the effectiveness of programmes to prevent mother-to-child HIV transmission in lower income countries. The two approaches have the advantage of being simple; requiring a short study time frame; and best suited to gather population-based results. These two approaches can also: measure trends over time; changes in programme uptake; and drug regimens. General causes of death can also easily be ascertained with a retrospective approach. Using this approach, the Demographic Health Surveys (DHS) are able to capture various areas such as: fertility rates; sero-sentinel surveys;

number of sexual partners; infant feeding practices; maternal and infant and child morbidity; and mortality rates (Stranger *et al*, 2009).

In conclusion, various evaluation methods exist and can be applicable to PMTCT programmes. What is important is for the evaluators of PMTCT programmes to diligently select a method most suitable to the evaluation objectives and purpose.

2.8 USES AND LIMITATIONS OF MEDICAL RECORDS.

2.8.1 Quality of data collection.

The key factor in quality health care information is data collection and the subsequent maintenance of data gathered. Equally important, in order for demographic and clinical data to be of use, it should be accurate, consistent, available and securely stored. Without these it is less valuable to medical science or health care management in general (WHO, 2003). Not only is it of limited value to health care management; it also affects practice at grass root level where the data is being used.

A survey was conducted on challenges for routine health system data management in a large public programme to prevent mother-to-child HIV transmission in KwaZulu Natal, South Africa. Findings revealed that from the 316 site reports that were submitted to the District Health Information System (DHIS), data was partly complete (50.3%) when analyzing the six PMTCT data elements (ANC client tested for HIV; ANC client found to be HIV positive; CD-4 testing of HIV-positive pregnant women; Nevirapine dose to women at antenatal or labour; Nevirapine dose to infant born to HIV-positive women; HIV PCR test of infant born to HIV-positive women at six weeks or later). The survey team excluded all missing data from both the clinic registers

or from the DHIS during accuracy calculations. Therefore, findings revealed data accuracy problems, with 29.2% and 87.1% from the DHIS, while the clinic registers were around 4.5% and 41.0% lower than the DHIS. Data completeness, with at least all 12-month reports completed, was found to be 62.7% with the best reported element being ANC client tested for HIV. Whilst the PCR test to infants born to HIV positive women at 6 weeks or later was found to be the poorest reported element at only 12.7% of the time, with no site providing complete data every month for the 12-month study period (Mate *et al*, 2009). In summary, this survey shows that the completeness and accuracy of the collected and reported data to track PMTCT service delivery in KwaZulu Natal, had serious deficiencies.

The causes and sources of poor quality data is a result of undefined and dysfunctional requirements for reporting, lack of reporting standards, lack of standardized data collection tools, and collected data that is inconsistent, inaccurate and incomplete (WHO, 2003). In many instances, lack of uniformed data collection and reporting tools has led to disintegrated, disjointed data that is difficult to collate. This contributes to misguided decisions by top management and operational level officers.

A study on improving the coverage of the PMTCT programme was conducted through participatory quality improvement interventions in Amujaba, KwaZulu Natal, South Africa. The authors report generally good record keeping at all the clinics and availability of guidelines and up to date registers for controlling their prophylaxis. They also found that there was high (85%) HIV testing, while the CD4 count tests were low. There were over 50% of HIV-positive women who received Nevirapine and 15% Nevirapine administration to infants. However, at six weeks only a section of the infants received DNA-PCR tests. The authors also reported poor support

supervision where only 47% of the health facilities were visited in the last six months of the study period. (Doherty *et al*, 2009).

2.8.2 Advantages and disadvantages of medical records.

The WHO (2001) puts forward that medical records can be used as:

- 1) A tracking tool to document the patient's sickness and management.
- 2) A correspondence tool for all clinicians and/or health care providers providing ongoing care of the patient, and gathering of health data.
- 3) An investigation tool for precise ailments of the patient.

Stringer *et al* (2009) outline facility-based sources as one of the best sources of information for PMTCT evaluation. Because of its easy access, facility-based systems can have technically skilled staffs who gather data from the clients in settings such as antenatal care, maternity/labour wards, and postnatal care and paediatric clinics. Such sources make the information more reliable for PMTCT cascade programme assessment. However, the noted limitations are that the data is not representative since not all populations of interest may have accessed the services. They continue to describe the option of facility-based as community-based. The advantage of this latter type of data is that it is representative and may have direct benefit to the family members. For instance, partner testing would benefit all the family in accessing treatment, care and support on HIV and those defaulting on the PMTCT services can easily be traced. The limitations are that in order to get a precise outcome, there is need for a large sample size and such studies are generally expensive (Stringer *et al*, 2009). In summary medical records are key in routine data monitoring and evaluation of a PMTCT programme's effectiveness.

2.9 HIV AMONG INFANTS AND PREGNANT WOMEN IN NAMIBIA.

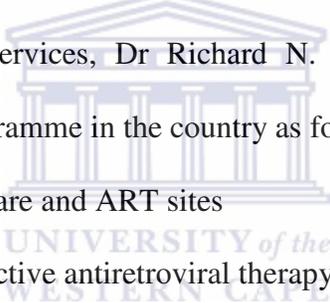
In the Ministry of Health's 2007/08 estimates and projections of the impact of HIV/AIDS in Namibia, it is stated that about 9 400 pregnant women were in need of PMTCT services. It is also estimated that this number will increase to 10 000 by the year 2012/13. The document continues to state that during the same year, 14 000 new HIV infections were estimated to occur. According to the estimates, on average 39 new infections occur every day and 9% of these occur in children under 15 years old. (MoHSS, 2008).

In 2007 in Namibia, an estimated 9% of children between the ages of 0-14 years had new infections, while 34% in females between the ages of 15-24 years, 10% in males between the ages of 15-24 years, and 18% of females above the age of 25 years were also estimated to have new HIV infections during the same period. The 9% new infections in children can be attributed to MTCT of HIV during pregnancy, labour and delivery, including breast-feeding (MoHSS, 2008).

The national PMTCT annual report of 2007 by the MoHSS, Windhoek, Namibia states that in 2006, 43 711 deliveries were reported at PMTCT sites, and of these, 8 190 were reported in Khomas region where this study is located. The Khomas region accounted for 14.26%, (1 168/8 190) of HIV-positive pregnant women, of which 86% of infants received Nevirapine. In the same report it shows that Khomas region, out of the 13 regions in the country, had the highest number of HIV-exposed infants who did not receive NVP prophylaxis during April 2006 to March 2007 (MoHSS, 2007).

In Namibia, a study has not been done to determine the effectiveness of Sd-NVP versus a combined regimen. Analysis of reported data was done and showed no significant differences between the two regimens. For instance in 2006, Sd-NVP recorded an HIV prevalence of 10.0% and other ARVs were 11.3%. While in 2007, Sd-NVP was 10.2 % and 9.9% for other ARVs. Similar results were recorded in 2008, at 8.7% and 8.5% respectively (MoHSS, 2009). The above information contradicts findings from several clinical trial findings, some of them mentioned above, and also the WHO recommendations on the PMTCT HIV prophylaxis and treatment of women infected with HIV and their infants.

During the HIV/AIDS implementers meeting held in Namibia, Windhoek in June 2009, the Minister of Health and Social Services, Dr Richard N. Kamwi, highlighted some of the challenges facing the PMTCT programme in the country as follows:

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- Poor linkages of antenatal care and ART sites
 - 5.9% of women on highly active antiretroviral therapy (HAART) are falling pregnant
 - Most HIV-positive women opt for breast-feeding, but little is known if exclusive breast-feeding is practiced
 - Not all HIV-positive pregnant women deliver in health facilities and access ARV prophylaxis
 - Follow-up on the HIV-exposed infants is still weak with missed opportunities at six weeks
 - Irregular and inaccurate reporting still noted in some sites
 - Poor community mobilization for PMTCT

- Poor male participation in PMTCT with only 4% of partners accepting to test (MoHSS, 2009).

The two hospitals where this study took place saw an increase (Katutura State Hospital from 27% to 36.7%) and Windhoek Central Hospital (from 11.8% to 14%) in HIV prevalence among adults aged 25-49 years during 2004 and 2006 respectively (MoHSS, 2006). Katutura State Hospital is one of the sero-sentinel survey sites that did not experience a fall in the youth HIV prevalence rate as indicated in the recent 2008 sentinel survey (MoHSS, 2008).

2.9.1 Progress with the PMTCT programme in Namibia.

The second edition of the guidelines for the prevention of mother-to-child transmission of HIV was launched in July 2008 to include a more efficacious regimen for PMTCT ART prophylaxis. The guidelines outlined that parents whose infants tested HIV-positive at any stage in life should be counselled and the infant managed as being HIV-positive. PMTCT guidelines also stated that counselling should also be offered to those parents whose infants are HIV-negative (MoHSS, 2008). However, it needs to be verified whether it is the current practice in all the PMTCT, paediatric, ART and outpatient sites. In support of the above, one of the objectives within the guidelines is:

“90% of HIV-positive pregnant women, their children and partners, have access to PMTCT services and receive a complete course of ARV prophylaxis to prevent mother-to-child transmission of HIV” (MoHSS, 2008:2).

According to the Minister of Health in Namibia (2009), PMTCT coverage rates in the country have improved dramatically over time in Namibia, with the large majority of women now knowing their HIV status at delivery. However, more effort is needed to ensure that all HIV-

positive pregnant women and their exposed infants receive full ARV prophylaxis, and that they are enrolled in the continuum of care. Downward trends in HIV DNA PCR-positive rates are encouraging, while on the other hand rapid scale-up of HIV DNA PCR has contributed to higher numbers of children in need of ART being put on treatment. The Minister stated that 7 622 were on ART as of March 2009, versus a projected need of 7 600 exposed infants. He added that with the introduction of combination ARV prophylaxis, continued scale-up of the PMTCT programme as well as the decline in the ANC HIV sero-prevalence, declines in number of HIV DNA PCR samples testing positive are expected (MoHSS, 2009).

The PMTCT annual report covering the period April 2008 to March 2009 for the Ministry of Health in Namibia states that by the end of March 2009, all 34 state hospitals, and 218 health centers out of the total 335 health facilities (98% coverage), were providing antenatal care services. The report further indicates a reduction in the number of health care providers trained in DNA-PCR testing in Khomas region during 2006/07 and 2007/08, from 9 to 4 respectively (MoHSS, 2009).

2.9.1 Data collection procedures in Namibia

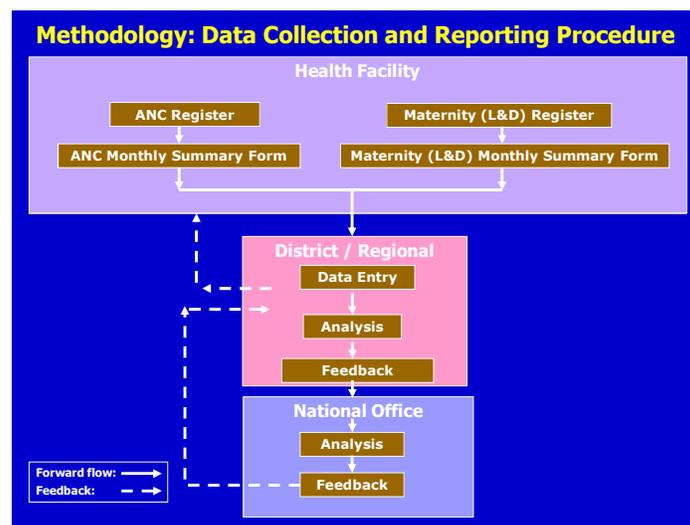


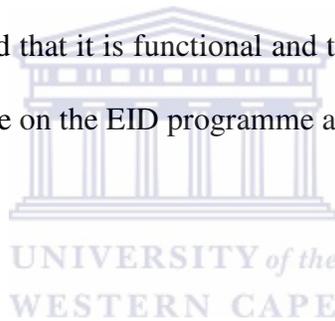
Figure 1: Namibia PMTCT information flow chart

Source: MoHSS-FHD-PMTCT and newborn unit

Figure 1 shows the channels of communication that are expected within the PMTCT of HIV programme in Namibia. An assessment needs to be done to verify the current practice.

The guidelines for the prevention of mother-to-child transmission of HIV in Namibia describe the MoHSS algorithm for early infant diagnosis (EID) and HIV infection using DNA-PCR. There is provision for ‘pre-test information’ before collecting blood for dried blood spot (DBS) and also ‘post-test counselling’ for infants who is HIV-positive (MoHSS, 2008).

With the above in place, it is hoped that it is functional and that the implementers are utilizing it optimally, but no data was available on the EID programme at the time of data collection.



CHAPTER THREE

METHODOLOGY

3.1 STUDY AIM

The study aim was to measure the operational effectiveness of Sd-NVP for PMTCT programmes among infants aged six weeks in Khomas region of Namibia.

3.2 STUDY OBJECTIVES

- 1) To determine HIV prevalence among known PMTCT-exposed infants aged 6 weeks in Khomas region of Namibia.
- 2) To examine the quality of the PMTCT programme delivered to women who tested positive for HIV during the antenatal period and their infants, including counselling, Nevirapine administration, delivery methods, infant feeding, follow-up and infant testing.
- 3) To assess the quality of the PMTCT information from maternity delivery and DNA-PCR test registers.

3.3 STUDY DESIGN

This study was a retrospective record review, gathering quantitative data from a cohort of HIV-positive women and their infants from delivery to six weeks postpartum (January to December 2007). This study design was chosen because it has the advantages of determining PMTCT reporting, uptake, medicine scheduling, and measuring programme performance.

3.4 STUDY POPULATION

All records of known HIV-positive pregnant women who delivered from January to December 2007 in Khomas regional hospitals, who received or did not receive a single dose of Nevirapine during labour, and their newborn infants (regardless of whether Nevirapine was given after birth or not), formed part of the sampling frame. In other words, all records of women who participated in the PMTCT from January to December 2007, regardless of whether they actually took their NVP, were included. Those records of women who delivered at home, and who had abortions did not form part of the study population.

The registers of 2007 PMTCT mothers and their infants were reviewed at six weeks postpartum. Among 13 health regions in the country, two hospitals in the Khomas region were purposively and conveniently selected. The clients of one of the facilities are mostly from the black community, or other previously disadvantaged communities in Namibia. The clients of the other facility are mostly a middle-income group from the central part of the city. The reason for choosing two hospitals in the same region out of the 13 regions in the country was threefold:

- 1) The researcher is a student and self-funded, and so it made more sense, was more convenient and cost-effective to conduct the study within the locality.
- 2) One of the hospitals was also one of the two pilot sites in 2002. Hence, the programme had been running longer in this facility.
- 3) The one hospital reaches out to about 95% of the poor, while the other covers more than 75% of the middle- and high-income community.

As a result, these two hospitals in one region were purposively selected in order to generalize the results to similar settings. Windhoek Central Hospital is a specialized referral hospital and mainly accommodates government subsidized medical aids and middle-income groups, while Katutura Hospital is a national referral hospital catering for the majority of the poor community and public servants. The latter hospital is located in Katutura location where the majority of the poor urban population resides. Windhoek Central Hospital is located in mid-town within reach of the better off middle- to high-income group. During the study period, the two hospitals were the only health facilities conducting antenatal care and deliveries for the whole Khomas region.

3.5 SAMPLE

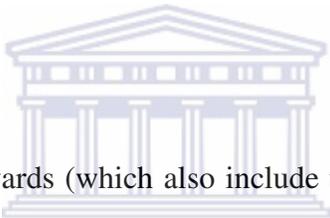
Registers were located and a full review of the basic programme data was completed to obtain a sampling frame and provide data for an examination of the PMTCT cascade. Systematic sampling followed with a random start of all known HIV-positive women and their infants during the PMTCT programme in 2007 in the two public hospitals of Khomas region. From each hospital, the maternity delivery registers were combined in no particular order, one register was chosen from that pile, a new register was opened and the first seen recorded HIV-positive women was picked out and then every other HIV-positive women that followed was systematically sampled. The PMTCT registers for the study period were used as the sampling frame, which was expected to have up to 1 168 HIV-positive women. The sample size was calculated using EpiInfo Version 3.43 (CDC 2007).

The required sample size for selected population estimates included:

Variables	Estimated prevalence % (+/- 95% CI)	Required sample size
Nevirapine administration to infant	75% (+/- 5%)	288
Exclusive breast-feeding at 6 weeks	40% (+/- 5%)	369
HIV prevalence in infants at 6 weeks	12% (+/- 3%)	451

Therefore, a sample size of at least 451 was required to estimate the primary outcome (infant HIV prevalence at 6 weeks). This suggests the sampling ratio was approximately 1:2 – half the women in the PMTCT register were needed for sampling. Hence, 451 were used as the desired final sample size based on the calculations in the table above.

3.6 DATA COLLECTION



Records from maternity delivery wards (which also include the postnatal information up to day seven or more after birth), antenatal care, and dried blood spot (DBS) or DNA-PCR testing registers for 2007 were reviewed. Initially, unlinked PMTCT cascade programme data was tallied, including: number of women attending antenatal care; number of women receiving HIV counselling and testing; receipt of test results; number HIV-positive women; ARV prophylaxis; CD4 testing; and infant testing. Then the delivery register (mother) was linked to the PCR register by using the antenatal care number, which is the same number used in maternity-delivery and PCR registers, hence making it easy to trace the linkage of mother-infant pairs. Information regarding Nevirapine administration to mothers and infants was collected. Other information that was collected included: age of mother; any available socio-demographic information; any counselling documentation; delivery method; maternal and neonatal complications; infant sex; infant feeding patterns at six weeks; infant HIV testing; infant HIV status, amongst others.

3.7 MEASUREMENT

Reviewing registers of mothers and infants exposed to HIV and who participated in the PMTCT programme, formed the main activity for this study. The records reviewed were from January to December 2007 in the maternity ward (delivery registers) and DNA-PCR testing registers. The researcher used the delivery and DNA-PCR registers during data collection. Data such as age, sex, number of infants tested for HIV at various stages, and HIV status outcomes, were assessed (Annexure 1 and 2)

3.8 VALIDITY AND RELIABILITY

The data extraction tool was developed with the consideration of similar tools previously used in South Africa, together with input from the researcher's supervisor. The tool was piloted before use. In addition, it was submitted to the Ministry of Health's Namibia Research Unit for their input, and experts reviewed the content. The data was checked daily for completeness and safely stored. The next step was processing or sorting out data, including performing quality control. The data extraction tools were in English as no mothers or health workers were interviewed, hence, the researcher was the person who collected data and reviewed the records. It was expected that about 584 records would be reviewed (1 168/2).

There were limitations to using routine register data, including missing and incomplete registers and data, or inaccurate data. The data extractor was a student at the University of the Western Cape in South Africa. She had previous experience of data collection within the health system. From each hospital, the maternity delivery registers were combined in no particular order, one register was chosen from that pile, a new register was opened and the first seen recorded HIV-

positive women was picked out and then every other HIV-positive women that followed was systematically sampled. All HIV-positive women in the PMTCT registers for 2007 were eligible for sampling, however, not all were sampled, because the register for a certain period of time could not be traced by the clerk, hence those in that specific register were not sampled. The other selection bias was that those who delivered during the last months of the year were not sampled, as their infants were not yet 6 weeks old at the time of the review.

3.9 GENERALIZATION OF STUDY

The study results are expected to be generalized to similar PMTCT settings in Namibia, such as the Oshakati intermediate referral hospital in the north west of the country, because it also has high volumes of PMTCT mothers, and it was one of the two pilot sites for the PMTCT programme, as was Katutura State Hospital. The other settings are the hospitals in the migrant towns of Walvis Bay and Swakopmund at the coast, because the population lifestyle is to some extent similar to Khomas region, in terms of socio-cultural and socio-economic status.

3.10 DATA CHECKING

All the data abstraction tools were checked and sorted in the field and again prior to data entry into the computer. Errors were corrected immediately by rechecking the records.

3.11 DATA CODING

Since the data extraction tools were only close-ended questions, pre-coding was applied throughout and consistency maintained.

3.12 DATA ENTRY

Data was entered onto Excel spread sheets by the researcher. A 10% random sample of entered data was verified with actual data extraction tools after data entry and corrections and/or further verification made, as was necessary.

3.13 DATA ANALYSIS

This analysis used descriptive statistics in line with the study objectives, which aim to describe the PMTCT programme. The analysis of this study data was done using the EpiInfo version 3.3 and Excel spread sheet. The EpiInfo version 3.3 was used to analyze data by using frequencies with 95% confidence intervals of categorical variables for one-way frequency tabulation; or summary statistics by calculating the appropriate means and standard deviations of continuous variables. Two-way frequency tables were used to compare infant HIV prevalence across selected factors. However as the primary intent of this analysis is descriptive and there is limited power for analytic comparisons of this data no statistical testing is included. Therefore all comparative analyses should only be considered exploratory for the purposes of this report.

3.14 ETHICAL CONSIDERATIONS

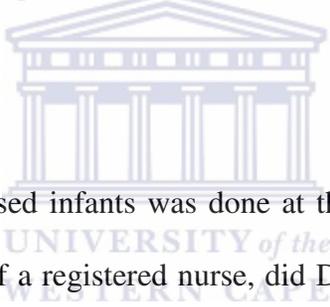
Ethical approval was sought from the University of the Western Cape and the Ministry of Health and Social Services (MoHSS) in Namibia prior to data collection. During data collection, seeking of permission from the officers in charge of the hospitals, and subsequently from antenatal and postnatal care, maternity and paediatric wards. Information collected was safely stored and kept confidential throughout the study period (Vaughan & Morrow, 1989). Study numbers were used rather than names on all data collection tools. The researcher signed a confidentiality agreement form before data collection.

CHAPTER FOUR

DATA PRESENTATION AND ANALYSIS OF RESULTS

4.1 REGISTERS AND DATA RETRIEVAL

The registers that were reviewed were from Windhoek Central Hospital (WCH) and Katutura State Hospital (KSH) in the Khomas region. At WCH, the delivery registers were not kept at the maternity ward, but with the assistance of the maternity matron, they were traced to the clerk responsible for accommodation for the hospital. The maternity delivery registers for the period January to December 2007 were requested. After verification of the flow of dates, two of the registers could not be traced.



The infant follow-up of HIV-exposed infants was done at the postnatal unit where community counsellors, with the supervision of a registered nurse, did DNA-PCR tests. At this unit, a hard cover exercise book was used to collect data and information collected was developed by the unit. At KSH, the registers were also kept by the clerk who was based within the postnatal ward, and was mainly responsible for medical record storage under the close supervision of the maternity section matron. A completed register for January could not be traced. At KSH the follow-up of HIV- exposed infants was done at the ART paediatric site. This register was different from the one found at WCH.

Despite the missing maternity registers for certain days or months in both hospitals, register reviews were carried out with existing registers. Based on the above, a total of 451 subjects of

HIV-positive women who delivered between January to December 2007 in WCH and KSH were reviewed in order to determine the HIV status of their infants at six weeks.

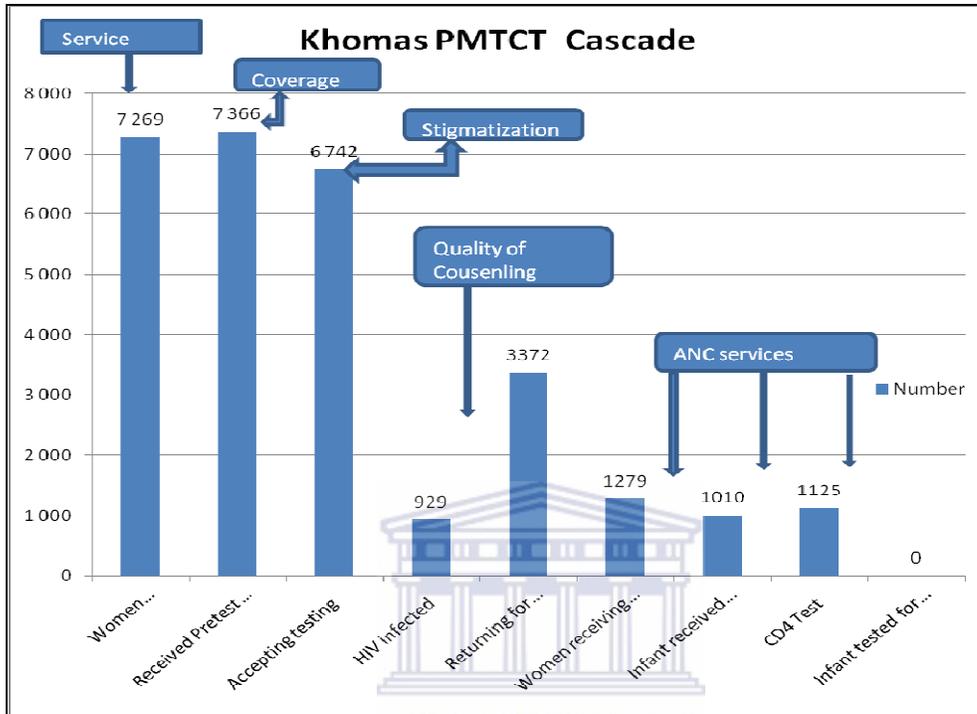
Approximately 434 HIV-exposed infants were traced at DNA-PCR testing sites in both hospitals. This is because out of the 451 PMTCT mothers' sampled from the registers reviewed in both study sites during March and April 2009, 17 (4%) of the mothers sampled from the PMTCT registers show either that the infant died in labour, was a still birth or died within six weeks after delivery. This gives a balance of 434 infants, of which 427 had the age of the mother recorded, while 411 had the sex of the infant entered on the registers.

It is important to note at this stage that record-keeping was a challenge in both sites. This resulted in a number of variables not measured as no data could be obtained from the reviewed registers. In particular, the birth weight, though provided for in the maternity deliver registers, were not entered at all, and HIV counselling types were not provided for in both delivery and DNA-PCR registers at both sites. Hence information on these variables was not collected.

Of the delivery registers that had discharge weight entered, 31% (95% CI, 27.0-36.0) were not filled in. The reason for why there were blank spaces with regards birth and discharge weight was not assessed.

4.2 PMTCT CASCADE

Figure 2: PMTCT cascade for Khomas region, fiscal year 2007/08



Source: MoHSS maternity and DNA-PCR Registers, 2007

WESTERN CAPE

Figure 2 data was not part of the sampled 451. Therefore, the findings in the figure are as a result of the review of the register to establish the sampling frame, similarly the data is from the full register review prior to the sampling of the delivery and DNA-PCR registers. The figures show recording problems for some of the data items such as the number of women receiving ARV prophylaxis being more than the number testing HIV positive; whilst some of the drop offs could be due to missed opportunities for instance, the number of women accepting to test and the number returning for test results being less than the number of antenatal care visits.

Further, the number of CD4 count tests done were more than the total infected pregnant women. This raises questions on the quality of reporting that existed. Similarly, infants who

received ARV prophylaxis, were more (1 010) compared to the total infected pregnant women of 929. During the analysis of the PMTCT Cascade areas, it was also noted that only four health workers were trained in DNA-PCR testing during the period under review. No data was available in the registers on infant DNA-PCR testing.

4.3 PRIMARY OUTCOME: INFANT HIV TESTING AND INFANT HIV PREVALENCE

Table 1: Infants who tested for HIV at six weeks or more for DNA-PCR tests, PMTCT programme, in 2007 Khomas region

Tested for HIV	Number	%	95%	CI
Yes	169	39	34.4	43.7
No	0	0		
Not recorded	265	61	56.3	65.6
Total	434	100		

Table 1 indicates that less than half (39%) of the infants sampled during the study period were tested, while the rest (61%) could not be traced in the DNA-PCR testing register during the period under review.

Table 2: HIV status of PMTCT exposed infants, who tested at six weeks or more, PMTCT programme, in 2007 Khomas region

HIV status	Number	%
Negative	159	95
Positive	8	5
Total	167	100

Table 2 indicates that out of the total (167) PMCT infants whose HIV status was recorded at six weeks during the review period, 5% tested positive.

4.4 MATERNAL AGE

Table 3: Age of PMTCT mothers at delivery, PMTCT programme, 2007 Khomas Region

Age of mother in years	Number	%	95% (CI)	
< 19	5	1.2	0.4	2.8
19 – 24	80	18.4	15.0	22.5
25 – 30	184	42.4	37.7	47.2
31 – 35	101	23.3	19.4	27.6
> 36	57	13.1	10.2	16.8
Not recorded	7	1.6	0.7	3.4
Total	434	100		

Table 3 above indicates that young women below the age of 25 years accounted for 19.6% of the total sampled HIV-positive women who delivered between January to December 2007 in Khomas region of Namibia. The age group for PMTCT mothers ranged from the youngest of 15 years to 47 years for the oldest mother. The mean age for PMTCT mothers was 28.7, while the median age was 29. The most commonly occurring age among the study group was 26. Table 3 shows a high percentage of those who delivered in the PMTCT programme in the Khomas region were aged 25-30 (42.4%, 95% CI, 37.7 – 47.2), followed by the 31-35 years at 23.3% (95% CI, 19.4 – 27.6). The lowest was under the age of 19 years at (1.2%, 95% CI, 0.4 – 2.8).

4.5 PMTCT PROGRAMME INDICATORS

Table 4: HIV-positive PMTCT-exposed infants by age of mother at delivery, PMTCT programme 2007 Khomas region

Age	Number HIV+ infants	Number HIV+ mothers	%
< 19	0	2	0
19 – 24	1	28	4
25 – 30	3	75	4
31 – 35	3	40	8
> 36	1	20	5
Total	8	165	5

Note that there were two infants who were tested but whose mother's age was not recorded, thus making the total infants tested 167 and not 165 as in the table. Table 4 above therefore shows that there was high prevalence among infants born to HIV-positive mothers aged between 31-35 years old, compared to the rest.

Table 5: Mothers who received NVP before and/or during labour, in the PMTCT programme, 2007 Khomas region

NVP in labour	Number	%	95% CI
Yes	396	91	88.1 – 93.7
No	31	7	5.0 – 10.1
Not Recorded	7	2	0.7 – 3.4
Total	434	100	

Table 5 shows that at least 91% HIV-positive pregnant women of those sampled in the study period received NVP in labour or before delivery.

Table 6: Hours before NVP was administered to the mother before delivery, PMTCT programme, 2007 Khomas region

Hours for NVP in labour	Number	%	95% CI	
< 2	55	13	9.8	16.3
2 - 4	241	56	50.7	6.2
> 4	97	22	18.6	26.6
Not Recorded	41	9	6.9	12.7
Total	434	100		

Table 6 indicates more than 70% of pregnant women received NVP at least 2 hours or more before delivery. However, 13% of these mothers received it less than 2 hours before delivery.



Table 7: Treatment regimen administered to the mother before and/or during labour, PMTCT programme in 2007, Khomas region

Treatment regimen	Number	%	95%	CI
Sd-NVP	286	66	61.2	70.3
Sd-NVP + AZT	8	2	0.9	3.7
Others	97	22	18.6	26.6
Not Recorded	43	10	7.3	13.2
Total	434	100		

Table 7 indicates that more than 65% of the pregnant women received NVP only, while 2% received Sd-NVP plus AZT prophylaxis. The other 22% that were recorded to have received other regimens other than the Sd-NVP, and Sd-NVP with AZT, either received one of the following as per maternity register code 4: AZT, 3TC + NVP <4 weeks; code 5: AZT, 3TC + NVP >=4 weeks; code 6: other ARV <4 weeks; code 7: other ARV >=4weeks.

Table 8: HIV-positive PMTCT-exposed infants by hours mother received NVP and/or ART prophylaxis within 72 hours, PMTCT programme, in 2007 Khomas region

Hours	Number HIV+ infants	Number HIV+ mothers	%
< 2	1	21	5
2-4	6	102	6
> 4	1	35	3
Total	8	158	5

Table 8 shows similar HIV prevalence among those infants whose mothers received ARV prophylaxis less than 2 hours (5%) and 2-4 hours (6%) before or during labour, with those taking >4 hours somewhat lower (3%).

Table 9: Reasons for mothers who didn't receive PMTCT prophylaxis before and/ or during labour, PMTCT programme in 2007 Khomas region

Why not NVP	Number	%	95% CI	
Head on perineum	2	2	0.2	5.8
Not recorded	74	60	50.9	68.9
Other	47	38	29.6	47.4
Total	123	100		

Heads on perineum was the only reason (2%) indicated among the reviewed records as the reason for the mother not to have received NVP during labour.

Table 10: Methods of delivery, PMTCT programme in 2007 Khomas region

Type of delivery	Number	%	95% CI	
Normal vertex delivery	329	76	71.4	79.7
Caesarean section	95	22	18.1	26.1
Other	1	0	0.0	1.5
Not recorded	9	2	1.0	4.0
Total	434	100		

Table 10 shows a high delivery mode for normal vertex delivery at 76% (95% CI, 71.4 – 79.7), followed by caesarean section at 22% (95% CI, 18.1 – 26.1).

Table 11: HIV-positive PMTCT-exposed infants by delivery type, PMTCT programme, 2007 Khomas region

Mode of delivery	Number HIV+ infants	Number HIV + mothers	%
Normal Vertex delivery	7	140	5
Caesarean Section	0	24	0
Others	1	1	100
Total	8	165	5

Table 11 shows that the highest (5%) HIV was among those infants who were delivered via normal vertex delivery, compared to other methods.

Table 12: Types of maternal and neonatal complications for PMTCT, PMTCT programme, 2007, Khomas region

Complication	Number	%	95% CI	
Premature	4	0.9	0.3	2.5
Prolonged labour	6	1.4	0.6	3.1
Foetal distress	7	1.6	0.7	3.4
Pre-eclampsia	3	0.7	0.2	2.2
Other	33	7.6	5.4	10.6
Not recorded	381	87.8	84.2	90.6
Total	434	100		

Complications such as placenta previa, antepartum haemorrhage (APH), mal-presentation, breech presentation, torn/doubtful membranes, cephalic pelvic disproportion (CPD) and postpartum haemorrhage (PPH) were responsible for 7.6% (n=33/434), (95% CI, 5.4 – 10.6) of the complications; while prematurity and prolonged labour was 2% or less respectively.

Table 13: HIV-positive exposed PMTCT infants by maternal and neonatal complications, PMTCT programme 2007 Khomas region

Complications	Number HIV+ infants	Number HIV+ mothers	%
Premature	0	1	0
Prolonged labour	0	4	0
Foetal distress	0	3	0
Pre-eclampsia	0	1	0
Others	1	9	11
Total	1	18	6

Table 13 shows only 1 infant with a history of prenatal complications was HIV-positive at 6 weeks of age.

Table 14: Sex of the PMTCT-exposed infants after delivery PMTCT programme, 2007 Khomas region.

Sex	Number	%	95% CI	
Male	206	47	42.7	52.3
Female	205	47	42.5	52.1
Not recorded	23	5	3.5	8.0
Total	434	100		

Table 14 indicates approximately the same distribution (47%) for both male and female infants sampled during the study period.

Table 15: PMTCT-exposed infants who received NVP within 72 hours after birth, PMTCT programme, 2007 Khomas region.

NVP within 72 hours	Number	%	95% CI	
Yes	300	69	64.5	73.4
No	79	18	14.8	22.2
Not Recorded	55	13	9.8	16.3
Total	434	100		

Table 15 indicates that 69% of the PMTCT-exposed infants received Nevirapine within 72 hours after birth, with 18% recorded as not having been given Sd-NVP.

Table 16: Feeding options of PMTCT-exposed infants, PMTCT programme, in 2007 Khomas region.

Feeding option	Number	%	95%	CI
Exclusive breast-feeding	173	40	35.3	44.7
Replacement feeding	84	19	15.8	23.5
Mixed feeding	3	1	0.2	2.2
Not recorded	174	40	35.5	44.9
Total	434	100		

Table 16 shows 40% of the infants were breastfed (95% CI, 35.3 -44.7), and less than 20% received replacement feeding.

Table 17: HIV-positive PMTCT-exposed infants by feeding options, PMTCT programme, 2007
Khomas region

Feeding option	Number HIV+ infants	Number HIV+ mothers	%
Exclusive breast-feeding	4	74	5
Replacement feeding	3	50	6
Mixed feeding	0	3	0
Total	7	127	6

Table 17 shows almost the same HIV prevalence among HIV-exposed infants by breast-feeding and replacement feeding, (5% and 6%) respectively.



CHAPTER FIVE

DISCUSSION AND INTERPRETATION

5.1 LIMITATIONS OF ROUTINE PMTCT DATA SYSTEM IN KHOMAS REGION.

The results of the PMTCT registers review conducted in Khomas region demonstrated severe incomplete data and the lack of a standardized data collection tool for HIV-exposed infants and/or mother-infant pair follow-up at six weeks for DNA-PCR testing during the study period. The findings are similar to the results of the challenges faced in routine health system data management in a large public programme to prevent mother-to-child transmission in South Africa (Mate *et al*, 2009), and the results from a study on routine service at the Coronation Women and Children Hospital (CWCH) in Johannesburg (Sherman *et al*, 2004). The commonality of incomplete data at both sites makes the continuous care, treatment and support of HIV-exposed infants difficult. This statement is supported by WHO (2003), stating inaccurate, incomplete and inconsistent data as valueless to the health care management.

The results from this study are better than those from an assessment in South Africa (Mate *et al*, 2009). The assessment in South Africa looked at challenges for routine health system data management in a large public management PMTCT HIV programme, in which the authors questioned the quality of the data tracking system and outcomes to improve performance. They found that only 12.7% of PCR tests conducted on infants born to HIV- positive women at six weeks, were reported. However, the South African study had a sample size of 316 sites, compared to only two sites in this study. They also found between 4.5% and 41.0% incidence of

missing data from the clinics registers. While in this study, missing data from the facility or unit registers was not measured, it was found that data was missing between 1.6% to 100% on the reviewed variables from the records. This study managed to trace only 38.5% HIV status of infants after the six week DNA-PCR test out of the total sampled infants during the study period.

In a descriptive study conducted over a 13-month period utilizing retrospective data obtained from hospital records, complemented by prospective data on a sample of patients enrolled in a study to determine an affordable HIV diagnostic protocol for infants at Coronation Women and Children Hospital (CWCH) in Johannesburg, South Africa, an HIV transmission rate of 8.7% was reported at the six-week HIV DNA-PCR test in a PMTCT programme (Sherman *et al*, 2004).

5.2 HIV PREVALENCE AMONG KNOWN PMTCT-EXPOSED INFANTS IN KHOMAS REGION.

This study used a retrospective maternity and DNA-PCR registers review to describe the PMTCT programme that was implementing primarily a Sd-NVP regimen. The HIV prevalence rate was found to be 5% among those infants who tested at six weeks. However, as noted above, less than 40% of infants were tested at six weeks representing a substantial loss to follow-up. This study, according to its study objectives, was therefore limited to assess HIV transmission rates in infants at six weeks.

However, despite the small number of infants tested at six weeks in this study, the outcome of 8/167 (5%) HIV prevalence among those tested, indicates that a single-dose NVP regimen

administered in resource-limited settings can potentially reduce mother-to-child transmission of HIV during perinatal and peripartum periods. Other authors reporting on the impact of single-dose NVP for PMTCT in Khayelitsha and Johannesburg, South Africa (Coetzee *et al*, 2005; Sherman *et al*, 2004), found a transmission rate of 8.8% and 8.7% respectively at 6 and 8 weeks post-delivery among 535 and 300 children respectively born to HIV-positive mothers. From the above figures therefore, it shows that single-dose NVP can effectively reduce early HIV transmission rates. Other authors such as McConell *et al* (2007), Gupta *et al* (2007) and Suksomboon *et al* (2004) report similar statements in their studies that Sd-NVP administered to infants within 72 hours after birth and to mothers at the onset of labour can reduce MTCT of HIV.

5.3 PMTCT CASCADE AND PROGRAMME INDICATORS.

In this study, the difference in the number accepting to test, and those returning for test results compared to the total figures for antenatal care visits could to some extent be due to missed opportunities. According to the data obtained from the MoHSS on the PMTCT Cascade, half (3 372/6 742, 50.0%) of all those who accepted to be tested returned for their results (MoHSS, 2007). Though this study did not assess the quality of counselling, a study on the effectiveness of Sd-NVP in preventing mother-to-child transmission of HIV in South Africa reported that those mothers who receive better counselling, have an increased chance of receiving NVP as per existing protocol and/or the PMTCT guidelines (Colvin *et al*, 2006).

The Khomas PMTCT Cascade areas revealed differences in the number of CD4 test done compared to women who tested HIV positive during Antenatal care; number of women who received ARV prophylaxis and the HIV exposed infants who received prophylaxis which can be

said to be due both to missed opportunities and record keeping. Since the results from this study had lots of missing data resulting in a very few infants testing at six weeks, it is difficult to link the results to the findings from the PMTCT Cascade.

This study found that only 38.5% (167/434) of infants tested for DNA-PCR at six weeks post delivery for the period January to December 2007. The result is different to the recommendations and targets of the Inter-agency Task Team (IATT) on the prevention of HIV infection in pregnant women, which calls for “at least 80% of infants born to women living with HIV to receive a virological HIV test within two months of birth” (WHO *et al*, 2009:91).

A study conducted on improving the coverage of the PMTCT programme through a participatory quality-improvement intervention in KwaZulu Natal, Amujaba, South Africa, found 85% HIV testing, low CD4 testing, and 15% of infants receiving NVP (Doherty *et al*, 2009). While this study also had major challenges with incomplete registers, it found good uptake within the PMTCT cascade, with more than 90% HIV testing, 79% of infants receiving NVP, and over 100% CD4 count tests done during 2007.

5.4 PMTCT RISK FACTORS

This study did not set out to determine HIV risk factor differences based on the regimen administered, however descriptive data on transmission was examined. The results found high HIV prevalence among infants whose mothers were aged between 31-35 years followed by 36 years and above. These results are similar to a study conducted on the effectiveness of the first district programme for the prevention of mother-to-child transmission of HIV in South Africa.

The study in South Africa used a multivariate analysis on the impact of a number of transmission factors and revealed that HIV transmission from mothers to their infants was more likely in women aged 25 years and above (Coetzee *et al*, 2005). Once again, the results from this study on age and HIV transmission from mothers to their infants is very much similar to the Ministry of Health, Namibia reports on the national HIV sentinel survey, which reports consistent high HIV prevalence rates among the age group 25 to 39 years for more than five years (MoHSS, 2006; MoHSS, 2008).

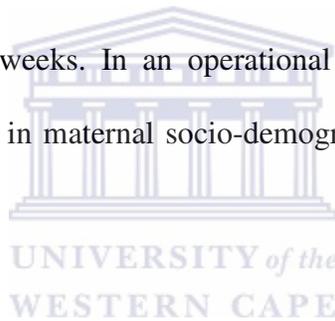
The findings also show higher HIV prevalence in those infants who were delivered via normal vertex delivery compared to none in the infants born by caesarean section. This is contrary to a study conducted in Uganda, which states that elective caesarean sections and perineum status were not associated with HIV transmission (Magoni *et al*, 2005). However it is consistent with a Cochrane review of efficacy of caesarean section which suggested PMTCT is reduced under certain conditions (Read & Newell, 2005).

Studies were conducted by Jackson *et al* (2006) on the operational effectiveness and 36-week HIV-free survival in the South African programme to prevent mother-to-child transmission of HIV-1; and Colvin *et al* (2006) on the operational effectiveness of a Sd-NVP in preventing mother-to-child transmission of HIV for the Good Start Study Group in Paarl, Umlazi and Rietvlei, South Africa. In these studies evidence was found that “ever breastfed” increased the risk of infants exposed to HIV becoming positive and/or even dying. Findings from the study on modes of infant feeding and HIV infection in children in a programme for prevention of mother-to-child transmission in Nsambya, Kampala, Uganda established that exclusive breast-

feeding is associated with postnatal transmission, and the results from this study were similar for those children receiving formula feeding, but less in those receiving mixed feeding. Results from this study did not show much difference between exclusive breast-feeding (EBF) and exclusive replacement feeding (ERF). The results showed similar findings of 5% and 6% respectively for both EBF and ERF.

5.5 STUDY LIMITATIONS.

A potential limitation of the study was that the results of the two sites were analyzed together which might HAVE resulted in biased outcomes in terms of data management and differences in the HIV status of infants at six weeks. In an operational study conducted in South Africa, significant differences were found in maternal socio-demographic variables between three sites (Jackson *et al*, 2006).



Due to the high volume of missing data across the variables reviewed, it became difficult to achieve the planned objectives. The 5% HIV prevalence out of the 167/434 (38%) who were traced as tested at six weeks, is not representative of the study population. Therefore, the reliability and value of the data reviewed is questionable and in this study the information could not be used to determine the operational effectiveness of Sd-NVP prevention of mother-to-child transmission in the HIV programme in Khomas region of Namibia.

Due to a high number of unrecorded complications, it was difficult to determine the extent of complication-related deliveries in this study. Even though it was not one of the specific objectives, there was a missed opportunity due to the study not interviewing mothers and/ or health care providers; hence loss to follow-up could not be described.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

In summary, it was difficult to measure the extent to which the study objectives were met due to poor record-keeping that was common throughout the data collected. The two sites used self-initiated registers to collect data on DNA-PCR testing at six weeks. Overall, less than 40% of the infants' HIV status was known and/or traced in order for this to be recorded at six weeks post-delivery in the study population. In those that did receive HIV testing, 5% of infants were HIV-positive. The 2007 PMTCT programme indicators are very erratic in influencing decisions and guiding programme implementation. However, the indicators are useful in complementing the current PMTCT guidelines and paving the way forward for strategic PMTCT programming.

Recommendations:

- Improve capacity of health care providers on monitoring the quality of maternity and DNA-PCR registers
- Standardize data collection and reporting tools
- Institutionalize the mother-infant pair follow-up system for all HIV-exposed infants
- Revise the PMTCT information flow chart to integrate and/or reflect linkages between antenatal care, maternity wards and paediatric clinics
- Train more health care providers to administer early infant diagnosis/DNA-PCR tests for improved mother-infant pair follow-up
- Revise and/or include other variables such as type of counselling to mothers during delivery, and follow up during the next maternity tool review

- Evaluate the national PMTCT programme in the country in order to have a comprehensive view of the programme implementation



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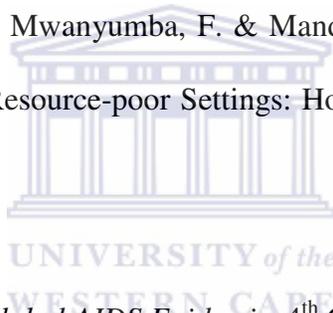
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ANNEXURES

Annexure 1. Data collection questionnaire.

Record no: _____

OPERATIONAL EFFECTIVENESS OF A SINGLE DOSE NEVIRAPINE PREVENTION OF PMTCT OF HIV & AIDS PROGRAMME

I am a registered student of the University of the Western Cape (UWC) for Masters degree in Public Health. As per study programme, I am conducting a research on the operational effectiveness of a single dose Nevirapine prevention of the PMTCT of HIV & AIDS programme. For ethical reasons there are no person's name mentioned and the responses collected from the registers will be kept confidential and only used for the purposes of this study. Permission was sought and granted from the Permanent Secretary of the Ministry of Health and in addition the researcher signed the confidentiality consent form.

Questionnaire Identification

Q101	Interviewer's Name		
Q102	Date	/____/____/____/ Day Month Year	
Q103	Facility Name	1. Referral Hospital 2. Intermediate Hospital 3. District Hospital	
Q104	Department	1. Antenatal(PMTCT) site	

		2. Maternity ward 3. Paediatric ward 4. Others (specify)	
Subject Information			
Maternal services			
I am going to be reviewing information on HIV positive mothers who benefited from the PMTCT programme at Antenatal care clinic and maternity ward.			
No.	Questions	Answers	SKIP
Q201	What is the Age of the Mother at delivery	1. Less than 19 Years 2. 19 – 24 years 3. 25 – 30 Years 4. 30 – 35 years 5. 36 and above	
Q2 02	Did the mother receive any counselling before delivery?	1. HIV/AIDS counselling 2. Feeding option counselling 3. Safe sex 4. Any other (please specify).....	
Q203	Did the mother receive a dose of Nevirapine during labour?	1. Yes 2. No	if No Skip to Q205
Q204	If yes, how many hours before delivery?	1. Less than 2 hours 2. 2- 4 hours	

		3. Greater than 4 hours	
Q205	If received Nevirapine during labour, what treatment regimen was used?	<ol style="list-style-type: none"> 1. Sd- NVP alone 2. Sd-NVP + AZT/3TC 3. Sd-NVP + AZT 4. Others (specify)..... 	
Q206	If no, why not?	<ol style="list-style-type: none"> 1. Head on perineum 2. Born Before Arrival (BBA) 3. Not recorded 4. Others (specify) 	
Q207	What type of delivery was it?	<ol style="list-style-type: none"> 1. Normal Vertex delivery (NVD) 2. Caesarean Section (SC) 3. Manual Vacuum Aspiration (MVA) 4. Other (specify)..... 	
Q208	Was there any maternal and neonatal complications?	<ol style="list-style-type: none"> 1. Yes 2. No 	
Q209	If yes what time of complication	<ol style="list-style-type: none"> 1. Premature labour 2. Prolonged labour 3. Foetal distress 	

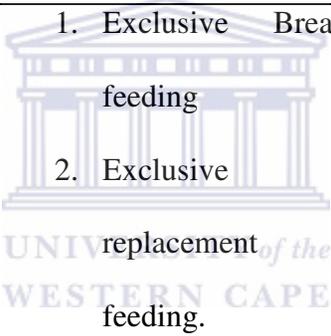
		4. Pre – eclampsia Other (specify).....	
Q210	Employment status of the mother	1. Employed 2. Unemployed 3. Other (specify).....	
Babies born to HIV positive mothers at PMTCT sites			
I am going to be collecting information on babies born to HIV positive mothers who benefited from the PMTCT of HIV prophylaxis at maternity and paediatric ART registers.			
Q301	What is the date of birth of the baby?	/ ____ / ____ / ____ / Day Month Year	
Q302	What is the weight at birth?	1. Less than 2.5 kg 2. 2.5 Kg- 3.5kg 3. 3.6 – 4.5kg 4. 4.6 kg and above	
Q303	What is the discharge weight?	1. Less than 2.5 kg 2. 2.5 Kg- 3.5kg 3. 3.6 – 4.5kg 4. 4.6 kg and above	
Q304	Sex	1. Male 2. Female	
Q305	What is the age at first	1. Less than six weeks	

	DBS/DNA-PCR testing?	<ol style="list-style-type: none"> 2. Six weeks 3. Six weeks and more 	
Q306	Type of counselling given at six weeks to the mother	<ol style="list-style-type: none"> 1. HIV/AIDS counselling 2. Feeding options 3. Others (specify)... 	



Information on single dose Nevirapine for PMTCT programme

Now I am going to collect information on the administration of a single dose Nevirapine and outcome to babies born from HIV positive mothers who received Nevirapine during labour.

No.	Questions	Answers	SKIP
Q401	Did this baby receive a dose of Nevirapine at birth or within 72 hours after birth?	<ol style="list-style-type: none"> 1. Yes 2. No 	
Q402	If yes, what feeding option did the baby receive?	 <ol style="list-style-type: none"> 1. Exclusive Breast feeding 2. Exclusive replacement of the Western Cape feeding. 3. Mixed feeding 4. Others (specify)..... 	
Q403	Was the baby tested for HIV/AIDS at six weeks?	<ol style="list-style-type: none"> 1. Yes 2. No 	If No Skip to Q405
Q404	What was the baby HIV status at six weeks test?	<ol style="list-style-type: none"> 1. Negative 2. Positive 3. Unknown 	

Q405	Why was the baby not tested at six weeks?	<ol style="list-style-type: none">1. Did not return for testing2. Returned after six weeks3. Others (specify).....	
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Annexure: 2 Additional self administered question on the PMTCT Cascade areas

To whom it may concern:

As you are aware that I am busy with study research on the operational effectiveness of a single dose NVP for PMTCT programme in Khomas region of Namibia; kindly provide me with the information in the table below for use in my mini-thesis study report. The information collected will be kept confidential and only used for the study purposes.

Kind regards, Gloria M. Siseho – UWC student.



PMTCT cascade	Khomas	National
	region	
	2007/08	2007/08
Women attending Antenatal Care		
Received Pretest counselling		
Accepting testing		
HIV infected		
Returning for results		
Women receiving Nevirapine (ARV prophylaxis)		
Safe Infant feeding practices established before discharge		

Testing of women with unknown HIV status in Labour		
Dual protection started for infants		
CD4 test		
CD4 >250		
CD4 <250		
Counselling on infant feeding options		
AFASS assessed among breastfeeding mothers at 5months		
Training in PMTCT for HWs		
Training in DNA-PCR test - HWs		
PCR repeated as per protocol		
Continued care for positive mothers and care for positive infants		

