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The follow-up of babies in the PMTCT programme in the West Rand

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CHAPTER ONE

INTRODUCTION

1.1 Background

South Africa has experienced one of the fastest growing HIV/AIDS epidemics in the world. The Third National HIV survey 2008 estimated that the HIV prevalence among South Africans of all age groups is 10.6%, with 5.2 million people estimated to be living with HIV. A decline in new infections has been noted among teenagers aged 15-19 and HIV prevalence has declined among children aged 2-14, from 5.6% in 2002 to 2.5% in 2008.[1] The change in HIV prevalence in children is most likely attributable to the successful implementation of interventions related to addressing HIV in early childhood, particularly the prevention of transmission of HIV to children, such as the prevention of mother-to-child transmission (PMTCT) programme.[1] As studies have shown, the provision of antiretroviral chemoprophylaxis and replacement feeding can cause a dramatic reduction in the risk of HIV transmission from mother to infant.[2]

In 2000, a programme offering a single dose of nevirapine (NVP) as antiretroviral chemoprophylaxis to HIV-positive pregnant women was introduced in South Africa, with two pilot PMTCT sites in each of the nine provinces. The NVP-based PMTCT protocol consisted of a single dose of 200 mg of NVP to the mother at the onset of labour, and a weight-adjusted dose to the infant within 72 hours of delivery, provision of free milk formula for the first six months of life in line with WHO recommendations, and follow-up for infants on cotrimoxazole prophylaxis from six

weeks of age to 12 months of age when their HIV infection status was determined using an HIV ELISA test.[3]

In May 2005, HIV polymerase chain reaction (PCR) testing at six weeks of life was introduced to test for HIV in infants to replace ELISA testing at 15 months. HIV PCR was offered to HIV-exposed babies in the PMTCT programme in order to reduce the duration that these infants would have to be on cotrimoxazole prophylaxis before their HIV status could be determined. HIV PCR tests have a high sensitivity, which allows for early detection of HIV infection in infants.[4,5] In 2008, the PMTCT policy changed yet again. Dual therapy was introduced to replace single dose NVP, and HIV PCR testing continued to be done at six weeks of age on infants irrespective of feeding option.[6] Dual therapy comprised a single dose of NVP and zidovudine (AZT) for seven days in infants whose mothers had started taking AZT for prophylaxis at 28 weeks gestational age, and had received single dose NVP during labour or AZT for 28 days in infants for the following indications:

- Mother received less than four weeks of AZT during pregnancy,
- Mother received less than four weeks of HAART during pregnancy,
- Mother received only single dose NVP,
- Mother did not receive any ARVs during pregnancy.

Further changes were made to the PMTCT policy in 2009. The new guidelines state that where mothers are receiving HAART for their own health, infants should receive NVP for six weeks after birth if the mother is breast feeding, and prophylaxis with either NVP or AZT for six weeks if the mother is not breastfeeding. Infant prophylaxis with NVP or AZT should be continued until the end of the breastfeeding period or for six weeks after birth in non-breastfeeding infants. Breastfeeding is to

continue until the infant is twelve months old in HIV-exposed but uninfected infants, and those of unknown HIV status, as long as the HIV-positive mother or baby is taking antiretrovirals during this time.[7,8]The revised policy further required that HIV-positive infants should be started on antiretroviral treatment as early as possible after the diagnosis has been made.[9]

This study was conducted in 2005, prior to the above changes to the PMTCT policy. The study was conducted in the West Rand district of Gauteng Province at Leratong hospital and two Midwife Obstetric Units (MOUs) that are located geographically close to the hospital. At the time of this study, Leratong hospital and the Midwife Obstetric Units all offered PMTCT services, using the PCR test protocol. In accordance with the national PMTCT protocol at the time, babies born to HIV-positive mothers in the PMTCT programme were given a NVP dose within 72 hours of delivery at the MOU or the hospital and then referred to PMTCT follow-up services located at Primary Health Care (PHC) centres, for PMTCT follow-up and PCR testing at six weeks.

Babies who tested HIV PCR-negative at six weeks, and were not breastfeeding, were discharged from PMTCT follow-up. Babies who tested HIV PCR-positive at six weeks were given cotrimoxazole prophylaxis from six weeks of age and were followed up monthly at PMTCT follow-up services. Babies whose mothers chose to breastfeed were not tested for HIV infection at six weeks and instead had the HIV PCR test six weeks after the cessation of breastfeeding if breastfeeding was stopped before 12 months. These babies were given cotrimoxazole prophylaxis until their HIV status was confirmed. Babies who tested HIV PCR-negative six weeks after the

cessation of breastfeeding were discharged from PMTCT follow-up. Babies who tested HIV PCR-positive continued taking cotrimoxazole prophylaxis and were followed up at PMTCT follow-up services. If breastfeeding continued to 12 months a rapid HIV ELISA test was done three months after the cessation of breastfeeding. If the rapid HIV result at this stage was negative and the baby had stopped breastfeeding, cotrimoxazole prophylaxis was stopped and the baby was discharged from PMTCT follow-up. If the rapid HIV test was positive, a repeat test was done three months later to confirm the infant's HIV status.

HIV-positive babies who became symptomatic of HIV disease at any stage during the follow-up period had clinical staging done to assess the severity of their disease, as well as an assessment of their CD4 count. Symptomatic HIV-positive babies were referred to ARV sites. Asymptomatic HIV-positive babies had their CD4 count assessed at six-month intervals and were referred to ARV sites when their CD4 counts fell to the threshold levels of <25% of their total lymphocyte count (TLC), or an absolute CD4 count of <1 500 cells/mm3 for children aged ≤11 months, and %CD4 level of <20% of TLC or an absolute CD4 count of <750 cells/mm3 for children aged 12−35 months, which was the prescribed level for starting ARV therapy in infants according to the South African National Antiretroviral Treatment Guidelines.[10,11]

1.2 Problem statement

Despite the availability of PMTCT services at MOUs, local clinics and hospitals, and the availability of ARV services at the antenatal and local clinics, the morbidity and mortality in children exposed to HIV in South Africa remains high.[3] Routine PMTCT

programmes have been shown to be highly effective in reducing the MTCT rate of HIV but generally fail in follow-up of HIV-positive children.[3,12,13]A study in Johannesburg found that 'more than one-third of infants never return for follow-up and more than 70% are lost to follow-up by four months of age.'[3]

Loss to follow-up in the PMTCT programme translates into failure in primary prevention of new infections in HIV-exposed infants, failure to identify HIV disease early in children, and a missed opportunity to reduce morbidity and mortality by placing children on antiretroviral treatment early. The opportunity to counsel, educate, medically manage and support HIV-affected families is lost, as is the ability to monitor PMTCT programmes.[3]It is this problem that prompted this study to assess the follow up of HIV-exposed babies in the PMTCT programmes in the West Rand.

1.3 Justification for the study

A pooled analysis of studies in Africa shows that an estimated 35.2% of children infected with HIV die by the age of one year. The mortality is significantly higher in children with early infection than in children who are infected at a later stage.[14] Child mortality could be averted by the early introduction of ARVs to HIV-positive children, which depends on early detection of HIV infection through successful PMTCT programmes. While the efficacy of PMTCT regimens in reducing MTCT has been established, at the time of this study it was not known what happened to many babies born of HIV-positive mothers who enrolled in the PMTCT programme in the West Rand. This research project provides data to document the extent to which babies in the West Rand were followed up for the first 12 months, and the extent of

loss to follow-up. These data were needed to give an indication of how successful the PMTCT programme was at identifying HIV-exposed babies who needed ART and referring them for treatment when needed. This study pre-dates recent changes in HIV/AIDS policy regarding ART in children - that all infants should be tested for HIV infection using the PCR test at six weeks, regardless of feeding choice, and that all HIV-positive babies should be started on ARVs as soon as possible after diagnosis irrespective of CD4 count or clinical staging. The results of this study could therefore provide a reflection of the PMTCT follow-up of children in the West Rand prior to the new paediatric ART policy and highlight some of the challenges that need to be addressed in order to ensure early HIV PCR testing of babies, early initiation of ART where indicated and improved retention of babies in the PMTCT programme.

1.4 Literature review

Mother-to-child transmission of HIV is the most significant route for acquiring HIV infection in children.[12] HIV is transmitted from mother to child in three distinct ways: during pregnancy, childbirth or during breastfeeding. Without intervention, about 35% of infants born to HIV-positive mothers will acquire the virus during pregnancy, labour, delivery, or breastfeeding.[15]An estimated 15-30% of MTCT of HIV will occur during pregnancy and delivery, and 10-20% through breast milk.[16]

In 2008, around 430 000 children under 15 years of age became infected with HIV, mainly through mother-to-child transmission. About 90% of these MTCT infections occurred in Africa where AIDS is beginning to reverse decades of steady progress in child survival.[17]Mother-to-child transmission of HIV is a major problem particularly

in developing countries where PMTCT programmes have traditionally been non-existent or had low coverage.

Core MTCT programmes involve various steps in the provision of the service, often referred to as a cascade.[18,19] 'The steps include 1) utilization of antenatal care; 2) receiving pre-test counselling; 3) acceptance of HIV test; and 4) receiving HIV test result and post-test counselling. For seropositive mothers the cascade continues with 5) use of ARV prophylaxis for mother and/or baby; 6) use of labour and delivery services which include specific PMTCT interventions during these periods; and 7) postnatal follow-up of the mother and baby with HIV testing of the exposed infant/child and linkage to care and support'. Attrition increases with each successive step as the term 'cascade' suggests. Attrition may occur as a result of poor understanding on the part of the patients, patient denial, fear of stigma, economic, educational, political, social, cultural, and/or health system factors.[18,19] Studies have shown attrition from PMTCT follow-up programmes to range from '70% at four months postpartum and close to 81% at six months after birth'.[3,20,21]

In Europe and the United States, PMTCT transmission rates are below 2% and paediatric AIDS has been almost completely eradicated due to administration of HAART to pregnant women and wide PMTCT service coverage, highly effective PMTCT regimen and systematic targeting of risk factors for attrition along each step of the PMTCT cascade.[21,22]

The efficacy of PMTCT regimens has been established in clinical trials.[3,13,23,24] The simplest of all PMTCT drug regimens was tested in the HIVNET 012 trial, which

took place in Uganda between 1997 and 1999. This study found that a single dose of NVP administered to women during labour and to their infants after delivery reduces MTCT of HIV type 1 by 47%,[24] and reduces HIV transmission rates to 12% at six weeks post-delivery.[13]Further research shows that use of dual therapy with NVP and AZT reduces HIV transmission rates to 2% at six weeks post-delivery, which renders this regimen more efficacious for reducing MTCT than use of single-dose NVP.[25,26,27]

The revised PMTCT guidelines in South Africa propose a dual therapy regimen which includes starting ARV prophylaxis in the third trimester (28 weeks) of pregnancy. The policy recommends a basic regimen of daily zidovudine (AZT) from 28 weeks gestational age and single-dose nevirapine at the onset of labour to the mother, as well as infant ART prophylaxis for one week after birth.[7,8] Because of concerns about drug resistance and relatively low effectiveness, there is now general agreement that single dose nevirapine alone should be used only when no alternative PMTCT drug regimen is available. Whenever possible, women should receive a combination of drugs to prevent HIV resistance problems and to decrease MTCT rates even further.[11,27]

Research-based evidence also shows that starting anti-retroviral therapy earlier in children improves health outcomes. Results from the Children with HIV Early Antiretroviral Therapy (CHER) Study found that starting ARVs in infants before 12 weeks of age, rather than treating only when their CD4 count dropped to below 25%, reduced early mortality by 75%.[28] These findings had implications on initiation of ARVs in early infancy. Prior to recent changes in the policy on initiation of ART in children in South Africa ARV therapy was initiated only when the CD4 level dropped to below 25% of the child's total lymphocyte count. In light of the evidence, it was

thus appropriate when National policy changed in 2009 to initiate babies on ART as soon as their HIV-positive status is confirmed at six weeks.[7,29]

However, without proper follow-up after birth, HIV-positive babies who need ART will be missed and the benefits of early initiation of ARVs will not be realised. Worldwide, high attrition rates preclude PMTCT programs from identifying and managing HIV-positive children early.[30] A study was done in Rwanda and Mozambique which involved outcome tracking at four sites using infant records from PMTCT follow-up. In a sample of 40 infant records reviewed, 40/40 (100%) mother-infant pairs were successfully linked using maternal ANC or HIV Care identification as documented in the infant record. In this sample, 90% (36/40) of infants were tested using DNA PCR, but only 69% (25/36) had documented eight-week infant outcomes.[31] South African studies done on PMTCT follow-up in infants have demonstrated that a large number of infants are lost to follow-up within the first four months of joining the programme.[3,12] Similar studies done in sub-Saharan Africa have shown cumulative losses in PMTCT follow-up programmes to range from '70% at four months postpartum and close to 81% at six months after birth'.[3,20,21]

Significant obstacles to improving paediatric HIV care include limited screening of infants for HIV infection at six weeks, a lack of affordable, simple diagnostic testing technologies for infants, a lack of human resources with the capacity to provide the care that is required, insufficient advocacy and understanding that ART is efficacious in children, limited experience with simplified, standardized treatment guidelines, and limited availability of affordable and practical paediatric ARV formulations.[32]

In summary, the literature reveals that though prevention of mother-to-child transmission of HIV programmes are highly effective in reducing the MTCT rate of HIV, they generally fail in follow-up of HIV-exposed children[3]. Loss to follow-up in the PMTCT programme translates into failure in primary prevention of new infections in HIV-exposed infants, failure to identify HIV disease early in children, and a missed opportunity for early referral of HIV-positive children to ARV sites.[30] Independent studies done in Johannesburg, South Africa, and other developing countries (Zambia, Zimbabwe, Kenya and Abidjan), have each shown high attrition rates of babies from PMTCT follow-up programmes,[3,18,20,21,22,30] with up to 70% of babies being lost to follow-up at four months of age and close to 81% at six months after birth.[3,21] Attrition from PMTCT follow-up programmes in developing countries is substantially higher than that observed in developed countries.

1.5 Aim and objectives of the study

Aim of the study

The purpose of this study is to describe the referral and follow-up of babies born to HIV-positive women during July to December 2005 in the PMTCT programme in the West Rand district of Gauteng.

Objectives

This study refers to babies born to HIV-positive mothers (who took Nevirapine for PMTCT) at Leratong hospital and its two referring MOUs during the period July 2005 to December 2005. The specific objectives were to:

- Describe the proportion of babies that received nevirapine within 72 hours after delivery.

- Describe the proportion of babies that were successfully referred to PMTCT follow-up services.
- Establish the percentage of successfully referred babies that had a HIV PCR test done at six weeks to confirm HIV status.
- Compare the proportion of babies that received the HIV PCR test at six weeks of age with the proportion of babies that received the HIV PCR test after six weeks of age.
- Describe the proportion of babies who tested HIV PCR-positive that was successfully referred to ARV clinics.
- Quantify the loss to follow-up of HIV-exposed babies in the first 12 months of life.

Definition of terms

Women in the PMTCT programme. This refers to HIV-positive pregnant women who were given NVP during labour.

Enrolment. This refers to a baby attending the PMTCT follow-up facility to which s/he was referred after taking NVP at birth. This was measured by finding the baby's name on the receiving clinics' attendance register.

PMTCT follow-up services. This refers to Mohlakeng and Bekkersdal MOUs, the POPD at Leratong hospital, and the Dietetics department at Leratong hospital, which were the recognised PMTCT follow-up sites in the West Rand during the period under study.

Successful referral to PMTCT follow-up services. This is referral of babies to child health services at Mohlakeng and Bekkersdal MOUs, POPD at Leratong hospital, or the Dietetics department at Leratong hospital within two months of birth, to coincide with the babies' first scheduled clinic immunization date, with a time allowance of two weeks for late clinic attendance. Success was determined by finding the baby's name on the receiving clinic's attendance register.

Successful referral to ARV clinics. This is referral of babies to a site within a health facility specifically designated for the provision of antiretroviral treatment services. Success was determined by finding the baby's name on the ARV clinic's enrolment register.

Successful follow-up. This is monthly follow-up visits to PMTCT services for primary prophylaxis with cotrimoxazole for the prevention of infection with PCP until the age of twelve months or until the baby tests HIV PCR-negative in accordance with the DOH South African IMCI clinical case management guidelines for infants of HIV-positive women.

ARV clinics. This refers to a site within a health facility specifically designated for the provision of antiretroviral treatment services.

CHAPTER TWO

METHODOLOGY

In this chapter the study design and setting are described. The selection of the study population, as well as inclusion and exclusion criteria, is explained and methods used to collect and ensure reliable data while maintaining patient confidentiality are also discussed. The chapter ends with a detailed description of how the data were processed and analysed.

2.1 Study design

This was a descriptive cross-sectional study involving a retrospective review of records for a cohort of babies born to HIV-positive mothers in the PMTCT programme in the West Rand during the period July 2005 to December 2005. The research utilized data obtained from patient records at Leratong hospital and two midwife obstetric units (MOUs) that refer patients to Leratong hospital. This six-month cohort was chosen because the study involved retrospective review of PMTCT follow-up data for 12 months from the date of birth. The last qualifying month of birth for inclusion in the study was December 2005 because routine HIV PCR testing of babies in the PMTCT programme in the West Rand was only introduced in May 2005, and so the six-month period preceding December 2005 allowed for 12 months of follow-up data (up to December 2006) to be available for the record review which commenced in 2007.

2.2 Study setting

Leratong hospital is a Regional (level 2) hospital that provides care requiring the intervention of specialists and general practitioners[33] in the West Rand district of Gauteng. It serves a population of 963 857 (STATS SA, 2009) with an uninsured population of 790 362 (DOH, 2009). There are 2 MOUs in the West Rand that refer complicated pregnancies and deliveries to Leratong hospital for advanced care. At the time of this study, all women attending antenatal clinic services at the MOUs in the West Rand were offered voluntary counselling and testing for HIV infection. If these women tested HIV-positive they were offered the opportunity to enrol in the PMTCT programme. Women who developed complications during pregnancy or labour were referred to Leratong hospital for continued follow-up where VCT was done for those who may have missed the opportunity at the MOU.

Babies born to HIV-positive mothers in the PMTCT programme at the hospital and the MOUs were given a follow-up date on discharge to register with PMTCT follow-up services within two weeks following the birth of the baby. Babies who tested HIV PCR-positive at six weeks, or subsequently, were followed up monthly by PMTCT follow-up services. During follow-up visits they received cotrimoxazole prophylaxis with six-monthly CD4 counts and clinical staging until such a time that the child qualified for referral to the ARV site, which, at the time of the study, was only available at Leratong Hospital (personal communication with West Rand region office). Children who developed AIDS-related illnesses at any time during follow-up were referred to Leratong hospital.

2.3 Study population and sampling

Leratong hospital and the only two MOUs within one sub-district of the West Rand were purposively included as the sites for this study. The two MOUs in the sub-district geographically closest to Leratong hospital were selected as they served the catchment population of the hospital and babies born at these MOUs were most likely to be referred to Leratong hospital in the event of their becoming ill.

The study population was all live babies born at Leratong or the two MOUs to known HIV-positive women who took NVP in labour (according to the existing PMTCT protocol at the time) during 1 July to 31 December 2005. The NVP records and PMTCT records of these babies were the data source. In order to identify and access the babies' records, the PMTCT records of their HIV-positive mothers were consecutively identified and included in the study. No sampling was done. Babies who were born before arrival at the hospital or the MOU, were included in the study provided the mother was enrolled in the PMTCT programme during pregnancy and took NVP during labour. HIV-positive women who were admitted in advanced labour and had not been given NVP during labour were excluded from the study. The ultimate study population comprised 887 babies (baby records) that met the inclusion criteria for the study.

2.4 Measurement

Two data collection sheets were developed to extract data from the maternal and baby PMTCT registers at Leratong hospital and the two MOUs.

2.4.1 Variables

Appendix A was designed to collect the following variables from the mothers and babies' PMTCT records at the labour wards at Leratong hospital and the two MOUs, and from the babies' PMTCT records at PMTCT follow-up sites:

- Number of HIV-positive mothers in the PMTCT programme who delivered during the period 1 July to 31 December 2005.
- Number of babies born to these HIV-positive mothers.
- Date of birth of baby.
- Place of delivery.
- Whether baby received NVP within 72 hours after birth.
- Whether the baby was referred to a PMTCT follow-up site.
- Referral – date of referral to PMTCT follow up site, and PMTCT follow up site referred to.
- Whether HIV PCR testing was done at six weeks at the PMTCT site the baby was referred to.
- Whether HIV testing was done at any subsequent period for those babies who were not tested at six weeks, or where further HIV testing was indicated.
- HIV PCR test result, whether positive, negative or unknown (baby did not return).
- Whether intervention with cotrimoxazole was implemented for babies who tested HIV PCR-positive.
- The date of the first and subsequent PMTCT follow-up visits for all babies in the PMTCT programme.
- The date of subsequent PMTCT follow-up visits for HIV-positive babies.

- Whether the baby was referred to an ARV site based on eligibility for referral.
- Date of referral to ARV site.

Appendix B was designed to ensure the confidentiality of the study participants. The following variables were collected from the mothers and babies' PMTCT records at the labour wards at Leratong hospital and the two MOUs:

- Mother's name and file number.
- Date of delivery.
- Facility mother delivered at.
- Baby's name and file number.

From these variables, a code was assigned to the mother and to the baby for purposes of subsequent identification. Codes were used to ensure confidentiality.

2.4.2 Data collection

Data on all HIV-positive women in the PMTCT programme who delivered at either of the three facilities during July to December 2005 were collected from the PMTCT registers at the labour wards at Leratong hospital and the MOUs. Data on babies born to HIV-positive women in the PMTCT programme were obtained from the NVP registers at the postnatal ward at the hospital and the MOUs. This data provided information on the number of babies born to the HIV-positive women in the PMTCT programme, the date of birth of the baby, place of delivery, and whether baby received NVP within 72 hours after birth. Mothers and babies' records were matched by verifying that the names, facility file numbers, and dates of birth of the babies in

the NVP registers at the postnatal ward corresponded with the mother's details in the labour ward PMTCT register.

Data on infants born at the hospital, who were successfully referred to PMTCT follow-up services, were obtained from PMTCT follow-up services from the dieticians' PMTCT follow-up register. The dieticians' PMTCT follow-up register was used at each visit to document each infant's weight gain and method of feeding for the purpose of supplying nutritional supplements and government subsidized milk formula if required. The register documented information on infants' HIV PCR test date, and result of the HIV PCR test, and also documented whether or not the infant was referred to an ARV site. This register provided the most reliable record of PMTCT follow-up. Data on infants born at the MOUs were obtained from the respective clinic's PMTCT register. The mothers name and hospital file number was included on the PMTCT file of all babies enrolled for PMTCT follow up at each of the three facilities. Babies' information on the PMTCT file was matched to data in the NVP registers in the respective postnatal wards using the confidential data sheet (Appendix B) to verify the babies and mothers identification. Information on babies who died in the study was obtained from the dietician's PMTCT follow up records at the hospital and from the PMTCT follow up records at the two MOUs.

Each subsequent visit to PMTCT follow-up services by an enrolled baby was documented in the babies' PMTCT follow-up file to the age of 12 months. This data included information on the age of the baby at each follow up visit, the mothers feeding choice, whether cotrimoxazole prophylaxis was issued, and whether the baby was tested for HIV infection using the HIV PCR test. For babies who tested HIV

PCR-positive data further included the clinical staging of the baby and the CD4 level at six- month intervals or when indicated. The data also reflected whether the baby was referred to an ARV site if indicated by clinical staging or CD4 level.

Babies who died before being discharged from the hospital or the MOU were excluded from the study. Babies whose hospital or clinic records could not be conclusively matched to their mothers' records were excluded from the analysis, as there was no confirmation that the women were from the West Rand catchment area. Babies whose mothers did not participate in PMTCT by taking NVP in labour were excluded from the analysis, as they did not meet the criteria for inclusion in the study.

A total of 898 mother-infant pairs were identified for inclusion in the study. Eleven babies whose mothers' names appeared in the PMTCT register in the labour ward could not be traced in the neonatal NVP register. These babies were presumed to have died before discharge from the hospital and were therefore not included for analysis. Twins were recognised as individual enrolments. The study participants therefore comprised 887 babies.

2.5 Data processing and analysis

All data collected were coded and entered into a computer database. STATA software was used to analyse data. Proportions were used to summarise categorical data for the following measures of interest.

- The proportion of babies born to mothers in the PMTCT programme who received NVP.

- The proportion of babies referred to PMTCT follow-up services within two months of birth.
- The proportion of babies tested for HIV infection with the HIV PCR test.
- The proportion of babies testing HIV-positive in the PMTCT programme.
- The proportion of HIV-positive babies successfully followed up to 12 months by PMTCT follow-up services.
- The proportion of HIV-positive babies referred to ARV sites.
- The proportion of HIV-positive babies who did not comply with the follow-up visits.

Statistical comparisons were made between the number of babies who had the HIV PCR test before six weeks and the number of babies that had the HIV PCR test after six weeks, and between the number of babies who were referred for ART initiation and the number of babies that were not referred for ART initiation. The Chi square test was used to measure statistical differences between the groups and *p*- values were generated. A survival analysis was done to determine the probability of babies remaining in the PMTCT follow up programme. Data was presented as aggregated for the two MOUs and Leratong hospital.

2.6 Ethics

Permission to review clinical records was obtained from the Gauteng Department of Health. The study was commenced after ethical clearance was obtained from the University of the Witwatersrand Committee for Research on Human Subjects (Medical). Ethics number M070336 (Appendix C).

Confidentiality was ensured by coding each mother and baby pair whose records were used for the study. The data extraction form (Appendix A) did not include the name or other identifier of the mother or the facility at which she delivered. For the purpose of positively identifying mother-infant pairs, in order to follow-up on babies in the PMTCT programme, a separate confidential data sheet was kept by the researcher (Appendix B). This data sheet was kept in a locked drawer to which only the researcher had access and was destroyed at the completion of the data collection period.

CHAPTER THREE

RESULTS

In this Chapter the results of the study are presented as aggregated for the two MOUs and Leratong hospital. The results are presented as per objectives. Tables and graphs are used to present the data.

All pregnant women who were tested for HIV infection at the MOUs and at the hospital and found to be HIV-positive agreed to enrol in the PMTCT programme and took NVP in early labour according to the PMTCT protocol. Babies born to women in the PMTCT programme were all given NVP within 72 hours following their birth in accordance with the PMTCT protocol with the exception of eleven babies whose mothers' names appeared in the PMTCT register in the labour ward, but who were not documented to have been given NVP in the neonatal NVP register. These babies were presumed to have died before discharge from hospital. This chapter presents data on babies who had records to indicate that they took NVP within 72 hours after birth.

3.1 Description of study participants

The study comprised 887 HIV-exposed babies who had all received NVP within 72 hours of birth. Seven hundred and thirty-seven of these babies (83.1%) were enrolled at the Hospital, 109 babies (12.3%) at MOU 1 and 41 babies (4.6%) at MOU 2. There were 18 sets of twins in the enrolled group.

During the course of the study, five babies are known to have died during the follow-up period. Of these, one infant was HIV PCR-positive and died at seven weeks of life from PCP; one was HIV PCR-negative and died at five months of life from gastroenteritis. Three babies' HIV status was not known at the time of death. Of these three babies, two were one of a set of twins from different mothers. They died at one month and 11 weeks of life respectively. The fifth baby died at 10 weeks of life from gastroenteritis.

Twenty-nine enrolled babies were subsequently referred to other clinics outside the West Rand for continued PMTCT follow-up. These babies were considered to have exited the study. A summary description of the study participants and their outcome is shown in Figure 3.1.1. The rest of this chapter presents these findings in more detail. The total person-time of observation for the study was 4616 weeks with a median time of observation of 21.3 weeks.

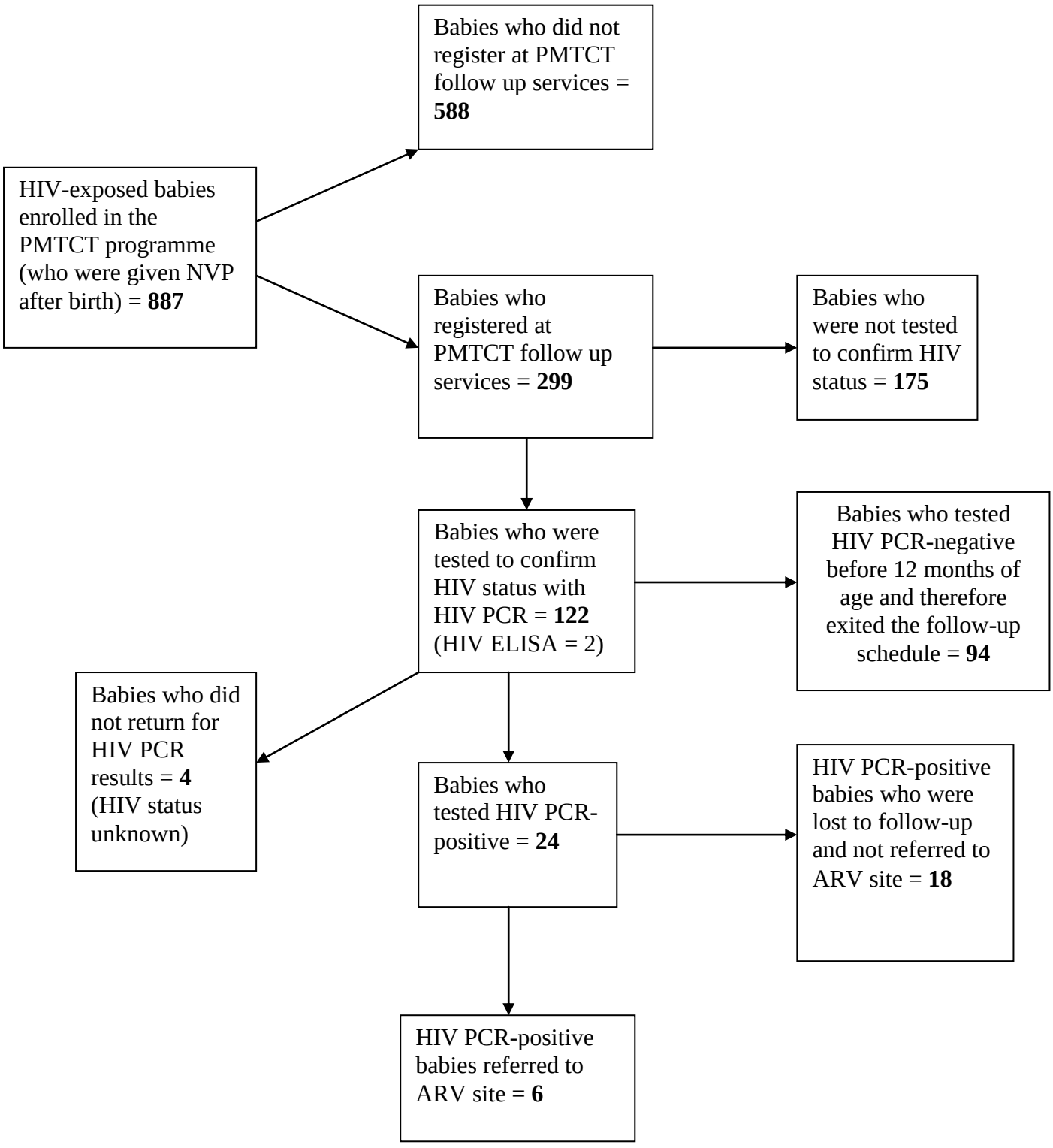


Figure 3.1.1: Flow diagram to describe flow of study participants in the PMTCT follow-up schedule

3.2 Registration at PMTCT follow-up services

Eight hundred and eighty-seven babies born to HIV-positive women were included in the study. All these babies in the PMTCT programme were referred for registration at PMTCT follow-up services on discharge from labour ward. The number of babies who registered is shown in table 3.2.1:

Table 3.2.1: Registration of babies at PMTCT follow-up services

Babies registered at PMTCT follow-up services	**Number**	**Percentage**
Yes	299	33.7
No	588	66.3
Total	**887**	**100**

Almost two-thirds of babies born to mothers in the PMTCT programme did not register at PMTCT follow-up services.

3.3 HIV-PCR testing

One hundred and twenty-two babies of the 299 who registered at PMTCT follow up sites were tested with the HIV PCR test to confirm HIV status (Table 3.3.1).

Table 3.3.1: Testing of babies to confirm HIV status

Test done for HIV infection	Number	Percent
HIV PCR	122	40.8
Not tested	175	58.5
HIV ELISA	2	0.7
Total	**299**	**100**

The age at which the HIV PCR test was done ranged from four weeks to 51 weeks with a median age of 16 weeks and mean age of 16.7 weeks (std dev = 9.23). Two babies (1.6%) were tested before six weeks; 46 (37.7%) between six and 10 weeks; 23 (18.9%) between 11 and 19 weeks; 41 (33.6%) between 20 and 25 weeks, and ten (8.2%) babies were tested over the age of 26 weeks. Two enrolled babies were tested for HIV infection using the ELISA method at 18 months of age. These two tests were not included in any further analysis as they fall outside the objectives of this study.

Table 3.3.2 reflects the HIV-exposed infants tested with a PCR test for HIV infection at or before six weeks of age versus those tested after six weeks of age.

Table 3.3.2: HIV PCR testing at six weeks of age

Age at which babies tested with HIV PCR	Number	Percent
At or before six weeks of age	19	15.6
After six weeks of age	103	84.4
Total	**122**	**100**

This difference was statistically significant. [Chi2 = 226; $p < 0.0001$]. Many more babies were tested after the age of six weeks than before six weeks, which was the prescribed age for HIV PCR testing according to the PMTCT protocol.

HIV PCR testing coverage at six weeks is indicated by the proportion of HIV-exposed infants who were PCR tested at six weeks as a fraction of the total number of HIV-exposed babies presenting at the six week PMTCT follow up visit. Table 3.3.3 reflects HIV PCR testing coverage at the six-week PMTCT follow up visit.

Table 3.3.3: HIV PCR testing coverage at the six-week PMTCT follow up visit

Number of babies tested with HIV PCR at or before six week visit	19
Number of babies who attended the six-week follow-up visit.	226
HIV-PCR testing coverage at six weeks.	**8.4%**

Timing of HIV PCR test by infant feeding practices

Mothers made voluntary infant feeding choices based on health education given at the antenatal clinics. They either chose to breastfeed exclusively for three months or to formula feed their babies. The chosen method of feeding was significant in that it determined the timing of the HIV PCR test. That is, babies of HIV-positive mothers who chose to exclusively breastfeed up to three months were HIV PCR tested only six weeks after cessation of exclusive breastfeeding.

The age at which HIV PCR testing was done in relation to infant feeding choice is presented in Table 3.3.4.

Table 3.3.4: Age at which HIV PCR test was done by infant feeding method

	Age in weeks at which infants were tested for HIV infection using the PCR method						
	≤6	**7-10**	**11-15**	**16-20**	**21-24**	**>24**	**Total**
Breastfed	6	3	5	6	26	10	**56**
Formula fed	13	26	8	6	8	3	**64**
Unknown method of feeding	0	0	0	0	0	2	**2**
Total	**19**	**29**	**13**	**12**	**34**	**15**	**122**

The data in Table 3.3.4 show that even amongst formula-fed children, the majority (79.7%) had HIV PCR test done only after six weeks of age.

Results of HIV PCR test

The HIV test results of the 122 babies tested are shown in Table 3.3.5. Around three-quarters of all babies tested HIV PCR-negative.

Table 3.3.5: HIV PCR test results of babies tested for HIV infection

HIV PCR result	Number	Percentage
Positive	24	19.7
Negative	94	77.0
Not known	4	3.3

3.4 PMTCT follow-up visits

Data on follow-up visits for the 299 babies who registered at PMTCT follow-up services were extracted for a period of 12 months from the date of birth in order to assess compliance with monthly visits for clinical monitoring and cotrimoxazole prophylaxis. Babies who tested HIV PCR-negative during follow-up and were thus required to stop attending PMTCT follow-up visits, and babies who were referred to ARV sites were considered to have exited the follow-up schedule. The attendance of babies at PMTCT follow-up visits in their first year of life is reflected in table 3.4.1.

A steady decrease in the number of babies attending PMTCT follow-up visits was noted over the duration of the follow-up period. There was a corresponding loss to follow up as the attendance declined.

Table 3.4.1: Attendance of babies at PMTCT follow-up visits (N=299)

	No. lost by this follow-up visit	**No. attended this follow-up visit**	**No. exited (HIV-ve or referred to other facility)**	**No. referred to ARV site**
Visit 1	73	226	0	0
Visit 2	37	189	0	0
Visit 3	23	155	11	0
Visit 4	20	119	16	0
Visit 5	12	88	18	1
Visit 6	27	55	6	0
Visit 7	1	23	30	1
Visit 8	4	9	9	1
Visit 9	0	7	0	2
Visit 10	0	5	2	0
Visit 11	0	4	0	1
Visit 12	2	1	1	0
Total	**179**		**93**	**6**

The attendance of babies at PMTCT follow up visits was such that babies who did not attend a particular follow up visit tended not to attend any subsequent follow up visits (this was seen at each of the three facilities); i.e. non-attendance at any particular stage of the PMTCT follow-up reflected a true loss to follow up. A high number of babies exited the study at the seventh visit. The seventh visit coincided with HIV PCR testing in babies who had exclusive breastfeeding – there was a distinct peak at the seventh follow-up visit when a large proportion of babies who tested HIV PCR-negative exited the follow-up schedule.

As shown in Figure 3.4.1, the number of babies who actually attended each follow up visit as a proportion of babies who should have attended (compliance) declined markedly over the 12 month period of follow-up. When calculations were done to assess loss to follow up in the PMTCT programme, babies who exited the follow-up schedule (for testing HIV-negative or being referred to another facility) and babies who were referred to an ARV site were excluded from the denominator as they were no longer expected to attend PMTCT follow-up services. The compliance with PMTCT follow-up visits is presented in Figure 3.4.1.

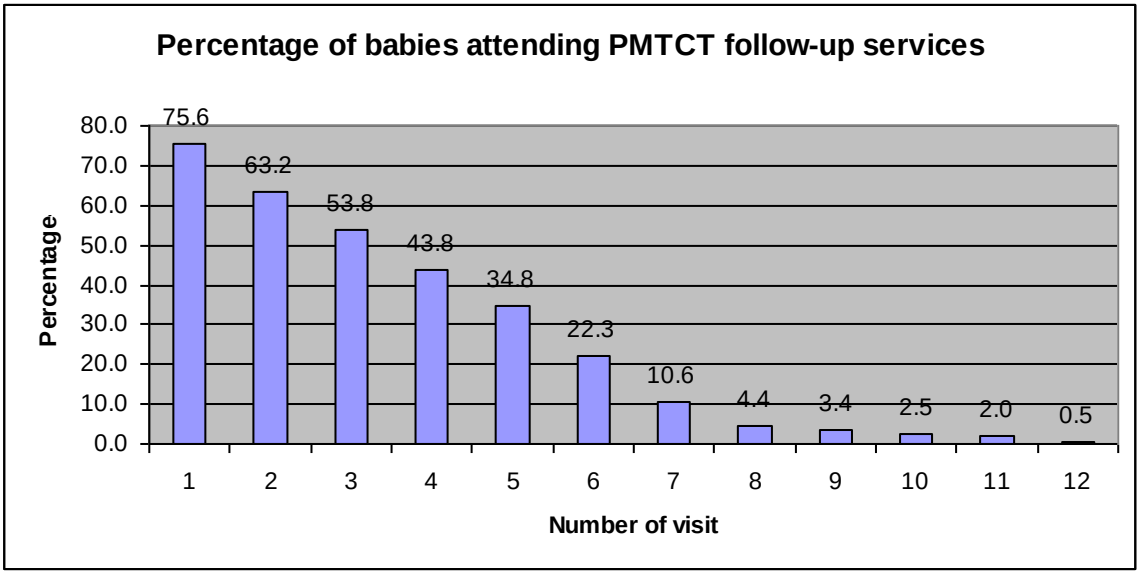


Figure 3.4.1: Compliance of babies with PMTCT follow-up visits

Referral to ARV site

Of the 24 babies found to be HIV PCR-positive at any point in the follow-up period, 18 were lost to follow-up at various stages of the PMTCT follow-up schedule and only six (25%) of these babies were successfully referred to the ARV site.

Table 3.4.2: Referral of HIV PCR-positive babies to ARV site

HIV PCR-positive babies referred to ARV site	**Number**	**Percentage**
Yes	6	25
No	18	75
Total	**24**	**100**

Of the six babies who were referred to ARV sites, one was referred at the fifth follow up visit, one at the seventh, one at the eighth, two at the ninth and one at the eleventh monthly visit before referral to an ARV site. The age of HIV PCR testing of these six babies was 12 weeks, 23 weeks, 11 weeks, 11 weeks, 22 weeks and 17 weeks respectively. The babies were referred to the ARV site on the basis of Clinical Staging for HIV disease or on the basis of the CD4 level. All the babies were referred to Leratong hospital, which was the only HIV referral site at the time of the study.

For the other 18 babies who tested HIV-positive but were not referred to an ARV site the median follow up period was seven visits. The minimum age at loss to follow up was 1.9 weeks and the maximum age was 47.57 weeks with a median age of 11.4 weeks at the time of loss to follow-up.

A Kaplan-Meier curve was constructed to demonstrate the probability of HIV-exposed babies remaining in the PMTCT programme after 12 months of follow-up. As figure 3.4.2 depicts, the probability of infants remaining in the programme decreased rapidly in the first few weeks of the follow-up period, such that by six weeks there was a probability of 0.5 that an infant would continue in the PMTCT

follow-up programme. The probability of an infant remaining in the PMTCT programme beyond 20 weeks was 0.04.

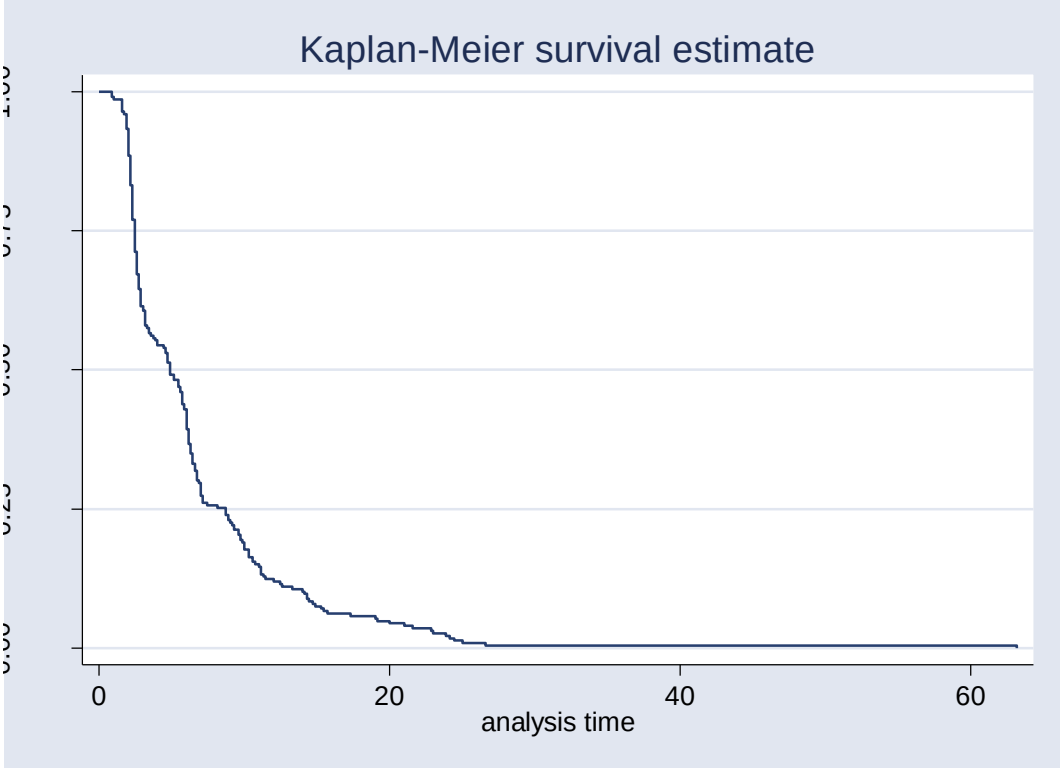


Figure 3.4.2: Probability of babies remaining in the PMTCT programme over time (in weeks).

CHAPTER FOUR

DISCUSSION

The aim of this study was to describe the referral and follow up of babies born to HIV-positive women in the PMTCT programme in the West Rand district of Gauteng Province, and to evaluate the extent of loss to follow up of these babies in the PMTCT programme in the first 12 months after birth. The findings of the study show the enrolment of HIV-exposed babies at PMTCT referral sites to be generally inadequate and loss to follow up in the PMTCT programme was unacceptably high at all stages within the first year of life. The study findings suggest that, due to poor enrolment and subsequent follow-up of those who do enrol, there are significant missed opportunities for early detection and treatment of HIV-positive babies who need ART.

High enrolment of babies in the PMTCT programme

The willing participation in the PMTCT programme (use of NVP during delivery) by pregnant women in the West Rand is encouraging. Further, babies born to women in the PMTCT programme were all given NVP within 72 hours following their birth in accordance with the PMTCT protocol with the exception of eleven babies who were presumed to have died before discharge from hospital. Assuming all women and babies who enter the programme complied with the prophylactic ART regimens, this high uptake of PMTCT prophylaxis would translate to a continuing decline in new vertically transmitted HIV infections and signify a positive step towards achieving one of the key Millenium Development Goals in Sub-Saharan Africa, namely reducing the mortality rate for children under five by two-thirds by 2015.[34]

Low enrolment of babies at PMTCT follow-up sites

Despite the successful recruitment of pregnant women into the PMTCT programme, good NVP prophylaxis coverage of infants born to HIV-positive women and high referral of these babies to PMTCT follow-up services, only about one-third of babies who received NVP enrolled in a PMTCT follow up site. This low enrolment of babies at PMTCT follow up sites suggests that referral linkages between the labour wards at the hospital and MOUs and the PMTCT follow up sites may have been weak. Referrals within the hospital were the least successful as only 20% of babies who received NVP at the hospital successfully enrolled at PMTCT follow up services.

These findings are concerning because the PMTCT programme ought to be the main avenue for early identification of infected infants in the first weeks or months of life. The referral of infants from one point of service to another within the same PMTCT system remains a challenge in most settings. Challenges for infant referrals include a lack of sufficiently trained health care personnel and inadequate facilities. The compartmentalization of the ART rollout programme makes it difficult for infants to enrol into appropriate HIV services.[34,35] The consequence of poor enrolment of babies at appropriate centres where they can receive follow-up and further care is that babies born infected with HIV are often not identified early and only gain access to comprehensive HIV care and treatment late in their disease resulting in high levels of morbidity and mortality among HIV-positive infants.[36]

Low coverage of infant HIV PCR testing

Our data show that out of all infants who received NVP prophylaxis and enrolled at a PMTCT follow-up site, less than 50% had a HIV PCR test done to confirm HIV

status. In fact, even before the HIV PCR test was due at six weeks, 25% of babies who had received NVP after birth were already lost to follow up in the PMTCT programme. Overall, only 41% of babies who registered at a PMTCT follow-up site had an HIV test done, while the rest were lost to follow-up before the HIV status could be confirmed.

Due to their mothers' feeding choices, not all babies were eligible for HIV PCR testing at six weeks as per protocol. When feeding choices were taken into account, a relatively larger proportion of formula fed babies were tested for HIV infection by six weeks of age, whereas a relatively large proportion of breastfed babies were tested for HIV infection only after the age of 21 weeks. However, as this study shows, even amongst formula fed babies (who should have all had a PCR test done at 6 weeks of age) only 20% were HIV PCR tested at 6 weeks.

The Ditrame Plus PMTCT project in Abidjan showed that formula feeding by HIV-positive women increased the probability of disclosure of HIV status to their partner[22]and that increased male involvement in the PMTCT programme improved womens' uptake of- and adherence to the PMTCT programme.[18] The level of support from male partners could thus have an influence on the coverage and timing of HIV PCR testing of infants.

The HIV PCR test has a sensitivity of 99.3% at six weeks, making it highly reliable for confirming HIV infection.[37] Early confirmation of HIV infection is critical to enable prompt referral of infected infants to HIV care programmes and goes a long way to reducing maternal anxiety.[38] Early confirmation of HIV status in HIV-exposed

infants also eliminates unnecessary follow up visits and the need to continue administering daily cotrimoxazole prophylaxis to babies who test HIV-negative. Further, it reduces clinic costs and other expenses that women, particularly those from lower socio-economic groups, would incur for getting to the health care facility every month.

In this study the proportion of babies having the HIV PCR test at six weeks (as per protocol) was statistically significantly lower than the proportion of those having the test after six weeks. This indicates a low coverage of HIV PCR testing at six weeks of age in HIV-exposed babies. Prior to 2008, there were no statistics indicating the number of babies who were HIV PCR tested at six weeks after birth. This is a new indicator that has only been collected since 2008.[39,40,41] There is a large variation in infant HIV PCR testing by province and district in South Africa. In Gauteng, during 2008/09, six-week HIV PCR rates were under 30% in all of Gauteng's six districts, except for Metsweding at 64.9%. The four districts from Northern Cape reporting data all had a testing rate of less than 30%. The North West appeared to perform better with all districts above 60% testing rates. In the Eastern Cape, all districts were above 50% testing rates. KwaZulu-Natal, which has the highest HIV/AIDS prevalence in the country, showed the largest variation within a province, with the lowest testing rate being Zululand at less than 10% and the highest in Umkhanyakude at 71%.[39] In Mpumalanga, which has the second highest HIV/AIDS prevalence, testing rates ranged from 20.7% to 46.2% across districts within the province.[40]

Low six-week PCR coverage is a problem as it prevents health care providers from offering optimal care and treatment of the HIV-positive infant; it interferes with

decisions on infant feeding, promotes needless stress on mothers and families and interferes with family life planning. Recognizing infants with infection before they become unwell is only possible through routine diagnostic testing, ideally at the six-week visit.[42] One of the objectives of the National Integrated Prevention of mother-to-child transmission of HIV Accelerated plan is to increase the proportion of HIV-exposed babies receiving a HIV PCR test at around six weeks to 85% by 2011.[39,43] It is hoped that as the PMTCT service improves, more babies will be tested at the six-week visit.

Early detection of HIV-positive infants is a priority for PMTCT programmes. Low-income countries such as Tanzania and Zambia manage to have a high number of paediatric patients in their HIV care programmes. Under the Elizabeth Glaser Paediatric AIDS Foundation (EGPAF) funded AIDS treatment programmes, 15 to 20 percent of the total patients on ARVs are children. This is achieved through aggressive efforts to find children by treating every encounter with a child as an opportunity to test for HIV and bring them into HIV/AIDS care programmes.[44]

In Zimbabwe, efforts have been made to improve the detection of HIV-exposed infants by including the mother's HIV status on the child health card in order that every presentation at a health facility is an opportunity to identify the HIV-positive child in time to initiate lifesaving ARV treatment.[44] This simple measure has resulted in an increase in the detection rate of HIV-positive children, especially the youngest patients who are most vulnerable to rapid advancement of the disease, and subsequently resulted in an increase in the number of children on ARVs.

Enrolment of babies at ARV sites

In this study one fifth of infants who were tested for HIV had a HIV PCR-positive result. Unfortunately only 25% (6/24) of the infants who tested HIV-positive were followed up and successfully referred to an appropriate health facility for appropriate paediatric HIV care and possible ART initiation. Three-quarters (18/24) of the infants who tested HIV-positive were lost to follow-up in the PMTCT follow up programme. These findings suggest that a significant percentage of HIV-positive babies did not have opportunity to get onto ART through the PMTCT programme, which should be the main avenue for ART intervention among infants. The consequence of delaying referral for ART is that although babies are being timely diagnosed HIV-positive, they are not initiated on treatment early enough to reduce the high morbidity and mortality associated with HIV disease.[17]

In a similar study conducted in Ethiopia in 2007 just over 50% of children testing HIV-positive were referred for paediatric ART initiation. Some reasons identified for insufficient referrals in the Ethiopian study included providers waiting for clinical symptoms to occur before referring children for treatment.[45] This was the case in South Africa, at the time of this study – the ART guidelines required that children start on ART only once CD4 count fell to a stated level.[3,26,46]

Data emerging from the CHER study however, showed the benefits of early initiation of HIV treatment in HIV-positive infants. This prompted subsequent changes to South African paediatric treatment guidelines to emphasize the well-recognised need to improve timely access of infants to care and treatment, particularly through improved

systems of early diagnosis.[37,47,48,49] The new guidelines require that all HIV-positive infants be commenced on ART immediately after HIV-positive status is confirmed. This is beneficial because it eliminates the need for monthly follow up visits if HIV can be confirmed at six weeks with the PCR test. However, given the findings of this study – that 25% of HIV-exposed babies were lost to follow up before the PCR could even be done to confirm HIV status – it will be important to think about ways of retaining HIV-exposed babies in care up to the time that the HIV status can be confirmed.

Timely access to care and early treatment initiation for HIV-positive infants has been shown to significantly reduce mortality in vertically infected infants.[34,47]Therefore, important challenges with timely referral and HIV treatment initiation for infants will need to be addressed as a matter of urgency.[34]

Loss to follow-up in the PMTCT programme

The causes of attrition of HIV-exposed infants from the PMTCT programme in this study were not established. But research shows that reasons for attrition from PMTCT programmes include: the difficulty women face in returning monthly to the health care facility to receive the drug for their infants because of logistical challenges (distance to the health care facility and resources needed to get there); fear of raising people's suspicions about the women's HIV status with repeat visits to the health care facility post-delivery, and the hostile atmosphere that prevails at some health care facilities due to uncaring or demoralized clinic staff.[45]

New WHO recommendations – which have been adopted in the South African guidelines - that all children under one year of age should receive ART irrespective of their clinical or immunological status should encourage adherence to the PMTCT follow up schedule as mother will see that definitive treatment will be seen to be done for HIV-positive infants.[9,29]Since the new guidelines require earlier commencement of ART, the long PMTCT follow-up schedules will fall away and so loss to follow-up may reduce. However, as the new paediatric ART guidelines are implemented, it will be important to ensure retention of babies in the PMTCT programme up to a point when the HIV status of an HIV-exposed baby can be confirmed, and to ensure positive babies actually get into ART care and are not lost to the system. Programme managers will therefore have to think about possible mechanisms that can be implemented to encourage retention and successful referral to ARV sites.

A study conducted in Zambia in 2005 showed that the uptake of PMTCT services could be increased throughout the cascade by using a participatory approach. The approach involved scaling up of services by incorporating non-health workers to provide additional coverage for health facilities, using lay counsellors to conduct counselling and testing, and mentoring of current health care workers. Expanded PMTCT services were integrated into the existing maternal and child health structure which required strengthening the health system management infrastructure. Information gaps were addressed among health care providers and communities to reduce stigma, discrimination and reluctance to use ARV prophylaxis for the mother and/or baby. Traditional and opinion leaders were mobilized to encourage more active male involvement in the PMTCT programme, and strong relationships were built with

the government at all levels of the health system to encourage government support and ownership of the programme.[18]

The problem of attrition cannot be addressed effectively without better information on those who are lost to follow-up in terms of what conditions, assistance, or incentives will be needed to retain them. High reported rates of loss to follow-up are a strong indication to improve patient tracing procedures, to minimize the number of patients who are lost for unknown reasons. Regrettably, long-term retention of patients in treatment programs, a prerequisite for achieving any adherence at all, has received little attention; perhaps because most large-scale treatment providers have few resources available to trace missing patients, and most research studies treat patient attrition as a side issue and focus solely on describing those patients who are retained in the programme.[36]

Studies have shown that maternal age and parity do not influence antenatal NVP uptake, and maternal age and parity do not have a significant influence on mortality in HIV-positive infants.[48] It would have been of interest to establish whether maternal age and parity had any influence on PMTCT follow-up compliance, as this would give an indication of where education on VCT and PMTCT needs to be strengthened (either at Secondary school level if younger women are found to be less compliant, or aimed more at church groups and Women's society groups if older women are found to be less compliant). Unfortunately there was insufficient material available to correlate between maternal age and loss to follow up or between parity and loss to follow up. The timing of a woman's first antenatal booking might give an indication

of how motivated the woman would be to continue in the programme after the birth of her baby. This information was also lacking in the maternal labour ward records.

Limitations of the study

The findings of this study need to be considered in the context of some limitations:

- Different data sources from different health facilities were used. This might account for differences in PMTCT protocol adherence across the health facilities.
- Data recording in the babies' files may not be accurate. Due to inadequate health worker–patient ratios, data omission in the babies' files is likely to have occurred.
- The sample size was limited due to time constraints.
- Due to insufficient material, it was not possible to examine all the factors that could possibly play a role in the reasons for loss to follow-up.

CHAPTER FIVE

CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

This study shows that though the PMTCT programme is well established in the West Rand and pregnant women were willing to accept VCT and to join the PMTCT programme; challenges exist with successful referral and HIV treatment initiation for babies born to HIV-positive women in the programme.

As with other local studies done on PMTCT follow-up in infants, this study demonstrated that most infants were lost to follow-up within the first few months of joining the programme and loss to follow up increased steadily during the first year of PMTCT follow-up. Reasons for the high rate of loss to follow-up were not established, but could be related to issues such as socio-economic factors, fear of stigmatisation, undocumented deaths, or women's poor understanding about the PMTCT programme, and the need for follow-up of their babies beyond taking NVP.

The high rate of loss to follow-up of babies in the PMTCT programme results in reduced opportunities for early detection of HIV disease in HIV-exposed babies in the West Rand, and may contribute to the high morbidity and mortality in HIV-positive children seen at Leratong hospital.[3,12,13] Retention of babies in PMTCT follow-up must be improved if the new paediatric treatment guidelines are to succeed.

5.2 RECOMMENDATIONS

In order to improve retention of HIV-exposed babies within the PMTCT programme, better patient tracking systems, better understanding of the reason for loss to follow up, and earlier initiation of ART to reduce mortality are needed. With more ARV sites being available in the West Rand, and more women being aware of the PMTCT programme through media advertising and governmental HIV campaigns, and the changes in guidelines for ART initiation in children, further research is needed to assess whether there has been an improvement in the follow-up of babies in the PMTCT programme in the West Rand since 2005. This study could form the baseline for further research. Specific recommendations are as follows:

- Strengthening of referral linkages within the PMTCT programme is essential. Referral linkages within the Hospital and between the hospital and the MOUs, is required to ensure that HIV exposed babies are followed up and retained in the PMTCT programme and successfully referred to ARV sites where needed.

- Training and mentoring of current health care workers is essential to improve the PMTCT follow-up service despite limited resources and limited capacity. Health care workers need to be attentive to make sure all babies who come to their facility receive HIV PCR test when needed.
- To avoid missing opportunities for NVP prophylaxis for babies whose mothers are registered in the PMTCT programme a unique patient identification system is required and maternal identifying information should be included on the baby's postnatal records.

- Establishment of efficient patient tracking systems to improve compliance with PMTCT follow-up schedules is important. With the new guidelines for ART initiation in children, it is even more important to introduce mechanisms to improve retention before six weeks of age when the HIV status of the baby can be established. Implementation of the patient Smart Card would assist with reducing loss to follow-up for patients who relocate to areas outside of the West Rand. With mobile technology accessible to most people, short message services (SMS) could also be employed as a means of reminding patients of their PMTCT follow-up appointments.

- Women should be informed, through antenatal programmes, about the benefits of early HIV testing of their babies after birth; and about advantages and benefits of early enrolment in the PMTCT follow-up programme if their babies test HIV-positive. They would also need information about the importance of complying with the PMTCT follow-up schedule to ensure early confirmation of HIV status of their babies.

- The reasons why women do not return with their babies to follow-up appointments should be established and addressed accordingly.

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APPENDICES

WEST RAND PMTCT FOLLOW-UP STUDY:

APPENDIX A: DATA EXTRACTION FORM

1. Client study code……...
2. Date of delivery…….
3. Age of mother…… Parity ……
4. NVP given (baby) Yes……. No……
5. Baby referred Yes……. No…….
6. Site referred to…….
7. Registered for PMTCT follow-up Yes (date)……. No……..
8. HIV-PCR done Yes (date)……. No……
9. PCR result Positive……. Negative…….
   Not known……...
10. 1st follow-up visit Yes (date)…….No…… Prophylaxis given
    Yes……No…….
11. 2nd follow-up visit Yes (date)…….No…… Prophylaxis given
    Yes……No…….
12. 3rd follow-up visit Yes (date)…….No…….Prophylaxis given
    Yes……No…….
13. 4th follow-up visit Yes (date)…….No…….Prophylaxis given
    Yes……No…….
14. 5th follow-up visit Yes (date)…….No…….Prophylaxis given
    Yes……No…….
15. HIV ELISA done Yes (date)…… No……
16. ELISA result Positive…… Negative…… Not known……
17. Referred to ARV site Yes (date)…… No……

APPENDIX B: CONFIDENTIAL DATA EXTRACTION SHEET

Mother's name and file number	Date of delivery	Facility mother delivered at	Code given (mother)	Baby's name and file number	Code given (baby)

APPENDIX C: ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Makhanya

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M070336**
PROJECT	The Follow-Up of Babies in the PMTCT Programme in the West Rand
INVESTIGATORS	Dr FM Makhanya
DEPARTMENT	School of Public Health
DATE CONSIDERED	07.03.30

DECISION OF THE COMMITTEE* APPROVED subject to measures being taken at these sites to ensure confidentiality i.e. the researcher mustbe the only person who reviews these registers and who has access to confidential information

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

DATE 07.04.03 **CHAIRPERSON** .....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr M Kawonga

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**